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9:00 a.m.–Noon

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2008–0057]

Mexican Fruit Fly; Designation of Portion of Willacy County, TX, as a Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Mexican fruit fly regulations by designating a portion of Willacy County, TX, as a quarantined area and restricting the interstate movement of regulated articles from that area. This action is necessary to prevent the spread of the Mexican fruit fly into noninfested areas of the United States.

DATES: This interim rule is effective June 5, 2008. We will consider all comments that we receive on or before August 4, 2008.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0057* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0057, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0057.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne D. Burnett, Domestic Coordinator, Fruit Fly Exclusion and Detection Programs, PPQ, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737–1234; (301) 734–4387.

SUPPLEMENTARY INFORMATION:

Background

The Mexican fruit fly (*Anastrepha ludens*) is a destructive pest of citrus and many other types of fruit. The short life cycle of the Mexican fruit fly allows rapid development of serious outbreaks that can cause severe economic losses in commercial citrus-producing areas.

The Mexican fruit fly regulations, contained in 7 CFR 301.64 through 301.64–10 (referred to below as the regulations), were established to prevent the spread of the Mexican fruit fly to noninfested areas of the United States. The regulations impose restrictions on the interstate movement of regulated articles from quarantined areas.

Section 301.64–3 provides that the Deputy Administrator for Plant Protection and Quarantine, Animal and Plant Health Inspection Service (APHIS), shall list as a quarantined area each State, or each portion of a State, in which the Mexican fruit fly has been found by an inspector, in which the Deputy Administrator has reason to believe the Mexican fruit fly is present, or that the Deputy Administrator considers necessary to regulate because of its proximity to the Mexican fruit fly or its inseparability for quarantine enforcement purposes from localities in which the Mexican fruit fly occurs.

Less than an entire State is designated as a quarantined area only if the Deputy Administrator determines that the State has adopted and is enforcing a quarantine or regulation that imposes restrictions on the intrastate movement of the regulated articles that are substantially the same as those that are imposed with respect to the interstate movement of the articles by the APHIS regulations and the designation of less than the entire State as a quarantined area will otherwise be adequate to prevent the artificial interstate spread of the Mexican fruit fly.

Recent trapping surveys by county agencies reveal that a portion of Willacy County, TX, is infested with the Mexican fruit fly.

Accordingly, to prevent the spread of the Mexican fruit fly to noninfested areas of the United States, we are amending the regulations in § 301.64–3 by designating that portion of Willacy County, TX, as a quarantined area for the Mexican fruit fly. The quarantined area is described in detail in the regulatory text at the end of this document. The Deputy Administrator has determined that it is not necessary to designate the entire State of Texas as a quarantined area.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the Mexican fruit fly from spreading to noninfested areas of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This rule amends the Mexican fruit fly regulations by designating a portion of Willacy County, TX, as a quarantined area and restricting the interstate movement of regulated articles from that area. This action is necessary to prevent the spread of the Mexican fruit fly into noninfested areas of the United States.

Within the quarantined area there are approximately 20 small entities that may be affected by this rule. These include two grocery stores, three fruit stands, four citrus producers, six truck vendors, four nurseries, and one recycling center. These 20 entities comprise less than 1 percent of the total number of similar entities operating in the State of Texas. Additionally, these small entities sell regulated articles primarily for local intrastate, not interstate movement, so the effect, if any, of this regulation on these entities appears to be minimal.

The effect on those few entities that do move regulated articles interstate will be minimized by the availability of various treatments that, in most cases, will allow these small entities to move regulated articles interstate with very little additional cost.

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 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.

Paperwork Reduction Act

This interim 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 § 301.64–3, paragraph (c) is amended by adding, in alphabetical order, under the heading ''Texas,'' an entry for Willacy County to read as follows:

§ 301.64–3 Quarantined areas.

* * * * *

(c) * * *

Texas

* * * * *

Willacy County. That portion of the county in the Raymondville/Lasara area bounded by a line as follows: Beginning at the intersection of FM 498 and FM 2845; then east on FM 498 to FM 2099; then north on FM 2099 to FM 490; then east on FM 490 to a point described as latitude 26.45360 and longitude −97.69919; then north from that point along an imaginary line to CR 3796; then west on CR 3796 to Santa Margarita Road; then north on Santa Margarita Road to Riggin Road; then west on Riggin Road to Cantu Road; then northwest along an imaginary line to a point described as latitude 26.57423 and longitude −97.70461; then west from that point along an imaginary line to the Willacy County line; then south, east, and south along the Willacy County line to FM 1921; then east on FM 1921 to FM 2845; then south on FM 2845 to the point of beginning.

Done in Washington, DC, this 29th day of May 2008.

Cindy J. Smith,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–12542 Filed 6–4–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. APHIS–2006–0164]

RIN 0579–AC35

Temporary Importation of Horses; Noncompetitive Entertainment Horses From Countries Affected With Contagious Equine Metritis

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to allow noncompetitive entertainment horses from countries affected with contagious equine metritis to be temporarily imported into the United States under certain conditions. The regulations currently provide for the temporary importation of horses from countries affected with contagious equine metritis to compete in specified events. In recent years it has become evident that similar provisions are needed for noncompetitive entertainment horses. This action will allow the temporary importation of horses into the United States solely for public exhibition and entertainment purposes while continuing to protect against the introduction and dissemination of contagious equine metritis.

DATES: *Effective Date:* July 7, 2008.

FOR FURTHER INFORMATION CONTACT: Dr. Ellen M. Buck, Veterinary Medical Officer, Import/Export Animals, National Center for Import and Export, VS, APHIS, 4700 River Road, Unit 39, Riverdale, MD 20737–1231; (301) 734–8364.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subpart C—Horses, §§ 93.300 through 92.326 of the regulations, pertains to the importation of horses into the United States.

Section 93.301 of the regulations contains specific provisions for the quarantine and testing of horses from regions affected with contagious equine metritis (CEM), a highly contagious bacterial venereal disease that affects breeding and fertility. This section also identifies regions where CEM exists and regions that trade horses freely with those where CEM exists without testing for CEM.

To prevent the introduction of CEM into the United States, § 93.301(c)(1) prohibits the importation of horses into the United States from listed regions unless the horses are imported in accordance with certain requirements. To be eligible for importation, the horses must fall into one of the following categories:

• Wild (non-domesticated) species of equidae if captured in the wild or imported from a zoo or other facility where it would be unlikely that the animal would come in contact with domesticated horses used for breeding;

- Geldings;
- Weanlings or yearlings whose age is certified on the import health certificate required under § 93.314(a);
- Horses imported in accordance with conditions prescribed by the Administrator as provided in § 93.301(a);
- Spanish Pure Breed horses imported for permanent entry from Spain or thoroughbred horses imported for permanent entry from France, Germany, Ireland, or the United Kingdom as provided in § 93.301(d);
- Stallions or mares over 731 days of age imported for permanent entry as provided in § 93.301(e);
- Horses over 731 days of age imported into the United States for no more than 90 days to compete in specified events as provided in § 93.301(f); and
- U.S. horses returning to the United States as provided in § 93.301(g).

The Animal and Plant Health Inspection Service (APHIS) has used the provisions in § 93.301(f), relating to the temporary importation of horses for competition, to allow the temporary importation of noncompetitive entertainment horses into the United States. Several performance horse groups have asked APHIS to extend the 90-day limit provided for in § 93.301(f) so that they may exhibit and show their horses in the United States for longer periods of time. In addition, the United States Animal Health Association has recommended that APHIS amend the regulations to establish a category for noncompetitive entertainment horses.

Accordingly, on August 2, 2007, we published in the **Federal Register** (72 FR 42318–42326, Docket No. APHIS–2006–0164) a proposal[1] to amend the regulations in § 93.301 to establish conditions under which noncompetitive entertainment horses from CEM-affected regions may be imported into the United States for longer than 90 days solely for public exhibition and entertainment purposes. Because the conditions are very similar to the conditions in § 93.301(f), which provides for the temporary importation of horses to compete in specified events, we proposed that § 93.301(f) apply to both types of imported horses. We also proposed to amend the regulations pertaining to import permits in § 93.304 to require the submission of additional information with the application for an import permit.

We solicited comments concerning our proposal for 60 days ending October 1, 2007. We received four comments by that date. The comments were from a private citizen, State animal health department, horse industry group, and a horse entertainment company. These comments are discussed below.

In the proposed rule we stated that, ''[b]ecause CEM is a venereal disease transmitted by sexual contact, there is virtually no risk that a horse will transmit the disease through casual contact with other horses during a performance, exhibition, or exercise.'' One commenter stated that APHIS should not lift the CEM restrictions unless there is absolutely no risk of spreading the disease. This commenter suggested that APHIS reconsider the proposed rule and tighten the CEM restrictions instead.

We disagree. As discussed in the proposed rule, APHIS has conducted a risk assessment to evaluate the risk of allowing the extended importation of noncompetitive entertainment horses from countries affected with CEM without requiring CEM testing, and the risk of the U.S. Department of Agriculture (USDA) losing track of these horses during extended importation. The risk assessment, titled ''Assessment of the Risk of Introduction of Contagious Equine Metritis (CEM) through the Extended Importation of Noncompetitive Entertainment Horses from CEM-affected countries,'' concluded that the risk posed by allowing the extended importation of noncompetitive entertainment horses from CEM-affected countries would be extremely low, with the application of the restrictions described in the rule. In addition, the risk assessment concluded that the risk of USDA losing track of the animals was extremely low due to the extensive supervision and involvement of APHIS personnel and the accredited veterinarian. The risk assessment is supported by our experiences with the importation of horses to compete in specified events under conditions very similar to those proposed for noncompetitive entertainment horses. Accordingly, we are making no changes based on this comment.

Another commenter stated that the regulations should protect the health of U.S. horses from imported horses regardless of the reason for their importation. Therefore, the commenter recommended that the health certificate and testing requirements set forth in proposed § 93.301(f)(3) for noncompetitive entertainment horses also be required for horses temporarily imported for competition.

In the proposed rule, we proposed to amend the regulations to require that, at the time of importation, each horse imported for competition or public exhibition and entertainment purposes be accompanied by an import permit in accordance with § 93.304 and a health certificate in accordance with § 93.314. However, for noncompetitive entertainment horses, we also proposed to require that the health certificate certify that cultures negative for CEM have been collected on three separate occasions within a 7-day period, with the last within 30 days of exportation. We proposed more stringent CEM testing requirements for noncompetitive entertainment horses because these horses could be imported for long periods of time, compared to horses imported for competition. Currently, § 93.301(f) provides that horses may be imported for competition for no more than 90 days under certain conditions. The requirement for CEM testing prior to importation for noncompetitive entertainment horses will help to ensure that horses infected with CEM do not enter this country and jeopardize the health of the U.S. horse population. For these reasons, we are making no change in response to this comment.

The commenter also requested that APHIS clarify that the average salary used in the trust fund/costs is the salary for APHIS personnel. Proposed § 93.301(f)(10) provides that the costs associated with the supervision and maintenance of the horse by an APHIS representative be reimbursed by the horse's owner or importer through user fees payable under 9 CFR part 130, which lists the hourly rate and minimum user fee for certain import-related services provided by APHIS. Proposed § 93.301(f)(11) set out the requirements for trust fund agreements. More specifically, that paragraph provided that the horse's owner or importer deposit with APHIS an amount equal to the estimated cost, as determined by APHIS, for the APHIS representative to inspect the premises at which the horse will compete, perform, or be exhibited and to conduct the monitoring and supervision required by the regulations. We do not believe that additional clarification is needed. We are making no change based on this comment.

One commenter supported the proposed rule but was concerned that USDA may not be able to provide the monitoring required by the regulations over extended periods of time.

APHIS is committed to providing the services specified in the proposed rule and this final rule to prevent the introduction of CEM into the United States by noncompetitive entertainment horses. As discussed in the proposed rule, we would require noncompetitive

[1] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0164.*

entertainment horses to be imported and maintained in the United States in accordance with a trust fund agreement executed by the horse's owner or importer. Such an agreement would ensure that the government is reimbursed for the services it provides while the horses are in the United States. We are making no change based on this comment.

A commenter stated that proposed § 93.301(f)(5)(iv)(B), which provides that horses must be kept on a premises that is or contains a building, is too restrictive. The commenter noted that entertainment horse shows often use stable installations, such as tents, that may be set up and taken down in each city. Thus, the commenter recommended that the regulations be amended to define the term ''building'' to include tent structures.

We agree that the regulations should be flexible enough to cover buildings as well as tent stables or other temporary structures for housing horses. Therefore, in this final rule, we are amending § 93.301(f)(5)(iv)(B) to provide that the horse must be kept on a premises that is or contains a building or temporary structure in which the horse can be kept in a stall that is separated from other stalls that contain horses that are not listed on the import permit, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 meters) high. The horse may be kept only on premises that have been approved by an APHIS representative.

The commenter also recommended amending § 93.301(f)(5)(iv)(B) to allow APHIS to approve isolation measures other than those set out in that paragraph. Specifically, the commenter recommended revising that paragraph to read as follows: ''Must be or contain a building in which the horse can be kept in a stall that is separated from other stalls that contain horses that are not listed on the import permit, either by an empty stall, by an open area across from which horses cannot touch each other, by a solid wall that is at least 8 feet (2.4 meters) high, or by such other means deemed appropriate by APHIS in the circumstances.''

As noted in the proposed rule, one of the primary safeguards against the horses transmitting CEM while in the United States is the stringent measures in the regulations to ensure that the horses are kept apart from horses that are not listed on the import permit. This final rule provides several means by which the necessary isolation from horses that are not listed on the import permit could be accomplished. We do not believe that additional flexibility is needed. Accordingly, we are making no change in response to this comment.

The same commenter recommended that proposed § 93.301(f)(6) be amended to allow last-minute changes to the itinerary in an emergency. Section 93.301(f)(6) provides that, if an owner or importer wishes to change the horse's itinerary or the methods by which the horse is transported from those specified on the import permit, the owner or importer must make the request for change in writing to the Administrator at least 15 days before the proposed date of change. The commenter noted that touring inevitably entails unforeseen changes of plans, venues, dates, etc.

We agree that the regulations should allow for changes to the itinerary or methods of transportation in an emergency. In this final rule, we are adding a new paragraph to provide that the horse's itinerary or methods of transportation may be changed, with the prior approval of an APHIS representative, in order to respond to an emergency or other unforeseen circumstances or events (e.g., weather-related transportation delays, vehicle breakdown, medical emergencies, etc.). Requests for such a change may be submitted to APHIS by telephone, postal mail, commercial delivery service, fax, or e-mail. We may approve the request for change orally or in writing. If the approval is oral, it will be confirmed in writing by the Administrator as soon as possible. These changes will provide greater flexibility for a horse's owner or importer to respond to emergencies or other unforeseen circumstances or events.

In this final rule, we are also amending paragraph (f)(6) to make it clear that written requests for change may be submitted via postal mail, commercial delivery service, fax, or e-mail. APHIS has always allowed such written requests for change; however, we are adding that provision to the regulations to make it clear to the public.

The commenter also recommended that APHIS amend proposed § 93.301(f)(8) to provide the Administrator the discretion to allow horses to perform pending resolution of an appeal of the cancellation of an import permit, provided that such performances would not pose a risk to U.S. horses and the owner or importer could demonstrate material harm from the interruption of performances.

Proposed § 93.301(f)(7) provides that the Administrator may cancel an import permit whenever the Administrator finds that the owner or importer of the horse has not complied with certain provisions in the regulations or any conditions imposed under those provisions. Proposed § 93.301(f)(8) provides that the horse is not permitted to enter competition, perform, or be exhibited from the date the owner or importer receives the notice of cancellation until the horse is moved out of the United States or until resolution of an appeal in favor of the owner or importer. The potential cancellation of an import permit for noncompliance with the regulations provides an incentive for a horse owner or importer to remain in compliance with the regulations; allowing the horse to continue to perform or be exhibited pending the resolution of an appeal would be counterproductive. Accordingly, we are making no change based on this comment.

Finally, the commenter recommended that proposed § 93.304(a)(1)(iii)(D) through (H), relating to the proposed length of stay and itinerary, be amended to allow the applicant for an import permit to provide some of this information to APHIS at the time of application and the rest at intervals to be set by APHIS and the applicant.

In the proposed rule, we listed the information that must be supplied to APHIS by the owner or importer with the application for an import permit. We noted that the specified information would allow APHIS to monitor the location of the horse while it is in the United States and to confirm compliance with the required isolation and handling procedures to ensure that the horse does not transmit CEM to any other horse while in this country. Given the potential for long stays in the United States for noncompetitive entertainment horses and our need for current information to monitor compliance with the regulations, we also proposed to require that, while in the United States, the owner or importer apply for and obtain from APHIS an import permit each year prior to the anniversary date of the horse's arrival in the United States. To accommodate changes to the itinerary following importation, in proposed § 93.301(f)(6), we also established provisions by which a horse owner or importer could request APHIS approval of a change to the horse's itinerary or the methods of transportation from those specified in the application for an import permit. We believe these provisions, in combination, provide the flexibility that the commenter is seeking. Accordingly, we are making no change in response to this comment.

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 changes discussed in this document.

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 are amending the regulations to establish conditions under which noncompetitive entertainment horses (stallions and mares) over 731 days of age from CEM-affected countries could remain in the United States for longer than 90 days for public exhibition and entertainment purposes without undergoing the CEM quarantine and testing prescribed in the regulations.

The horse industry plays an important role in the U.S. economy. According to the 2002 Census of Agriculture, there were 542,223 farms with 3.644 million horses valued at $9.9 billion in the United States in 2002. According to a recent study done for the American Horse Council, the number and value of horses are much larger than those reported in the 2002 Census of Agriculture: 2 million people owning 9.2 million horses with direct value of about $39 billion.[1] Both sets of data underscore the importance of the equine industry. In addition, other agricultural and nonagricultural sectors are dependent on the horse industry for their economic activity. Horses are a highly valued asset, especially those with a specific pedigree. Horses also play an important role in U.S. international trade. The value of U.S. horse exports ($449 million) was more than the combined export value of cattle, hogs and sheep and goats ($65 million) between 2003 and 2005.[2]

The United States imported a total of 31,198 horses in 2005. Nearly 67 percent of horses imported were from Canada and 7.6 percent were from Mexico. Of the total imports, 25,564 were from non-CEM countries and the remaining 5,634 were from CEM countries. The proportion of horse imports that are pure breeding horses is small. Of the above total, 2,341 were purebred breeding horses. Only 340 purebred breeding horses were imported from CEM countries.[3] However, horses supplied by CEM-affected countries are generally highly valued. In 2005, for example, the average value of purebred breeding horses imported from CEM-affected regions was $41,220, whereas the average value of purebred breeding horses imported from countries not affected by CEM was $17,180.

Although the disease does not result in death, CEM can be economically costly. The direct consequence may include the closing of breeding operations, production losses as a result of abortion, and costs of disease control. A CEM outbreak would result in the quarantine of affected horse farms, temporary cessation of breeding operations, and restriction of both intrastate and interstate movement. For some breeders, this could mean the loss of thousands or even millions of dollars in stud fees and breeding losses. Other consequences include trade restrictions that may be imposed by international trading partners.

The noncompetitive entertainment horses that will be affected by this rule will not be allowed to have direct contact with horses outside those listed on their permit and may not be used for breeding purposes at any time while in the United States, including breeding with horses in the same show. Additionally, these horses may not undergo any genital examinations (unless required for diagnosis and treatment of a medical condition with prior approval of an APHIS representative), semen collection, or artificial insemination. Furthermore, since these are very specialized performance animals, domestic breeders will not be affected if this rule were to increase the amount of time the imported horses are in the United States.

Horses arriving in the United States from abroad are quarantined at a USDA animal import center, generally for 3 days. Horses temporarily imported are required to exit the United States and be readmitted, following quarantine and testing, every 90 days. Each entry after 90 days is considered a new entry into the United States. The USDA charges a minimum of $810 for the 3-day quarantine. In addition to this facility charge, user fees of $80 are charged for blood testing, resulting in a total quarantine and testing cost per horse of $890. The final rule will allow imported performance horses to stay in the United States longer than 90 days without their owners having again to pay USDA import quarantine and testing costs. This is a savings that accrues to the importing entities and likely to counterbalance their costs associated with supervisory activities of APHIS and/or an accredited veterinarian.

The number of entities and horses expected to be directly affected by this rule is not large. We anticipate that between 1 and 10 performing groups varying in size from 5 to 40 horses (or a total of between 5 and 400 horses) will utilize the proposed exception each year. Given that there are over 1 million domestic show horses, even the upper quantity represents a very small fraction of the total supply (0.04 percent).

The Small Business Administration (SBA) has established guidelines for determining which types of firms are to be considered small entities under the Regulatory Flexibility Act. This rule may affect operations such as zoological parks (North American Industry Classification System [NAICS] code 712130), and animal performances including circuses, carnivals, and amusement parks (NAICS code 711190). SBA classifies these operations as small entities if their annual receipts are not more than $6.5 million. Of the approximately 850 such establishments, about 12.5 percent are considered to be large. The subset of these entities that temporarily import noncompetitive entertainment horses from CEM countries will benefit from the forgone costs associated with the horses having to exit and reenter the United States every 90 days. On the other hand, they will bear the cost of supervisory activities by APHIS and/or an accredited veterinarian. The overall impact is expected to be insignificant, given the relatively small number of noncompetitive entertainment horses imported from CEM countries.

Other operations that may remotely be affected are domestic suppliers of similar horses (NAICS code 112920). According to the 2002 Census of Agriculture, that year there were 542,223 horse farms with 3,644,278 horses in the United States, of which 124,596 farms sold 470,423 horses that had a total value of over $1.13 billion.[4] An unknown share of these farms supply show horses that could be comparable to the noncompetitive entertainment horses imported temporarily from CEM-affected countries. SBA classifies horse farms as small entities if their annual receipts are

[1] Deloitte Consulting LLP for American Horse Council, National Economic Impact of the U.S. Horse Industry, 2005.

[2] Global Trade Information Services, World Trade Atlas.

[3] Id.

[4] As stated above, the census total is much less than the total reported by the American Horse Council Foundation. According to that report, there were 9,222,847 horses in 2005 (Deloitte Consulting LLP, National Economic Impact of the U.S. Horse Industry). Of this total, 9 percent were racing, 30 percent showing, 42 percent recreation, and 19 percent other (*http://www.horsecouncil.org/statistics.htm*).

not more than $750,000;[5] over 99 percent are considered to be small.

Entities that may be affected by the rule are principally small businesses, but the impact of the rule is not expected to be significant. Because the pool of noncompetitive entertainment horses that are temporarily imported is a small fraction of the total number of show horses in the United States, any effects of the rule on U.S. entities will be very small.

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.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0324.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

[5] SBA, Small Business Size Standards matched to NAICS, Effective July 31, 2006; and U.S. Census Bureau, 2002 Economic Census: Manufacturing-Industries Series, Wholesale Trade-Subject Series and Transportation and Warehousing-Subject Series, Issued August, 2006.

List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 93 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 93.301 is amended as follows:

■ a. In paragraph (c)(2)(vii), by removing the words ''paragraph (f)'' and adding the words ''paragraph (f)(1)'' in their place, and by removing the word ''and'' at the end of the sentence.

■ b. By redesignating paragraph (c)(2)(viii) as paragraph (c)(2)(ix) and adding a new paragraph (c)(2)(viii) to read as set forth below.

■ c. In footnote 6, by removing the words ''Jefatura de Cria Caballar Registro Matricula for Spain'' and adding the words ''Asociacion National de Criadores de Caballos de Pura Raza Espanola for Spain'' in their place.

■ d. By revising paragraph (f) and the Office of Management and Budget citation at the end of the section to read as set forth below.

§ 93.301 General prohibitions; exceptions.

* * * * *

(c) *Specific prohibitions regarding contagious equine metritis; exceptions*—

* * *

(2) * * *

(viii) Horses over 731 days of age imported into the United States for noncompetitive public exhibition and entertainment purposes if the horses meet the requirements of paragraph (f)(2) of this section; and

* * * * *

(f) *Special provisions for temporary importation for competition or entertainment purposes.*

(1) Horses over 731 days of age may be imported into the United States for no more than 90 days to compete in specified events provided that the conditions in paragraphs (f)(3) through (f)(12) of this section are met.

(2) Horses over 731 days of age may be temporarily imported into the United States solely for noncompetitive public exhibition and entertainment purposes provided that the conditions in paragraphs (f)(3) through (f)(12) of this section are met.

(3) At the time of importation, each horse must be accompanied by an import permit in accordance with § 93.304 and a health certificate issued in accordance with § 93.314. For horses imported in accordance with paragraph (f)(2) of this section, the health certificate must also certify that cultures negative for CEM were obtained from sets of specimens collected on three separate occasions within a 7-day period from the mucosal surfaces of the clitoral fossa and the clitoral sinuses of any female horses and from the surfaces of the prepuce, the urethral sinus, and the fossa glandis, including the diverticulum of the fossa glandis, of any male horses. For both female and male horses, the sets of specimens must be collected on days 1, 4, and 7 of the 7-day period, and the last of these sets of specimens must be collected within 30 days of exportation. All specimens required by this paragraph must be collected by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate.

(4) Following the horse's arrival in the United States:

(i) A horse imported in accordance with paragraph (f)(1) of this section may remain in the United States for not more than 90 days, except as provided in paragraph (f)(9) of this section.

(ii) A horse imported in accordance with paragraph (f)(2) of this section may remain in the United States indefinitely, except as provided in paragraph (f)(9) of this section, as long as the conditions of paragraphs (f)(3) through (f)(12) of this section are met and the horse's owner or importer applies for and obtains from APHIS an import permit, as provided for in § 93.304, each year prior to the anniversary date of the horse's arrival in the United States.

(5) While the horse is in the United States, the following conditions must be met:

(i) A horse imported in accordance with paragraph (f)(2) of this section:

(A) Must not be entered in competitions.

(B) Must be regularly used in performances or exhibitions, unless sick or injured. A horse that is no longer performing or being exhibited must be exported or made eligible for permanent entry in accordance with paragraph (f)(9) of this section.

(C) Must be kept with the other horses listed on the import permit, unless otherwise approved by an APHIS representative.

(ii) Except as provided in paragraph (f)(5)(viii) of this section, the horse must be moved according to the itinerary and methods of transport specified in the import permit provided for in § 93.304.

(iii) The horse must be monitored by an accredited veterinarian or APHIS representative to ensure that the provisions of paragraphs (f)(5)(ii), (f)(5)(vi), and (f)(5)(vii) of this section are met. If the monitoring is performed by an accredited veterinarian, the Veterinarian in Charge will ensure that the accredited veterinarian is familiar with the requirements of this section and spot checks will be conducted by an APHIS representative to ensure that the requirements of this section are being met. If an APHIS representative finds that requirements are not being met, the Administrator may require that all remaining monitoring be conducted by APHIS representatives to ensure compliance.

(iv) Except when in transit, the horse must be kept on a premises that has been approved by an APHIS representative. For horses imported in accordance with paragraph (f)(1) of this section, such approval may be oral or in writing. If the approval is oral, it will be confirmed in writing by the Administrator as soon as circumstances permit. For horses imported in accordance with paragraph (f)(2) of this section, the approval will be in writing. To receive approval, the premises:

(A) Must not be a breeding premises; and

(B) Must be or contain a building or temporary structure in which the horse can be kept in a stall that is separated from other stalls that contain horses that are not listed on the import permit, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 meters) high.

(v) While in transit, the horse must be moved in either an aircraft or a sealed van or trailer. If the horse is moved in a sealed van or trailer, the seal may be broken only by an APHIS representative at the horse's destination, except in situations where the horse's life is in danger.

(vi) Except when actually competing, performing, or being exhibited or exercised, the horse must be kept in a pasture approved by APHIS or in a stall that is separated from other stalls containing horses that are not listed on the import permit, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 meters) high.

(vii) The horse may not be used for breeding purposes (including artificial insemination or semen collection) and may not have any other sexual contact with other horses. The horse may not undergo any genital examinations, except that a horse imported in accordance with paragraph (f)(2) of this section may undergo genital examinations for diagnosis or treatment of a medical condition with the prior approval of an APHIS representative.

(viii) The horse may be moved for diagnosis or treatment of a medical condition with the prior approval of an APHIS representative.

(ix) After the horse is transported anywhere in the United States, any vehicle in which the horse was transported must be cleaned and disinfected in the presence of an APHIS representative, according to the procedures specified in §§ 71.7 through 71.12 of this chapter, before any other horse is transported in the vehicle.

(x) The cleaning and disinfection specified in paragraph (f)(5)(ix) of this section must be completed before the vehicle is moved from the place where the horse is unloaded. In those cases where the facilities or equipment for cleaning and disinfection are inadequate at the place where the horse is unloaded, the Administrator may allow the vehicle to be moved to another location for cleaning and disinfection when the move will not pose a disease risk to other horses in the United States.

(xi) The owner or importer of the horse must comply with any other provisions of this part applicable to him or her.

(6) Except as provided in paragraph (f)(7) of this section, if the owner or importer wishes to change the horse's itinerary or the methods by which the horse is transported from that which he or she specified in the application for the import permit, the owner or importer must make the request for change in writing to the Administrator. Requests for change must be submitted to APHIS no less than 15 days before the proposed date of the change. Requests may be submitted to APHIS by postal mail, commercial delivery service, fax, or e-mail. The change in itinerary or method of transport may not be made without the written approval of the Administrator, who may grant the request for change when he or she determines that granting the request will not endanger other horses in the United States and that sufficient APHIS personnel are available to provide the services required by the owner or importer.

(7) In response to an emergency or other unforeseen circumstances or events (e.g., weather-related transportation delays, vehicle breakdown, medical emergencies, etc.), the horse's itinerary or methods of transportation may be changed, with the prior approval of an APHIS representative, from that which is specified in the application for an import permit. Requests for such a change may be submitted to APHIS by telephone, postal mail, commercial delivery service, fax, or e-mail. Approval may be oral or in writing. If the approval is oral, it will be confirmed in writing by the Administrator as soon as circumstances permit.

(8) The Administrator may cancel, orally or in writing, the import permit provided for under § 93.304 whenever the Administrator finds that the owner or importer of the horse has not complied with the provisions of paragraphs (f)(3) through (f)(7) of this section or any conditions imposed under those provisions. If the cancellation is oral, the Administrator will confirm the cancellation and the reasons for the cancellation in writing as soon as circumstances permit. Any person whose import permit is canceled may appeal the decision in writing to the Administrator within 10 days after receiving oral or written notification of the cancellation, whichever is earlier. If the appeal is sent by mail, it must be postmarked within 10 days after the owner or importer receives oral or written notification of the cancellation, whichever is earlier. The appeal must include all of the facts and reasons upon which the person relies to show that the import permit was wrongfully canceled. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(9) Except in those cases where an appeal is in process, any person whose import permit is canceled must move the horse identified in the import permit out of the United States within 10 days after receiving oral or written notification of cancellation, whichever is earlier. The horse is not permitted to enter competition, perform, or be exhibited from the date the owner or importer receives the notice of cancellation until the horse is moved out of the United States or until resolution of an appeal in favor of the owner or importer. Except when being exercised, the horse must be kept, at the expense of the owner or importer, in a stall on the premises where the horse is located when the notice of cancellation is received or, if the horse is in transit when the notice of cancellation is

received, on the premises where it is next scheduled to compete, perform, or be exhibited according to the import permit. The stall in which the horse is kept must be separated from other stalls containing horses that are not listed on the import permit, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 meters) high. In cases where the owners of the above specified premises do not permit the horse to be kept on those premises, or when the Administrator determines that keeping the horse on the above specified premises will pose a disease risk to horses in the United States, the horse must be kept, at the expense of the owner or importer, on an alternative premises approved by the Administrator.

(10) Stallions or mares over 731 days of age that are imported in accordance with paragraphs (f)(1) or (f)(2) of this section may be eligible to remain in the United States if the following is completed:

(i) Following completion of the itinerary specified in the import permit provided for in § 93.304, the horse's owner or importer applies for and receives a new import permit that specifies that the stallion or mare will be moved to an approved State listed in paragraph (h)(6) or (h)(7) of this section; and

(ii) The stallion or mare is transported in a sealed vehicle that has been cleaned and disinfected to an approved facility in an approved State where it is quarantined under State or Federal supervision until the stallion or mare has met the testing and treatment requirements of paragraph (e)(3) or (e)(5) of this section.

(11) All costs and charges associated with the supervision and maintenance of a horse imported under paragraphs (f)(1) or (f)(2) of this section will be borne by the horse's owner or importer. The costs associated with the supervision and maintenance of the horse by an APHIS representative at his or her usual places of duty will be reimbursed by the horse's owner or importer through user fees payable under part 130 of this chapter.

(12) In the event that an APHIS representative must be temporarily detailed from his or her usual place of duty in connection with the supervision and maintenance of a horse imported under this paragraph (f), the owner or importer of the horse must execute a trust fund agreement with APHIS to reimburse all expenses (including travel costs, salary, per diem or subsistence, administrative expenses, and incidental expenses) incurred by the Department in connection with the temporary detail. Under the trust fund agreement, the horse's owner or importer must deposit with APHIS an amount equal to the estimated cost, as determined by APHIS, for the APHIS representative to inspect the premises at which the horse will compete, perform, or be exhibited; to conduct the monitoring required by paragraph (f)(5)(iii) of this section; and to supervise the cleaning and disinfection required by paragraph (f)(5)(ix) of this section. The estimated costs will be based on the following factors:

(i) Number of hours needed for an APHIS representative to conduct the required inspection and monitoring;

(ii) For services provided during regular business hours (8 a.m. to 4:30 p.m., Monday through Saturday, except holidays), the average salary, per hour, for an APHIS representative;

(iii) For services provided outside regular business hours, the applicable rate for overtime, night differential, or Sunday or holiday pay, based on the average salary, per hour, for an APHIS representative;

(iv) Number of miles from the premises at which the horse competes, performs, or is exhibited to the APHIS office or facility that is monitoring the activities;

(v) Government rate per mile for automobile travel or, if appropriate, cost of other means of transportation between the premises at which the horse competes, performs, or is exhibited and the APHIS office or facility;

(vi) Number of trips between the premises at which the horse competes, performs, or is exhibited and the APHIS office or facility that APHIS representatives are required to make in order to conduct the required inspection and monitoring;

(vii) Number of days the APHIS representative conducting the inspection and monitoring must be in ''travel status'';

(viii) Applicable Government per diem rate; and

(ix) Cost of related administrative support services.

(13) If a trust fund agreement with APHIS has been executed by the owner or importer of a horse in accordance with paragraph (f)(12) of this section and APHIS determines, during the horse's stay in the United States, that the amount deposited will be insufficient to cover the services APHIS is scheduled to provide during the remainder of the horse's stay, APHIS will issue to the horse's owner or importer a bill to restore the deposited amount to a level sufficient to cover the estimated cost to APHIS for the remainder of the horse's stay in the United States. The horse's owner or importer must pay the amount billed within 14 days after receiving the bill. If the bill is not paid within 14 days after its receipt, APHIS will cease to perform the services provided for in paragraph (f)(5) of this section until the bill is paid. The Administrator will inform the owner or importer of the cessation of services orally or in writing. If the notice of cessation is oral, the Administrator will confirm, in writing, the notice of cessation and the reason for the cessation of services as soon as circumstances permit. In such a case, the horse must be kept, at the expense of the owner or importer and until the bill is paid, in a stall either on the premises at which the horse is located when the notice of cessation of services is received or, if the horse is in transit when the notice of cessation of services is received, on the premises at which it is next scheduled to compete, perform, or be exhibited according to the import permit. The stall in which the horse is kept must be separated from other stalls containing horses that are not listed on the import permit, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 meters) high. In cases where the owners of the premises where the horse would be kept following a cessation of services do not permit the horse to be kept on those premises, or when the Administrator determines that keeping the horse on the premises will pose a disease risk to other horses in the United States, the horse must be kept, at the expense of the owner or importer, on an alternative premises approved by the Administrator. Until the bill is paid, the horse is not permitted to enter competition, perform, or be exhibited. Any amount deposited in excess of the costs to APHIS to provide the required services will be refunded to the horse's owner or importer.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0165, and 0579–0324).

■ 3. Section 93.304 is amended as follows:

■ a. In paragraph (a)(1)(ii), by removing the citation ''§ 93.301(f)'' both times it occurs and adding the citation ''§ 93.301(f)(1)'' in its place.

■ b. By redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv) and adding a new paragraph (a)(1)(iii) to read as set forth below.

■ c. By adding an Office of Management and Budget citation at the end of the section to read as set forth below.

§ 93.304 Import permits for horses from regions affected with CEM and for horse specimens for diagnostic purposes; reservation fees for space at quarantine facilities maintained by APHIS.

(a) *Application for permit; reservation required.* (1) * * *

(iii) Horses intended for importation under § 93.301(f)(2) must meet the permit requirements of paragraph (a)(1)(i) of this section. Additionally, for horses intended for importation under § 93.301(f)(2), the horse's owner or importer must include the following information with the application for permit that is required by paragraph (a)(1)(i) of this section:

(A) The individual identifying information required in paragraph (a)(1)(i) of this section for all horses to be imported.

(B) The permanent electronic identification of each horse to be imported, if applicable. In the event that a horse has permanent electronic identification, the horse must be accompanied by a compatible reader.

(C) Photographs (head and lateral views) that are sufficient to identify each horse on an electronic medium approved by APHIS.

(D) The proposed total length of stay in the United States.

(E) A description of the shows or events in which the horse will perform while in the United States.

(F) The names, dates, and locations of the venues in which the horse will perform while in the United States.

(G) The names and locations of the premises on which the horse will be kept while in the United States, and the dates the horse will be kept on each premises.

(H) The methods and routes by which the horse will be transported while in the United States.

(I) A written plan for handling sick or injured horses that includes:

(*1*) The name, address, and phone number of each accredited veterinarian who will provide veterinary services in the United States;

(*2*) The name, address, and phone number of medical facilities to be used to diagnose or treat sick or injured horses while in the United States; and

(*3*) A plan to return sick or injured horses to performance condition.

(J) An application for a trust fund or escrow account agreement with APHIS in accordance with § 93.301(f)(12).

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0324).

Done in Washington, DC, this 29th day of May 2008.

Cindy J. Smith,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–12543 Filed 6–4–08; 8:45 am]

BILLING CODE 3410–34–P

FARM CREDIT ADMINISTRATION

12 CFR Part 652

RIN 3052–AC36

Federal Agricultural Mortgage Corporation Funding and Fiscal Affairs; Risk-Based Capital Requirements

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA, Agency, or we) adopts a final rule that amends capital regulations governing the Federal Agricultural Mortgage Corporation (Farmer Mac or the Corporation). The final rule updates the Risk-Based Capital Stress Test (RBCST, RBC model, model) in response to recent changes in Farmer Mac's operations that are not addressed in the current version (Version 2.0). The final rule also amends the current model's assumption regarding the carrying costs of nonperforming loans to better reflect Farmer Mac's actual business practices. In addition, the final rule adds a new component to the model to recognize counterparty risk on nonprogram investments through application of discounts or ''haircuts'' to the yields of those investments and makes technical amendments to the layout of the model's Credit Loss Module. The effect of the rule is to update the model so that it continues to appropriately reflect risk in a manner consistent with statutory requirements for calculating Farmer Mac's regulatory minimum capital level under a risk-based capital stress test.

DATES: *Effective Date:* This regulation will be effective the later of 30 days after publication in the **Federal Register** during which time either or both Houses of Congress are in session, or June 30, 2008. We will publish a notice of the effective date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

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or

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SUPPLEMENTARY INFORMATION:

I. Purpose

Under section 8.32 of the Farm Credit Act of 1971, as amended,[1] the FCA established the RBCST for Farmer Mac in 2001. It is the Agency's objective that the RBCST continues to determine regulatory capital requirements in a manner consistent with statutory requirements and constraints. The purpose of this final rule is to revise the risk-based capital regulations that apply to Farmer Mac to more accurately reflect changes in Farmer Mac's operations and business practices. The substantive issues addressed in this final rule include the treatment of program loan volume with certain credit enhancement features (e.g., Off-Balance Sheet AgVantage volume, subordinated interests, and program loan collateral pledged in excess of Farmer Mac's guarantee obligation (hereafter, ''overcollateral'')), counterparty risk on nonprogram investments, and the carrying costs associated with the funding of nonperforming loans. We also describe minor formatting changes to the structure of the Credit Loss Module and the RBC model that are in the nature of technical changes. The preamble to the proposed rule, which was published in the **Federal Register** on September 13, 2007, contains a full description of the proposed changes. The proposed rule provided for a 45-day comment period that ended on October 29, 2007.[2] Below we discuss only those provisions on which we received comments.

The final rule (Version 3.0 of the RBC model) is adopted with one revision from the proposed rule. The revision permits the Director of the Office of Secondary Market Oversight to reduce the haircut level applied to unrated investments.

II. Background

Our analysis of the RBCST has identified a need to update the model in response to changing financial markets, new business practices and the evolution of the loan portfolio at Farmer Mac, as well as continuing development of industry best practices among leading financial institutions. Our goal is to ensure that the RBCST reflects changes in the Corporation's business structure and loan portfolio that have occurred

[1] 12 U.S.C. 2279bb–1.

[2] 72 FR 52301 (Sept. 13, 2007).

since the model was originally developed by FCA, while complying with the statutory requirements and constraints on the model's design.

III. Comments

We received one comment letter on the proposed rule from Farmer Mac. In general, Farmer Mac agreed with FCA's objective to revise the RBCST to reflect Farmer Mac's actual business risks more accurately but offered specific comments on three aspects of the proposed rule—the method of calculating the loan loss resolution time factor (LLRT), funding rate assumptions applied to nonperforming loan volume, and the treatment of unrated Government-sponsored enterprises (GSE) for purposes of applying discounts (or ''haircuts'') to nonprogram investments.

IV. Description of Comments on the Proposed Rule and FCA's Response

Below is a description of the three specific comments on the proposed rule and FCA's responses to the comments.

A. Treatment of Unresolved Nonperforming Loans in the LLRT Calculation

The proposed rule's method for calculating the LLRT called for first calculating the average LLRT of nonperforming loans for all such loans that have resolved by the calculation date.[3] This average is then adjusted to incorporate the LLRT to date of unresolved nonperforming loans currently on Farmer Mac's books where the individual unresolved loan's LLRT to date is greater than the average LLRT of resolved loans. The average is calculated on an Unpaid Principal Balance (UPB)-weighted basis. Farmer Mac did not object to the proposed UPB weighting or generally to the method for measuring time in nonperforming loan status. Farmer Mac disagreed with the specific method for incorporating the influence of censored data.[4] Farmer Mac asserted that excluding data from the portion of the data set made up of unresolved nonperforming loans with individual LLRTs lower than the average of resolved loans would bias the overall LLRT calculation. To correct this perceived bias, Farmer Mac suggested either using only loans that have resolved or employing statistical tests that formally accommodate censored observations in order to accommodate the influence of the unresolved defaults in the data set. Farmer Mac suggested that such an approach would improve the LLRT accuracy by providing an unbiased estimate of ''life expectancy'' of a nonperforming loan (i.e., LLRT).

In developing the proposed approach, we considered several issues related to the application of duration or survival models, including the uniformity of the ''arrivals'' into default, the possible impact of UPB at time of default on remaining resolution experience, and general sample characteristics including length of observation window, fraction censored, and average life relative to observation window. The proposed approach was intended to balance the demands of a more complex modeling approach with the limits of the data set over the relatively short window (roughly 11 years), the relatively small set of loans in default and the observed high relative rate of default in a period centered near 2002 that substantially departs from a uniform arrival pattern. Farmer Mac correctly implies that excluding loans with relatively short durations in default as of the calculation date avoids a downward influence on the calculated LLRT. However, the treatment of unresolved nonperforming loans that have individual LLRTs greater than the average of those that have resolved as of the calculation date carries the opposite effect (i.e., avoids an upward influence) relative to their eventual resolution experience, because the current life at the calculation date is used in the weighted average calculation rather than its yet-to-be-determined actual life. The current life of this subset of loans at the calculation date necessarily understates their eventual LLRT and, thus, exerts an offsetting influence on the excluded subset. While there is not a formal statistical test for the relative impact of these two effects (treatment of both longer-than- and shorter-than-average LLRT), the adopted approach is intended to balance the two offsetting influences.

Farmer Mac suggested consideration of a more formal method to accommodate censored data in a duration or life-survival type model, and we conducted several related analyses. Importantly, the bulk of the defaults occurred in a period of time relatively early in the observation window. While the rate of arrival into default is non-uniform, the censored distribution displays the statistically useful property of increasing smoothly toward the censoring date. We calculated several measures of mean time in default on both UPB-weighted and unweighted bases, with alternative treatments of the unresolved data. Under all subsets of data examined, the UPB-weighted LLRT values are consistently 15 to 20 percent larger than the unweighted LLRT estimates.

We also estimated alternative specifications of the related hazard and survival functions using data supplied by Farmer Mac on all loans that had entered default status as of October 1, 2007, under (i) standard direct life tables with censored data, (ii) Kaplan-Meier methods, and (iii) Cox censored regression methods. The Kaplan-Meier method provides a direct method for recovery of the mean survival time accommodating the influence of the censored data at 1.79 years on an unweighted UPB basis. This value can be contrasted with a value of 1.60 on an unweighted basis using the method in the proposed rule for the same data set. Including the influence of UPB-weighting results in the proposed rule's method increasing from 1.6 to 1.88, a value below that which we expect to find from any form of a censored regression or Lifetest model after weighting by UPB. Importantly, the survival function models we estimated generally confirm the significance of UPB on time-in-default and further argue for the use of UPB-weighted LLRT. Our testing of the suggested general approaches has shown that the joint treatment of excluded loans with lower than average current LLRTs and the conservative treatment of loans with longer than average but currently unresolved LLRTs results in a similar but slightly lower LLRT value compared with the censored regression methods suggested by Farmer Mac.

We conclude that the simplicity of the proposed approach is warranted because of the similarity in estimated values and the fact that Farmer Mac would have to re-run this test every quarter to update the LLRT. We note that, as the observation window continues to lengthen and the influence of censored loan data continues to decline, the specific treatment employed becomes less important because we expect the censored data effects to become more diluted.

B. Carrying Costs of Nonperforming Loans

Farmer Mac commented that the proposed funding rates applied to nonperforming loan volume do not reflect its actual operations and reiterated the comments in its letter of April 17, 2006, which related to the proposed rule for Version 2.0 of the RBC

[3] By ''resolved,'' we mean loans that were in default for some period but were later paid current, paid off, liquidated, or transferred to real estate-owned, and are therefore no longer in nonperforming loan status.

[4] Censored data are loans that have entered nonperforming loan status but have not resolved as of the calculation date.

model.[5] That letter encouraged FCA to treat on- and off-balance sheet nonperforming loans in the model as being funded at the less than 1 year (short-term) rate or in keeping with Farmer Mac's actual practice of using the lowest funding rate available at the time a loan became nonaccrual given yield curve conditions existing at that time. Given the consolidated reporting of funding in only two categories—less than 1 year and greater than 1 year—we determined that tying the incremental carrying costs to the short-term rate was acceptable.

The Agency acknowledged in the proposed rule that, under unusual conditions, the short-term rate may not be the minimum rate, and Farmer Mac could potentially reallocate to some degree debt on its books in order to fund nonperforming loans at a point on its corporate yield curve that might be more advantageous than the short-term rate. Such a reallocation could necessitate a corresponding reallocation of funding to a different asset to offset the debt associated with the now-optimally funded nonperforming loan position. We did not attempt to reflect forward discretionary management behavior or develop an ''optimal'' funding practice that would result in effective funding durations changing throughout the modeled 10-year period of the RBCST. In the proposed rule, we discussed this possibility and rejected a more complex LLRT funding assumption in favor of the proposed approach, particularly in light of the fact that the model is cast with only two maturity groupings (''buckets'') of debt securities. To do otherwise would require adding substantial complexity to the components of the model reflecting funding costs—components which we believe are reasonably well calibrated to actual operations of Farmer Mac in their current aggregated form (i.e., two duration buckets).

We believe the proposed approach reflects Farmer Mac's typical practices under normal conditions, and Farmer Mac has confirmed this is true in the preponderance of cases. To attempt to build an ''optimal'' or ''discretionary'' future duration-of-funding model that depends on the projected forward balance sheet composition in the model is beyond the scope of the model.

C. Treatment of Unrated GSE Securities

Farmer Mac commented that the proposed method of applying haircuts to unrated GSE securities should be changed. Specifically, Farmer Mac believes the model should treat such securities as AAA-rated, rather than limiting such treatment only to GSE securities that are fully guaranteed by a GSE. Farmer Mac asserts that this approach would both reflect the low risk of default on all GSE securities and be consistent with FCA's approach to risk-weighting similar assets on the balance sheets of other Farm Credit System (System) institutions.[6] FCA regulations of other System institutions permit a 20-percent risk weighting to ''all securities'' of GSEs without regard to credit rating. Farmer Mac asserts that FCA has recognized the low risk associated with GSE securities in the context of Agency regulations governing nonprogram investments and liquidity because they permit much higher obligor limits for eligible GSE investments than other types of nonprogram investments.[7] Lastly, Farmer Mac asserts that the Agency would be justified in applying an automatic AAA-rating equivalent treatment to both unrated and GSE securities rated lower than AAA because the GSEs are closely regulated by Federal regulatory agencies that have access to more comprehensive and current information concerning the financial condition of the regulated GSE. The comment effectively encourages FCA to supersede the ratings of nationally recognized statistical rating organizations (NRSRO). This would be contrary to our stated goal for the regulation to avoid such a de facto re-rating process by the Agency in applying investment haircuts. However, we acknowledge there could be circumstances under which a reduction in the haircuts applicable to unrated investments that are not guaranteed by a GSE might be appropriate based on the risk characteristics of the investment. We believe that such circumstances could exist for non-GSE instruments as well as for GSE instruments. Therefore, in the final rule, while the default haircut on unrated instruments will remain as proposed, we have made a change in response to this comment that gives the Director of the Office of Secondary Market Oversight the discretion to apply a lower haircut on unrated investments on a case-by-case basis in accordance with the risk characteristics of the instrument.

We disagree with Farmer Mac's assertion that the risk-based capital framework for other System institutions provides support for a policy that would apply AAA haircuts to all GSE securities regardless of their rating. The risk-based capital framework for other System institutions is fundamentally different from the RBCST applied to Farmer Mac as required by section 8.32 of the Farm Credit Act. The purpose of the regulations governing System capital requirements is to protect a System institution against unexpected losses arising from all types of risk, unlike this component of the RBC model, the purpose of which is to estimate counterparty risk. Comparing the proposed haircuts with capital requirements is not a relevant comparison because equity requirements to cover all types of unexpected losses applied as a percentage of volume are not comparable to haircuts to reflect counterparty risk that are applied by reducing estimated future cashflows over the RBC model's 10-year time horizon on a gradually increasing basis. Accordingly, GSE investments with ratings will be haircut in accordance with the schedule in this rule.

V. Technical Changes to the RBCST in the Final Rule

In Version 3.0, we have revised the loan seasoning codes previously used in the Credit Loss Module to make off-balance sheet loan seasoning codes the same as those used for on-balance sheet loans and made other conforming data entry changes in the RBCST module. We have also incorporated a specification for senior subordinated loans in the Credit Loss Module to reduce the loss impact by the degree of subordination as referenced in the proposed rule.

VI. Impact of Changes on Required Capital

Our tests indicate that changes related to the LLRT would have the most significant impact on risk-based capital calculated by the model. The table below provides an indication of the relative impact of each revision for the quarter ended December 31, 2007, using preliminary model submission information for the fourth quarter 2007. The lines labeled ''Impact of Carrying Costs of Nonperforming Loans within Ver. 3.0 (estimated),'' ''Impact of Investment Haircuts within Ver. 3.0 (estimated),'' and ''Impact of Treatment of Off-Balance Sheet AgVantage Program Volume and Other Credit-Enhanced Program Volume (e.g., Subordinated Interests) within Ver. 3.0 (estimated)'' present the minimum risk-based capital level calculated if that revision were excluded from the final

[5] 70 FR 69692 (Nov. 17, 2005). We discussed this comment in the preamble to the 2007 proposed rule (72 FR at 52305, Sept. 13, 2007).

[6] The FCA's capital rules for System banks and associations are set forth at 12 CFR part 615, subparts H and K. The risk weightings are in 12 CFR 615.5210–615.5212.

[7] *See* 12 CFR 615.5140.

rule, Version 3.0 of the RBCST. The scenario used to estimate the impact of AgVantage Program Volume and Other Credit-Enhanced Program Volume excluded those two portfolios completely. As the table shows, the individual estimated impacts do not have an additive relationship to the total impact on the model relative to Version 2.0. This is due to the interrelationship of the changes with one another when they are combined in Version 3.0.

Calculated regulatory capital ($ in thousands)	12/31/2007
RBCST Version 2.0	42,754
RBCST Version 3.0 (estimated)	59,965
Impact of Carrying Costs of Nonperforming Loans within Version 3.0 (estimated)	20,623
Impact of Investment Haircuts within Version 3.0 (estimated)	707
Impact of the Treatment of Off-Balance Sheet AgVantage Program Volume and Other Credit-Enhanced Program Volume (e.g., Subordinated Interests) within Version 3.0 (estimated)	(2,620)

VII. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), FCA hereby certifies the rule will not have a significant economic impact on a substantial number of small entities. Farmer Mac has assets and annual income over the amounts that would qualify it as a small entity. Therefore, Farmer Mac is not considered a ''small entity'' as defined in the Regulatory Flexibility Act.

List of Subjects in 12 CFR Part 652

Agriculture, Banks, Banking, Capital, Investments, Rural areas.

■ For the reasons stated in the preamble, part 652 of chapter VI, title 12 of the Code of Federal Regulations is amended to read as follows:

PART 652—FEDERAL AGRICULTURAL MORTGAGE CORPORATION FUNDING AND FISCAL AFFAIRS

■ 1. The authority citation for part 652 continues to read as follows:

Authority: Secs. 4.12, 5.9, 5.17, 8.11, 8.31, 8.32, 8.33, 8.34, 8.35, 8.36, 8.37, 8.41 of the Farm Credit Act (12 U.S.C. 2183, 2243, 2252, 2279aa–11, 2279bb, 2279bb–1, 2279bb–2, 2279bb–3, 2279bb–4, 2279bb–5, 2279bb–6, 2279cc); sec. 514 of Pub. L. 102–552, 106 Stat. 4102; sec. 118 of Pub. L. 104–105, 110 Stat. 168.

Subpart B—Risk-Based Capital Requirements

■ 2. Amend § 652.65 by redesignating paragraph (b)(5) as new paragraph (b)(6) and adding a new paragraph (b)(5) to read as follows:

§ 652.65 Risk-based capital stress test.

* * * * *

(b) * * *

(5) You will further adjust losses for loans that collateralize the general obligation of Off-Balance Sheet AgVantage volume, and for loans where the program loan counterparty retains a subordinated interest in accordance with Appendix A to this subpart.

* * * * *

■ 3. Amend § 652.85 by revising paragraph (d) to read as follows:

§ 652.85 When to report the risk-based capital level.

* * * * *

(d) You must submit your quarterly risk-based capital report for the last day of the preceding quarter by the earlier of the reporting deadlines for Securities and Exchange Commission Forms 10–K and 10–Q, or the 40th day after each of the quarters ending March 31st, June 30th, and September 30th, and the 75th day after the quarter ending on December 31st.

■ 4. Appendix A of subpart B, part 652 is amended by:

■ a. Revising the table of contents;

■ b. Revising the first and second sentences of section 2.0;

■ c. Redesignating existing section 2.4 as new section 2.5;

■ d. Adding a new section 2.4;

■ e. Revising section 4.1 e.;

■ f. Revising the last sentence of section 4.2 b.(3) introductory text;

■ g. Redesignating existing section 4.2 b.(3)(C) and (D) as new paragraphs (3)(F) and (G);

■ h. Adding new section 4.2 b. (3)(C), (D), and (E);

■ i. Revising section 4.4;

■ j. Revising section 4.5 a.;

■ k. Removing the word ''unretained'' and adding in its place, the word ''retained'' in the ninth sentence of section 4.6 b.

Appendix A—Subpart B of Part 652—Risk-Based Capital Stress Test

1.0 Introduction.
2.0 Credit Risk.
2.1 Loss-Frequency and Loss-Severity Models.
2.2 Loan-Seasoning Adjustment.
2.3 Example Calculation of Dollar Loss on One Loan.
2.4 Treatment of Loans Backed by an Obligation of the Counterparty and Loans for Which Pledged Loan Collateral Volume Exceeds Farmer Mac-Guaranteed Volume.
2.5 Calculation of Loss Rates for Use in the Stress Test.
3.0 Interest Rate Risk.
3.1 Process for Calculating the Interest Rate Movement.
4.0 Elements Used in Generating Cashflows.
4.1 Data Inputs.
4.2 Assumptions and Relationships.
4.3 Risk Measures.
4.4 Loan and Cashflow Accounts.
4.5 Income Statements.
4.6 Balance Sheets.
4.7 Capital.
5.0 Capital Calculations.
5.1 Method of Calculation.

* * * * *

2.0 Credit Risk

Loan loss rates are determined by applying the loss-frequency equation and the loss-severity factor to Farmer Mac loan-level data. Using this equation and severity factor, you must calculate loan losses under stressful economic conditions assuming Farmer Mac's portfolio remains at a ''steady state.'' * * *

* * * * *

2.4 Treatment of Loans Backed by an Obligation of the Counterparty and Loans for Which Pledged Loan Collateral Volume Exceeds Farmer Mac-Guaranteed Volume

You must calculate the age-adjusted loss rates for these loans that include adjustments to scale losses according to the proportion of total submitted collateral to the guaranteed amount as provided for in the ''Dollar Losses'' column of the transformed worksheets in the Credit Loss Module based on new data inputs required in the ''Coefficients'' worksheet of the Credit Loss Module. Then, you must adjust the calculated loss rates as follows.

a. For loans in which the seller retains a subordinated interest, subtract from the total estimated age-adjusted dollar losses on the pool the amount equal to current unpaid principal times the subordinated interest percentage.

b. Some pools of loans underlying specific transactions could include loan collateral volume pledged to Farmer Mac in excess of Farmer Mac's guarantee amount (''overcollateral''). Overcollateral can be either: (i) Contractually required according to

the terms of the transaction, or (ii) not contractually required, but pledged in addition to the contractually required amount at the discretion of the counterparty, often for purposes of administrative convenience regarding the collateral substitution process, or (iii) both (i) and (ii).

1. If a pool of loans includes collateral pledged in excess of the guaranteed amount, you must adjust the age-adjusted, loan-level dollar losses by a factor equal to the ratio of the guarantee amount to total submitted collateral. For example, consider a pool of two loans serving as security for a Farmer Mac guarantee on a note with a total issuance face value of $2 million and on which the counterparty has submitted 10-percent overcollateral. The two loans in the example have the following characteristics and adjustments.

Loan	Origination balance	Age-adjusted loss rate (percent)	Estimated age-adjusted losses	Guarantee amount scaling adjustment (2/2.2) (Percent)	Losses adjusted for overcollateral
1	$1,080,000	7.0	$75,600	90.91	$68,727
2	1,120,000	5.0	56,000	90.91	50,909

2. If a pool of loans includes collateral pledged in excess of the guaranteed amount that is required under the terms of the transaction, you must further adjust the dollar losses as follows. Calculate the total losses on the subject portfolio of loans after age adjustments and any adjustments related to total submitted overcollateral as described in ''1.'' above. Calculate the total dollar amount of contractually required overcollateral in the subject pool. Subtract the total dollars of contractually required overcollateral from the adjusted total losses on the subject pool. If the result is less than or equal to zero, input a loss rate of zero for this transaction pool in the Data Inputs worksheet of the RBCST. A new category must be created for each such transaction in the RBCST. If the loss rate after subtracting contractually required overcollateral is greater than zero, proceed to additional adjustment for the risk-reducing effects of the counterparty's general obligation described in ''3.'' below.

3. Loans with a positive loss estimate remaining after adjustments in ''1.'' and ''2.'' above are further adjusted for the security provided by the general obligation of the counterparty. To make this adjustment, multiply the estimated dollar losses remaining after adjustments in ''1.'' and ''2.'' above by the appropriate general obligation adjustment factor based on the counterparty's whole-letter issuer credit rating by a nationally recognized statistical rating organization (NRSRO).

A. The following table sets forth the general obligation adjustment factors and their components by whole-letter credit rating (Adjustment Factor = Default Rate × Severity Rate).[15]

Whole-letter rating	Default rate (percent)	Severity rate (percent)	General obligation adjustment factor (percent)
AAA	0.897	54	0.48
AA	2.294	54	1.24
A	2.901	54	1.57
BBB	7.061	54	3.82
Below BBB and Unrated	26.827	54	14.50

B. The adjustment factors will be updated annually as Moody's annual report on Default and Recovery Rates of Corporate Bond Issuers becomes available, normally in January or February of each year. In the event that there is an interruption of Moody's publication of this annual report, or FCA determines that the format of the report has changed enough to prevent or call into question the identification of updated factors, the prior year's factors will remain in effect until FCA revises the process through rulemaking.

4. Continuing the previous example, the pool contains two loans on which Farmer Mac is guaranteeing a total of $2 million and with total submitted collateral of 110 percent of the guaranteed amount. Of the 10-percent total overcollateral, 5 percent is contractually required under the terms of the transaction. The pool consists of two loans of slightly over $1 million. Total overcollateral is $200,000, of which $100,000 is contractually required. The counterparty has a single ''A'' credit rating, and after adjusting for contractually required overcollateral, estimated losses are greater than zero. The net loss rate is calculated as described in the steps in the table below.

		Loan A	Loan B
1	Guaranteed Volume	$2,000,000	
2	Origination Balance of 2-Loan Portfolio	$1,080,000	$1,120,000
3	Age-adjusted Loss Rate	7%	5%
4	Estimated Age-adjusted Losses	$75,600	$56,000
5	Guarantee Volume Scaling Factor	90.91%	90.91%
6	Losses Adjusted for Total Overcollateral	$68,727	$50,909
7	Contractually required Overcollateral on Pool (5%)	$100,000	
8	Net Losses on Pool Adjusted for Contractually Required Overcollateral	$19,636	
9	General Obligation Adjustment Factor for ''A'' Issuer	1.57%	
10	Losses Adjusted for ''A'' General Obligation	$308	
11	Loss Rate Input in the RBCST for this Pool	0.02%	

[15] Emery, K., Ou S., Tennant, J., Kim F., Cantor R., ''Corporate Default and Recovery Rates, 1920–2007,'' published by Moody's Investors Service, February 2008—the most recent edition as of March 2008; Default Rates, page 24, Recovery Rates (Severity Rate = 1 minus Senior Unsecured Average Recovery Rate) page 20.

A. The net, fully adjusted losses are distributed over time on a straight-line basis. When a transaction reaches maturity within the 10-year modeling horizon, the losses are distributed on a straightline over a timepath that ends in the year of the transaction's maturity.

B. [Reserved]

* * * * *

4.1 Data Inputs

* * * * *

e. *Weighted Haircuts for Non-Program Investments.* For non-program investments, the stress test adjusts the weighted average yield data referenced in section 4.1 b. to reflect counterparty risk. Non-program investments are defined in § 652.5. The Corporation must calculate the haircut to be applied to each investment based on the lowest whole-letter credit rating the investment received from a NRSRO using the haircut levels in effect at the time. Haircut levels shall be the same amounts calculated for the general obligation adjustment factor in section 2.4 b.3.A. above. The first table provides the mappings of NRSRO ratings to whole-letter ratings for purposes of applying haircuts. Any ''+'' or ''−'' signs appended to NRSRO ratings that are not shown in the table should be ignored for purposes of mapping NRSRO ratings to FCA whole-letter ratings. The second table provides the haircut levels by whole-letter rating category.

FCA WHOLE-LETTER CREDIT RATINGS MAPPED TO RATING AGENCY CREDIT RATINGS

FCA Ratings Category	AAA	AA	A	BBB	Below BBB and Unrated.
Standard & Poor's Long-Term	AAA	AA	A	BBB	Below BBB and Unrated.
Fitch Long-Term	AAA	AA	A	BBB	Below BBB and Unrated.
Moody's Long-Term	Aaa	Aa	A	Baa	Below Baa and Unrated.
Standard & Poor's Short-Term	A–1+, SP–1+	A–1, SP–1	A–2, SP–2	A–3	SP–3, B, or Below and Unrated.
Fitch Short-Term	F–1+	F–1	F–2	F–3	Below F–3 and Unrated.
Moody's		Prime–1, MIG1, VMIG1.	Prime–2, MIG2, VMIG2.	Prime–3, MIG3, VMIG3.	Not Prime, SG and Unrated.
Fitch Bank Ratings	A	B, A/B	C, B/C	D, C/D	E, D/E.
Moody's Bank Financial Strength Rating.	A	B	C	D	E.

FARMER MAC RBCST MAXIMUM HAIRCUT BY RATINGS CLASSIFICATION

Ratings classification	Non-program investment counterparties (excluding derivatives) (percent)
Cash	0.00
AAA	0.48
AA	1.24
A	1.57
BBB	3.82
Below BBB and Unrated	14.50

1. Certain special cases will receive the following treatment. For an investment structured as a collateralized obligation backed by the issuer's general obligation and, in turn, a pool of collateral, reference the Issuer Rating or Financial Strength Rating of that issuer as the credit rating applicable to the security. Unrated securities that are fully guaranteed by Government-sponsored enterprises (GSE) such as the Federal National Mortgage Corporation (Fannie Mae) will receive the same treatment as AAA securities. Unrated securities backed by the full faith and credit of the U.S. Government will not receive a haircut. Unrated securities that are not fully guaranteed by a GSE will receive the haircut level in place at that time for ''Below BBB and Unrated'' investments unless the Director, at the Director's discretion, determines to apply a lesser haircut. In making this determination, the Director will consider the risk characteristics associated with the structure of individual instruments.

2. If portions of investments are later sold by Farmer Mac according to their specific risk characteristics, the Director will take reasonable measures to adjust the haircut level applied to the investment to recognize the change in the risk characteristics of the retained portion. The Director will consider relevant similar methods for dealing with capital requirements adopted by other Federal financial institution regulators in similar situations.

3. Individual investment haircuts must then be aggregated into weighted-average haircuts by investment category and submitted in the ''Data Inputs'' worksheet. The spreadsheet uses these inputs to reduce the weighted-average yield on the investment category to account for counterparty insolvency according to a 10-year linear phase-in of the haircuts. Each asset account category identified in this data requirement is discussed in section 4.2, ''Assumptions and Relationships.''

* * * * *

4.2 Assumptions and Relationships

* * * * *

b. * * *

(3) *Elements related to income and expense assumptions.* * * * These parameters are the gain on agricultural mortgage-backed securities (AMBS) sales, miscellaneous income, operating expenses, reserve requirement, guarantee fees and loan loss resolution timing.

* * * * *

(C) The stress test assumes that short-term cost of funds is incurred in relation to the amount of defaulting loans purchased from off-balance sheet pools. The remaining unpaid principal balance on this loan volume is the origination amount reduced by the proportion of the total portfolio that has amortized as of the end of the most recent quarter. This volume is assumed to be funded at the short-term cost of funds and this expense continues for a period equal to the loan loss resolution timing period (LLRT) period minus 1. We will calculate the LLRT period from Farmer Mac data. In addition, during the LLRT period, all guarantee income associated with the loan volume ceases.

(D) The stress test generates no interest income on the estimated volume of defaulted on-balance sheet loan volume required to be carried during the LLRT period, but continues to accrue funding costs during the remainder of the LLRT period.

(E) You must update the LLRT period in response to changes in the Corporation's actual experience with each quarterly submission.

* * * * *

4.4 Loan and Cashflow Accounts

The worksheet labeled ''Loan and Cashflow Data'' contains the categorized loan data and cashflow accounting relationships that are used in the stress test to generate projections of Farmer Mac's performance and condition. As can be seen in the worksheet, the steady-state formulation results in account balances that remain constant except for the effects of discontinued programs, maturing Off-Balance Sheet AgVantage positions, and the LLRT adjustment. For assets with maturities under 1 year, the results are reported for convenience as though they matured only one time per year with the additional convention that the earnings/cost rates are annualized. For the pre-1996 Act assets, maturing balances are added back to post-1996 Act account balances. The liability accounts are used to satisfy the accounting identity, which requires assets to equal liabilities plus owner equity. In addition to the replacement of maturities under a steady state, liabilities are increased to reflect net losses or decreased to reflect resulting net gains. Adjustments must be made to the long- and short-term debt accounts to maintain the same relative proportions as existed at the beginning period from which the stress test is run with the exception of changes associated with the funding of defaulted loans during the LLRT period. The primary receivable and payable accounts are also maintained on this worksheet, as is a summary balance of the volume of loans subject to credit losses.

4.5 Income Statements

a. Information related to income performance through time is contained on

the worksheet named ''Income Statements.'' Information from the first period balance sheet is used in conjunction with the earnings and cost-spread relationships from Farmer Mac supplied data to generate the first period's income statement. The same set of accounts is maintained in this worksheet as ''Loan and Cashflow Accounts'' for consistency in reporting each annual period of the 10-year stress period of the test with the exception of the line item labeled ''Interest reversals to carry loan losses'' which incorporates the LLRT adjustment to earnings from the ''Risk Measures'' worksheet. Loans that defaulted do not earn interest or guarantee and commitment fees during LLRT period. The income from each interest-bearing account is calculated, as are costs of interest-bearing liabilities. In each case, these entries are the associated interest rate for that period multiplied by the account balances.

* * * * *

Dated: May 28, 2008.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

[FR Doc. E8–12245 Filed 6–4–08; 8:45 am]

BILLING CODE 6705–01–P

POSTAL SERVICE

39 CFR Part 111

Service Barcode Required for Priority Mail Open and Distribute Container Address Labels

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: In this final rule the Postal Service provides new mailing standards to require the use of a concatenated UCC/EAN Code 128 Service barcode with a unique Service Type Code ''55'' on all Priority Mail® Open and Distribute container address labels. A proposed rule was published in the **Federal Register** on May 24, 2007 (Volume 72, Number 100), requiring the use of a concatenated UCC/EAN Code 128 Delivery Confirmation™ service barcode. Although no comments were received in response to the proposed rule, because of the modification we decided to publish a second proposed rule. No comments were received in response to the second proposed rule published on April 21, 2008 (Volume 73, Number 77). However, we have extended the effective date from May 12, 2008, to July 1, 2008.

DATES: *Effective Date:* July 1, 2008.

FOR FURTHER INFORMATION CONTACT: Cheryl DuBois at 202–268–3146 or Garry Rodriguez at 202–268–7281.

SUPPLEMENTARY INFORMATION:

Comments

There were no comments received on the May 24, 2007, or April 21, 2008 proposed rules.

Background

Priority Mail Open and Distribute is designed to enhance the Postal Service's ability to provide mailers with expedited service to destination delivery units and other mail processing facilities. Mailers are currently provided an option to use Delivery Confirmation service to receive performance information and confirmation that their containers arrived at the destination facility, along with the date, ZIP Code™, and time their Priority Mail Open and Distribute containers are received at the destination facility.

Summary

In order to verify the arrival at the destination facility for all Priority Mail Open and Distribute containers, the Postal Service is requiring mailers to place a barcode on all Priority Mail Open and Distribute address labels. The barcode is required to be a concatenated UCC/EAN 128 Service barcode with a unique Service Type Code (STC) ''55''. The text, ''USPS SCAN ON ARRIVAL,'' above the barcode is exclusive to this service and will assist in facilitating correct scan behavior.

The decision to require the use of the Service barcode instead of the Delivery Confirmation barcode will lessen any confusion as to the appropriate scans the barcode should receive and ensure the customer gets the appropriate performance information. This will provide better visibility to the customer and enable the USPS® to monitor service performance based on the product.

The requirement is in accordance with instructions for barcode specifications, electronic file format and testing, and certification process, in Publication 91, *Confirmation Services Technical Guide*. Updates to this guide were published in the April 10, 2008, *Postal Bulletin*.

Implementation

The required use of a Service barcode with Priority Mail Open and Distribute service will be effective July 1, 2008.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM®), which is incorporated by reference in the *Code of Federal Regulations*. See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

■ Accordingly, 39 CFR 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 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*, Domestic Mail Manual (DMM), as follows:

* * * * *

700 Special Standards

* * * * *

705 Advanced Preparation and Special Postage Payment Systems

* * * * *

16.0 Express Mail Open and Distribute and Priority Mail Open and Distribute

* * * * *

16.4 Additional Standards for Priority Mail Open and Distribute

* * * * *

16.4.2 Extra Services

[Revise the first sentence in the introductory text of 16.4.2 as follows:]

No extra services are available for Priority Mail Open and Distribute containers. * * *

* * * * *

16.5 Preparation

* * * * *

16.5.4 Tags 161 and 190—Priority Mail Open and Distribute

* * * * *

[Delete item c.]

* * * * *

16.5.6 Address Labels

[Revise the text in 16.5.6 as follows:]

In addition to Tag 157, Label 23, Tag 161, or Tag 190, USPS-supplied containers and envelopes and mailer-supplied containers used for Express Mail Open and Distribute or Priority Mail Open and Distribute must bear an address label that states ''OPEN AND DISTRIBUTE AT:'' followed by the facility name. Find the facility name and other information for addressing the labels, according to the type of facility, in 16.5.8 through 16.5.12.

[Replace heading of 16.5.7, Delivery Confirmation Service, with new 16.5.7

heading, Address Label Barcode Requirement, and revise text as follows:]

16.5.7 Address Label Service Barcode Requirement

An electronic Service barcode using the concatenated UCC/EAN Code 128 symbology must be incorporated in the address label. Mailers must prepare address labels using the formats in 16.5.8 through 16.5.12, including the service type code ''55'' to identify the service and the human-readable text ''USPS SCAN ON ARRIVAL'' above the barcode. USPS certification is required from the National Customer Support Center (NCSC) for each printer used to print barcoded open and distribute address labels, except for barcodes created using USPS Shipping Assistant. NCSC contact information, formatting specifications for barcodes and electronic files, and certification, are included in Publication 91, *Confirmation Services Technical Guide*. Mailers can use any of the following options available to create a label with a Service barcode for Priority Mail Open and Distribute address labels:

a. Select a service software developer from the list of companies that have met Postal Service specifications for the electronic file and barcode available at *http://www.usps.com/shipping/shipsystems.htm*.

b. Register and download the USPS Shipping Assistant desktop application available at *http://www.usps.com/shippingassistant/*.

c. Register and integrate the USPS Web Tools Application Program Interface (API) for Priority Mail Open and Distribute using your own developers, available at *http://www.usps.com/webtools/*.

d. Use Publication 91, *Confirmation Services Technical Guide*, for technical specifications and requirements.

16.5.8 DDU Address Labels

[Revise the second sentence in 16.5.8 as follows:]

* * * For the DDU address label, use the destination facility name, the street address, city, state, and ZIP+4 found in the Drop Entry Point View File available at USPS' FAST Web site: *https://fast.usps.com* (click on ''Reports,'' ''Mail Direction Search,'' then ''Drop Entry Point View''). * * *

Exhibit 16.5.8 DDU Address Label

[Revise Exhibit 16.5.8 to replace the Delivery Confirmation barcode and human-readable text above and below, with a Service barcode and human-readable text.]

16.5.9 SCF Address Labels

[Revise the first sentence in 16.5.9 as follows:]

For the SCF address label, use SCF followed by the city, state, and ZIP Code found in the Drop Entry Point View File available at USPS' FAST Web site: *https://fast.usps.com*. * * *

Exhibit 16.5.9 SCF Address Label

[Revise Exhibit 16.5.9 to replace the Delivery Confirmation barcode and human-readable text above and below, with a Service barcode and human-readable text.]

16.5.10 ADC Address Labels

[Revise the first sentence in 16.5.10 as follows:]

For the ADC address label, use ADC followed by the city, state, and ZIP Code found in the Drop Entry Point View File available at USPS' FAST Web site: *https://fast.usps.com*. * * *

Exhibit 16.5.10 ADC Address Label

[Revise Exhibit 16.5.10 to replace the Delivery Confirmation barcode and human-readable text above and below, with a Service barcode and human-readable text.]

16.5.11 BMC Address Labels

[Revise the first sentence in 16.5.11 as follows:]

For the BMC address label, use BMC followed by the city, state, and ZIP Code found in the Drop Entry Point View File available at USPS' FAST Web site: *https://fast.usps.com*. * * *

Exhibit 16.5.11 BMC Address Label

[Revise Exhibit 16.5.11 to replace the Delivery Confirmation barcode and human-readable text above and below, with a Service barcode and human-readable text.]

[Renumber current 16.5.12, Markings on Enclosed Mail, as 16.5.13. Add new 16.5.12, ASF Address Labels, and Exhibit 16.5.12, ASF Address Label, as follows:]

16.5.12 ASF Address Labels

For the ASF address label, use ASF followed by the city, state, and ZIP Code found in the Drop Entry Point View File under BMC available at USPS' FAST Web site: *https://fast.usps.com*. See Exhibit 16.5.12 for an example of an ASF address label.

Exhibit 16.5.12 ASF Address Label

[Add new Exhibit 16.5.12, as follows:]

* * * * *

Neva R. Watson,

Attorney, Legislative.

[FR Doc. E8–12056 Filed 6–4–08; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule, correction.

SUMMARY: On May 7, 2008, FEMA published in the **Federal Register** a final rule that contained an erroneous table. This notice provides corrections to that table, to be used in lieu of the information published at 73 FR 25542. The table provided here represents the flooding source, location of referenced elevation, effective and modified elevation, and communities affected for the Union County and Incorporated Areas. Specifically, it addresses flooding source ''Blythe Creek.''

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3151 or (e-mail) *bill.blanton@dhs.gov*.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) publishes proposed determinations of Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs for communities participating in the National Flood Insurance Program (NFIP), in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These final BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other

Federal, State, or regional entities. These final elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

Correction

In the final rule published at 73 FR 25542 in the May 7, 2008 issue of the **Federal Register**, FEMA published a table under the authority of 44 CFR 67.4. The table, entitled ''Union County, North Carolina and Incorporated Areas'' addressed flooding source ''Blythe Creek.'' That table contained inaccurate information as to the location of referenced elevation, effective and modified elevation in feet, or communities affected for these flooding sources. In this notice, FEMA is publishing a table containing the accurate information, to address these prior errors. The information provided below should be used in lieu of that previously published.

Flooding source(s)	Location of referenced elevation**	*Elevation in feet (NGVD) +Elevation in feet (NAVD) #Depth in feet above ground Modified	Communities affected
Union County, North Carolina, and Incorporated Areas Docket Nos.: FEMA–D–7668 and FEMA–D–7808			
Blythe Creek	Approximately 0.4 mile upstream of Bud Huey Road (State Route 115).	+549	Unincorporated Areas of Union County, Town of Waxhaw.
	At the confluence with East Fork Twelvemile Creek	+510	

Dated: May 27, 2008.

David I. Maurstad,

Federal Insurance Administrator of the National Flood Insurance Program, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. E8–12516 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register
Vol. 73, No. 109
Thursday, June 5, 2008

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

NUREG–1886, ''Joint Canada—United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages, Draft Report for Comment''

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of document availability and request for public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the availability of and is seeking public comment on the draft NUREG–1886, ''Joint Canada—United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages.''

DATES: Comments on this document should be submitted by August 19, 2008. Comments received after this date will be considered if it is practical to do so, however we are only able to assure consideration for comments received on or before this date. To ensure efficient and complete comment resolution, comments should include reference to the section, page, and line numbers of the document to which the comment applies, if possible.

ADDRESSES: Members of the public are invited and encouraged to submit written comments to Michael T. Lesar, Chief, Rulemaking, Directives and Editing Branch, Mail Stop T6–D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Comments may be submitted by electronic mail to *nrcrep@nrc.gov*. Comments may also be hand delivered to 11555 Rockville Pike, Rockville, Maryland 20852, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

Copies of comments received may be viewed at the NRC's Public Document Room, One White Flint North, Public File Area O1–F21, 11555 Rockville Pike (First Floor), Rockville, Maryland.

This document, NUREG–1886 [ML073300230], is available at the NRC's Agencywide Document Access and Management System (ADAMS) Public Electronic Reading Room on the Internet, accessible through the NRC's public Web site at *http://www.nrc.gov*. This Web site provides text and image files of the NRC's public documents. The public can gain entry into ADAMS through the agency's public Web site at *http://www.nrc.gov/reading-rm/adams.html*, under Accession No. ML073300230. The document may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), One White Flint North, 11555 Rockville Pike, Room O1–F21, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference Staff at (800) 397–4209, (301) 415–4737, or by e-mail to *pdr@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Michele M. Sampson, Office of Nuclear Material Safety and Safeguards, NRC, Washington, DC 20555–0001; telephone: (301) 492–3292; e-mail: *Michele.Sampson@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The International Atomic Energy Agency (IAEA) ''Regulations for the Safe Transport of Radioactive Material'' (TS–R–1) are designed to provide a uniform and adequate level of safety for the transport of radioactive materials. The standards for packaging of radioactive material, the IAEA regulations, TS–R–1, are adopted by member states, providing the basis for each member state's transport package approval. In principle, this ''unilateral'' approval can be accepted by all other member states, with little or no requirement for additional technical review. However, the U.S. and other member states have routinely performed some form of technical review for Type B(U) and fissile material transport packages.[1]

Under the U.S. Department of Transportation (DOT) regulations, 49 Code of Federal Regulations (CFR) part 173.471–473, for a Type B or fissile material package design, a ''U.S. Competent Authority Certificate'' must be obtained from the DOT prior to import or export of Type B or fissile material packages. The June 8, 1979, Memorandum of Understanding (MOU; 44 FR 38690, July 2, 1979) describes the roles and responsibilities of both DOT and NRC in jointly regulating the transportation of radioactive material in the U.S. DOT, assisted by NRC as needed, performs a technical review as part of validation for each foreign-approved package design prior to issuance of a U.S. Certificate of Competent Authority.

In practice, the acceptance of approvals for Type B(U) and fissile material packages, without additional package review by affected member states, has remained an elusive goal. Implementation of a separate technical review is influenced by the perspectives that individual member states have concerning risk, safety margins, and because of other differences in engineering standards, documentation, and quality assurance requirements. Progress towards member state acceptance of Type B(U) and fissile materials transportation packages requires a framework in which these different perspectives, as well as the qualification of technical reviewers, can be addressed, resolved, and documented.

The purpose of this NUREG is to provide the framework to achieve United States and Canadian validation of Competent Authority Type B(U) and fissile materials transportation package approvals for export and import without significant additional technical review.

The NUREG was developed by a working group of DOT, NRC, and Canadian Nuclear Safety Commission (CNSC) staff. The NUREG is to be used by applicants in submitting safety analysis reports for the certification of packages and by DOT and NRC reviewers in assessing these reports. The NUREG describes a method that is acceptable to the staffs of the DOT, NRC, and CNSC for complying with the United States regulations in 10 CFR part 71 and 49 CFR part 173, the Canadian Packaging and Transport of Nuclear Substances Regulations, and TS–R–1, upon which the domestic United States and Canadian regulations are based. Where differences in the regulatory requirements exist, guidance is provided in the NUREG to assist the applicant in appropriately addressing the specific regulatory requirement. The

[1] See 10 CFR 71.4 for definitions of Type B(U) and fissile material transport package classifications.

NUREG is not intended as an interpretation of the regulations, and does not have the force or effect of regulations.

The NUREG applies specifically to applications for approval of Type B(U) and fissile material (Type A and Type B) transportation packages for import or export. The NUREG does not apply to approval of special form materials, certain air shipments of Type B packages, low dispersible material, Type C packages, or fissile materials in less than Type A packages. The NUREG does not change the certification requirements for domestic shipment within the United States or Canada.

The CNSC has a companion Regulatory Document, ''Joint Canada—United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages'' (RD–364) which provides the same guidance to applicants in submitting safety analysis reports to the CNSC for the certification of packages and to CNSC reviewers in assessing these reports, as NUREG–1886. The CNSC document is being published for public comment in Canada.

II. Bi-Lateral Agreement

The United States and Canada, through the working group process, envision a formal process, such as a Memorandum of Agreement, to implement use of NUREG–1886 in the United States and RD–364 in Canada. The protocol for implementation of this formal agreement is expected to detail the process to be followed by the United States and Canada.

The following elements have been identified for implementation:

- Procedures for periodic review of both NUREG–1886 and RD–364 to ensure the documents remain current with regulatory changes.
- NRC and CNSC agreement on minimum qualification of staff assigned to review packages that are part of the bi-lateral agreement.
- Periodic audit by NRC and CNSC of each other's review process.
- Periodic full review by both NRC and CNSC of packages that are part of the bi-lateral agreement.
- Periodic meetings between NRC, DOT, and CNSC staff to discuss technical issues related to package approvals that are part of the bi-lateral agreement.

The formal bi-lateral agreement between NRC, DOT, and CNSC will be made available to the public through a separate notice in the **Federal Register**.

III. Public Participation

The NRC is seeking public comment in order to receive feedback from the widest range of interested parties and to ensure that all information relevant to developing NUREG–1886 is available to the NRC staff. The NRC will provide copies of public comments received to the CNSC and DOT. In addition, public comments received by the CNSC on RD–364 will be provided to the NRC and DOT. The NRC will review all public comments, incorporate suggested changes as necessary, and then issue the final NUREG–1886 for use.

Dated at Rockville, Maryland, this 22nd day of May 2008.

For the Nuclear Regulatory Commission.

Edwin Hackett,

Acting Director, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E8–12583 Filed 6–4–08; 8:45 am]

BILLING CODE 7590–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2008–0189; FRL–8576–5]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Section 110(a)(1) 8-Hour Ozone Maintenance Plan and 2002 Base-Year Inventory for the Schuylkill County Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania. The Pennsylvania Department of Environmental Protection (PADEP) submitted a SIP revision consisting of a maintenance plan that provides for continued attainment of the 8-hour ozone national ambient air quality standard (NAAQS) for at least 10 years after the April 30, 2004 designations, as well as a 2002 base-year inventory for the Schuylkill County Area. EPA is proposing approval of the maintenance plan and the 2002 base-year inventory in accordance with the requirements of the Clean Air Act (CAA).

DATES: Written comments must be received on or before July 7, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2008–0189 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–2008–0097, 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–2008–0189. 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 Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Melissa Linden, (215) 814–2096, or by e-mail at *linden.melissa@epa.gov.*

SUPPLEMENTARY INFORMATION: On December 17, 2007, PADEP formally submitted for approval, under section 110(a)(1) of the CAA, a SIP revision for the 8-hour ozone maintenance plan and the 2002 base-year inventory for the Schuylkill County Area.

I. Background

Section 110(a)(1) of the CAA requires that states submit to EPA plans to maintain the NAAQS promulgated by EPA. EPA interprets this provision to require that areas that were maintenance areas for the 1-hour ozone NAAQS, but attainment for the 8-hour ozone NAAQS, submit a plan to demonstrate the continued maintenance of the 8-hour ozone NAAQS.

On May 20, 2005, EPA issued guidance that applies to areas that are designated unclassifiable/attainment for the 8-hour ozone standard. The purpose of this guidance is to address the maintenance requirements in section 110(a)(1) of the CAA, and to assist the states in the development of a SIP. The components from EPA's guidance include: (1) An attainment emissions inventory, which is based on actual ''typical summer day'' emissions of volatile organic compounds (VOCs) and nitrogen oxides (NO_X) for a 10-year maintenance period, from a base-year chosen by the state; (2) a maintenance demonstration, which demonstrates how the area will remain in compliance with the 8-hour ozone standard for a period of 10 years following the effective date of designation unclassifiable/attainment (June 15, 2004); (3) an ambient air monitoring network, which will be in continuous operation in accordance with 40 CFR Part 58 to verify maintenance of the 8-hour ozone standard; (4) a contingency plan, that will ensure that in the event of a violation of the 8-hour ozone NAAQS, measures will be implemented as promptly as possible; (5) a verification of continued attainment, indicating how the state intends on tracking the progress of the maintenance plan.

II. Summary of SIP Revision

The Commonwealth of Pennsylvania has requested approval of its 8-hour ozone maintenance plan and 2002 base-year inventory for the Schuylkill County Area. The PADEP 8-hour ozone maintenance plan addresses the five components of EPA's May 20, 2005 guidance, which pertains to the maintenance requirements in section 110(a)(1) of the CAA.

Attainment Emission Inventory: An attainment emissions inventory includes emissions during the time period associated with the monitoring data showing attainment. PADEP has provided an emissions inventory for VOCs and NO_X, using 2002 as the base-year from which to project emissions. The 2002 inventory is consistent with EPA guidance, is based on actual ''typical summer day'' emissions of VOCs and NO_X, and consists of a list of sources and their associated emissions. PADEP prepared comprehensive VOCs and NO_X emissions inventories for the Schuylkill County Area. In the maintenance plan, PADEP included information on the man-made sources of ozone precursors, VOCs and NO_X (e.g., ''stationary sources,'' ''stationary area sources,'' ''highway vehicles,'' and ''nonroad sources'').

Pennsylvania projected emissions for beyond 10 years from the effective date of the April 30, 2004 designations for the 8-hour ozone standard. PADEP has developed an emissions inventory for ozone precursors for the year 2002, 2009, and 2018. Tables 1 and 2 show the VOCs and NO_X emissions reduction summary for 2002, 2009, and 2018.

TABLE 1.—VOC EMISSIONS SUMMARY: 2002, 2009 AND 2018

[tons per summer day]

Major source category	2002	2009	2018
Stationary Point Sources	1.16	0.92	1.09
Stationary Area Sources	7.74	7.19	7.56
Highway Vehicles	9.02	4.89	2.73
Nonroad Sources	2.59	2.38	1.86
Total	20.51	15.38	13.24

TABLE 2.—NO_X EMISSIONS SUMMARY: 2002, 2009 AND 2018

[tons per summer day]

Major source category	2002	2009	2018
Stationary Point Sources	3.62	4.42	4.37
Stationary Area Sources	0.86	0.92	0.94
Highway Vehicles	16.71	9.00	3.80
Nonroad Sources	2.42	1.85	1.11
Total	23.61	16.19	10.22

EPA believes Pennsylvania has demonstrated that the VOCs and NO_X emissions in the Schuylkill County Area will improve due to permanent and enforceable reductions in emissions resulting from implementation of the SIP, federal measures, and other state-adopted measures.

Maintenance demonstration: As Tables 1 and 2 indicate, the Schuylkill County Attainment Area plan shows maintenance of the 8-hour ozone NAAQS by demonstrating that future emissions of VOCs and NO_X remain at

or below the 2002 base-year emissions levels through the year 2018.

Based upon the comparison of the projected emissions and the 2002 base-year inventory emissions, along federal and state measures, EPA concludes that PADEP successfully demonstrates that the 8-hour ozone standard will be maintained in the Schuylkill County Area. Further details of Schuylkill County Attainment Area's 8-hour ozone maintenance demonstration can be found in a Technical Support Document (TSD) prepared for this rulemaking.

Ambient Air Quality Monitoring: With regard to the ambient air monitoring component of the maintenance plan, Pennsylvania commits to continue operating its current air quality monitoring stations in accordance with 40 CFR Part 58, to verify the attainment status of the area, with no reductions in the number of sites from those in the existing network unless pre-approved by EPA.

Contingency Plan: Section 110(a)(1) of the CAA requires that the state develop a contingency plan which will ensure that any violation of a NAAQS is promptly corrected. The purpose of the contingency plan is to adopt measures, outlined in the maintenance plan, in order to assure continued attainment in the event of a violation of the 8-hour ozone NAAQS. The maintenance plan should identify the events that would ''trigger'' the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the state would adopt and implement the measure(s).

Since the Schuylkill County Area does not have a monitor, contingency measures will be considered if for two consecutive years the fourth highest 8-hour ozone concentrations at the design monitor for the Reading Area are above 84 parts per billion (ppb). If this trigger point occurs, PADEP will evaluate whether additional local emission control measures should be implemented in Schuylkill County in order to prevent a violation of the air quality standard. PADEP will analyze the conditions leading to the excessive ozone levels and evaluate what measures might be most effective in correcting the excessive ozone levels. PADEP will also analyze the potential emissions effect of federal, state, and local measures that have been adopted but not yet implemented at the time the excessive ozone levels occurred. PADEP will then begin the process of implementing the contingency measures outlined in their maintenance plan.

Verification of continued attainment: PADEP will track the attainment status of the 8-hour ozone NAAQS for Schuylkill County by reviewing air quality at the design monitor for the Reading Area and emissions data during the maintenance period. An annual evaluation of vehicle miles traveled and emissions reported from stationary sources will be performed and compared to the assumptions about the factors used in the maintenance plan. PADEP will also evaluate the periodic (every three years) emission inventories prepared under EPA's Consolidated Emission Reporting Regulation (40 CFR 51, Subpart A) for any unanticipated increases. Based on these evaluations, PADEP will consider whether any further emission control measures should be implemented.

III. Proposed Action

EPA is proposing to approve the maintenance plan and the 2002 base-year inventory for the Schuylkill County Area, submitted on December 17, 2007, as revisions to the Pennsylvania SIP. EPA is proposing to approve the maintenance plan and 2002 base-year inventory for the Schuylkill County Area because it meets the requirements of section 110(a)(1) of the CAA. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under the CAA, 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 CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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 CAA; 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 proposed rule to approve the maintenance plan and the 2002 base-year inventory for the Schuylkill County Area in the Commonwealth of Pennsylvania does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.

Dated: May 28, 2008.

William T. Wisniewski,

Acting Regional Administrator, Region III.

[FR Doc. E8–12601 Filed 6–4–08; 8:45 am]

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Notices

Federal Register

Vol. 73, No. 109

Thursday, June 5, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[FDMS Docket No. FSIS–2008–0004]

International Standard-Setting Activities

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the sanitary and phytosanitary standard-setting activities of the Codex Alimentarius Commission (Codex), in accordance with section 491 of the Trade Agreements Act of 1979, as amended, and the Uruguay Round Agreements Act, Public Law 103–465, 108 Stat. 4809. This notice also provides a list of other standard-setting activities of Codex, including commodity standards, guidelines, codes of practice, and revised texts. This notice, which covers the time periods from June 1, 2007, to May 31, 2008, and June 1, 2008, to May 31, 2009, seeks comments on standards under consideration and recommendations for new standards.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection Service'' from the agency drop-down menu, and then click on ''Submit.'' In the Docket ID column, select FDMS Docket Number FSIS–2008–0004 to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ''Advanced Search'' function in Regulations.gov.
- 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 2534, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250–3700.

All submissions must include the Agency name and docket number FSIS–2008–0004. Please state that your comments refer to Codex and, if your comments relate to specific Codex committees, please identify those committees in your comments and submit a copy of your comments to the delegate from that particular committee. All comments submitted in response to this proposal will be posted to the regulations.gov Web site. The comments also will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2008_Notices_Index/index.asp.*

FOR FURTHER INFORMATION CONTACT: Karen Hulebak, PhD, Acting Manager, U.S. Codex Office, U.S. Department of Agriculture, Office of the Under Secretary for Food Safety, Room 4861, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250–3700; (202) 205–7760. For information pertaining to particular committees, the delegate of that committee may be contacted. (A complete list of U.S. delegates and alternate delegates can be found in Attachment 2 to this notice.) Documents pertaining to Codex are accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp.* The U.S. Codex Office also maintains a Web site at *http://www.fsis.usda.gov/Regulations_&_Policies/Codex_Alimentarius/index.asp.*

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established on January 1, 1995, as the common international institutional framework for the conduct of trade relations among its members in matters related to the Uruguay Round Trade Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade (GATT). U.S. membership in the WTO was approved and the Uruguay Round Agreements Act was signed into law by the President on December 8, 1994. The Uruguay Round Agreements became effective, with respect to the United States, on January 1, 1995. Pursuant to section 491 of the Trade Agreements Act of 1979, as amended, the President is required to designate an agency to be ''responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization.'' The main organizations are Codex, the World Organisation for Animal Health, and the International Plant Protection Convention. The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the U.S. Department of Agriculture as the agency responsible for informing the public of SPS standard-setting activities of each international standard-setting organization. The Secretary of Agriculture has delegated to the Administrator, Food Safety and Inspection Service (FSIS), the responsibility to inform the public of the SPS standard-setting activities of Codex. The FSIS Administrator has, in turn, assigned the responsibility for informing the public of the SPS standard-setting activities of Codex to the U.S. Codex Office, FSIS.

Codex was created in 1962 by two U.N. organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the principal international organization for encouraging fair international trade in food and protecting the health and economic interests of consumers. Through adoption of food standards, codes of practice, and other guidelines developed by its committees and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers, ensure fair trade practices in the food trade, and promote coordination of food standards work undertaken by international governmental and non-governmental organizations. In the United States, the United States Department of Agriculture (USDA) the Food and Drug Administration (FDA),

Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA) manage and carry out U.S. Codex activities.

As the agency responsible for informing the public of the SPS standard-setting activities of Codex, FSIS publishes this notice in the **Federal Register** annually. Attachment 1 (Sanitary and Phytosanitary Activities of Codex) sets forth the following information:

1. The SPS standards under consideration or planned for consideration; and

2. For each SPS standard specified:

a. A description of the consideration or planned consideration of the standard;

b. Whether the United States is participating or plans to participate in the consideration of the standard;

c. The agenda for United States participation, if any; and

d. The agency responsible for representing the United States with respect to the standard.

To Obtain Copies of Those Standards Listed in Attachment 1 That Are Under Consideration by Codex, Please Contact the Codex Delegate or the U.S. Codex Office. This notice also solicits public comment on those standards that are currently under consideration or planned for consideration and recommendations for new standards. The delegate, in conjunction with the responsible agency, will take the comments received into account in participating in the consideration of the standards and in proposing matters to be considered by Codex.

The United States delegate will facilitate public participation in the United States Government's activities relating to Codex Alimentarius. The United States delegate will maintain a list of individuals, groups, and organizations that have expressed an interest in the activities of the Codex committees and will disseminate information regarding United States delegation activities to interested parties. This information will include the status of each agenda item; the United States Government's position or preliminary position on the agenda items; and the time and place of planning meetings and debriefing meetings following Codex committee sessions. In addition, the U.S. Codex Office makes much of the same information available through its Web page, *http://www.fsis.usda.gov/Regulations_&_Policies/Codex_Alimentarius/index.asp.* Please visit the Web page or notify the appropriate U.S. delegate or the U.S. Codex Office, Room 4861, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250–3700, if you would like to access or receive information about specific committees.

The information provided in Attachment 1 describes the status of Codex standard-setting activities by the Codex Committees for the time periods from June 1, 2007, to May 31, 2008, and June 1, 2008, to May 31, 2009. Attachment 2 provides the list of U.S. Codex Officials (includes U.S. delegates and alternate delegates). A list of forthcoming Codex sessions may be found at: *http://www.codexalimentarius.net/web/current.jsp?lang=en.*

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2008_Notices_Index/.* FSIS will also 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 constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and 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 to export information to 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: May 30, 2008.

Paulo Almeida,

Acting Manager U.S. Codex.

Attachment 1:—Sanitary and Phytosanitary Activities of Codex

Codex Alimentarius Commission and Executive Committee

The Codex Alimentarius Commission will hold its Thirty-First Session June 30–July 4, 2008, in Rome, Italy. At that time, it will consider standards, codes of practice, and related matters brought to its attention by the general subject committees, commodity committees, *ad hoc* Task Forces and member delegations. It will also consider options to implement recommendations from the review of Codex committee structure and mandates of Codex committees and task forces, the management of the Trust Fund for the Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius, as well as budgetary and strategic planning issues. At this Session, the Commission will elect a Chairperson and three Vice Chairpersons.

Prior to the Commission meeting, the Executive Committee will have met at its Sixty-First Session on June 24–27, 2008. It is composed of the chairperson, vice-chairpersons, and seven members elected from the Commission, one from each of the following geographic regions: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, and South-West Pacific. Additionally, regional coordinators from the six regional committees serve as members of the Executive Committee. It will consider the Codex Strategic Plan 2008–2013; review the Codex committee structure and mandate of Codex committees and task forces; review matters arising from reports of Codex Committees, proposals for new work, and standards management issues; and review the Trust Fund.

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Residues of Veterinary Drugs in Foods

The Codex Committee on Residues of Veterinary Drugs in Foods determines priorities for the consideration of residues of veterinary drugs in foods and recommends Maximum Residue Limits (MRLs) for veterinary drugs. The Committee also develops codes of practice as may be required and considers methods of sampling and analysis for the determination of veterinary drug residues in food. A veterinary drug is defined as any substance applied or administered to a food producing animal, such as meat or

milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behavior.

A Codex Maximum Limit for Residues of Veterinary Drugs (MRLVD) is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be permitted or recognized as acceptable in or on a food. An MRLVD is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI) or on the basis of a temporary ADI that utilizes an additional safety factor. The MRLVD also takes into account other relative public health risks as well as food technological aspects.

When establishing an MRLVD, consideration is also given to residues that occur in food of plant origin or the environment. Furthermore, the MRLVD may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

An Acceptable Daily Intake (ADI) is an estimate by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg).

The 17th Session of the Codex Committee on Residues of Veterinary Drugs in Foods met in Breckenridge, Colorado, on September 3–7, 2007.

The following items will be considered by the Commission at its 31st Session in June 2008.

To be considered at Step 8:

- Draft MRLs for Colistin in cattle, sheep, goat, pig, chicken, turkey and rabbit tissues, in cattle and sheep's milk and in chicken eggs, Ractopamine in cattle and pig tissues

To be considered at Step 5/8:

- Proposed Draft Maximum Residue Limits for Erythromycin in chicken and turkey tissues

The Committee completed work on the following:

- At the 17th CCRVDF, the Committee completed a Priority of Veterinary Drugs Requiring Evaluation or Reevaluation by JECFA. These drugs are Dexamethasome, Tylosin, Avilamycin, Malachite Green, Tilmicosin, Monensin, Narasin, Triclabendazole, Melengestrol acetate.

The Committee will continue work on the following:

- Draft Maximum Residue Limits for Erythromycin.
- Draft Maximum Residue Limits for Melengesterol Acetate (MGA) in cattle tissue.
- Proposed Draft Maximum Residue Limits for Triclabendazole in cattle, sheep and goat tissues.
- Draft Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Foods.
- Proposed Draft Risk Management Recommendation/Guidance for Veterinary Drugs for which no ADI and MRL have been recommended by JECFA due to specific health concerns.
- Discussion Paper on Consideration of Methods of Analysis and Sampling in CCRVDF (Report of the Electronic Working Group on Methods of Analysis and Sampling).
- Draft Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA and Working Document Listing Veterinary Drugs of Potential Interest (Report of the Electronic Working Group on Priority).
- Discussion Paper on Current Practices and Needs for Further Work by the Committee on the Use of the Estimated Daily Intake (EDI) concept; Utilization of full ADI; Starter culture; and Appending Risk Management. Recommendation(s) to MRLs (Report of the Electronic Working Group on Risk Management Topics and Options for the CCRVDF)

The following work will be discontinued:

- Draft and Proposed Draft Maximum Residue Limits for Flumequine (Black tiger shrimp and shrimps).

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Contaminants in Foods

The Codex Committee on Contaminants in Foods (CCCF) was established by the 29th Session of the Commission when it decided to split the former Codex Committee on Food Additives and Contaminants into two committees. The CCCF establishes or endorses permitted maximum levels for contaminants and naturally occurring toxicants in food and feed, prepares priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), considers methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed, considers and elaborates standards or codes of practice for related subject, and considers other matters assigned to it by the Commission in relation to contaminants and naturally occurring toxicants in food and feed. The Committee held its second session in The Hague, Netherlands from March 31st–April 4, 2008. The relevant document is ALINORM 08/31/41. The following items are to be considered by the 31st Session of the Commission from June 30–July 4, 2008.

To be considered for adoption:

- Proposed Draft Provisions Applied to Contaminants in the ''Relations between Commodity Committees and General Committees'' in the Procedural Manual.
- Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA.

To be considered at Step 8:

- Draft Maximum Level for 3–MCPD in Liquid Condiments Containing Acid-Hydrolyzed Vegetable Oriteins (Excluding Naturally Fermented Soy Sauce).
- Draft Code of Practice for Reduction of 3-Monocloropropane-1,2-diol (3–MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid-HVPs.
- Draft Maximum Level for Ochratoxin A in Raw Wheat, Barley and Rye.
- Draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts, and Pistachios ''For further processing'' and ''Ready to eat.''

To be considered at Step 5/8:

- Proposed Draft Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-Eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios.
- Proposed Draft Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs.

To be considered at Step 5:

- Proposed Draft Code of Practice for the Reduction of Acrylamide in Food.
- Proposed Draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes.

New Work:

- Proposed Draft Maximum Levels for Total Aflatoxins in Brazil Nuts.
- Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee.

The Committee is continuing to work on:

- Proposed Draft Revision of the Preamble of the GSCTF.
- Discussion Paper on Fumonisins.
- Discussion Paper on Benzene in Soft Drinks.

• Discussion Paper on Cyanogenic Glycosides.
• Discussion Paper on Mycotoxins in Sorghum.
• Discussion Paper on Ethyl Carbamate in Alcoholic Beverages.
Responsible Agencies: HHS/FDA; USDA/FSIS.
U.S. Participation: Yes.

Codex Committee on Food Additives

The Codex Committee on Food Additives was re-established by the 29th Session of the Commission, which split the former Codex Committee on Additives and Contaminants into two committees. The Committee is to establish or endorse permitted maximum levels for individual food additives, prepare a priority list of food additives for risk assessment by JECFA, assign functional classes to individual food additives, recommend specifications of identity and purity for food additives for adoption by the Commission, consider methods of analysis for the determination of additives in food, and to consider and elaborate standard for codes for related subjects such as the labeling of food additives when sold as such. The Committee met in Beijing, China, on April 15–25, 2008. The relevant document is ALINORM 8/31/12. The following items will be considered by the 31st Session of the Commission in June 2008.

To be considered for adoption:
• Amendment to the Annex to Table 3 of the GFSA.
• Amendment to the provisions for colours of GFSA.
• Priority List of Food Additives Proposed for Evaluation by JECFA.

To be considered at Step 8 and 5/8:
• Draft and proposed draft food additive provisions of the General Standard for Food Additives (GSFA).
• Draft and proposed draft Guidelines for the Use of Flavourings for adoption at Step 8 (Sections 1, 2, 3, 5, 6 and 7) and Step 5/8 (Section 4).

To be considered at Step 8:
• Draft revision of the Codex Class Names and International Numbering System for Food Additives—CAC/GL 36–2003.

To be considered at Step 5/8:
• Proposed draft revision of the Food Category System (FCF) of the GSFA.
• Proposed draft amendments to the International Numbering System (INS) for Food Additives.
• Proposed and Draft Specifications for the Identity and Purity of Food Additives.

The Committee will continue to work on:
• Draft and proposed draft Food Additive Provisions of the GSFA.
• Guidelines and Principles for the Use of Substances used as Processing Aids.
• Amendments to the INS List.
• Specifications for the Identity and Purity of Food Additives arising from the 69th JECFA meeting.
• Discussion Paper on Scope of Selected Food Categories and Use of Colours.
• Report of the Electronic Working Group on the GSFA.
• Discussion Paper on Identification of Problems and Recommendations Related to the Inconsistent Presentation of Food Additive Provisions in Codex Commodity Standards.
• Inventory of Substances Used as Processing Aids (IPA).
• Discussion Paper on Inconsistencies in the Names of Compounds in Codex Specifications and the INS.
• Priority List of Food Additives Proposed for Evaluation by JECFA (including proposals for the revision of the Circular Letter).
• Working Document for Information and Support to the Discussion on the GSFA.

Discontinued work:
• Food Additive Provisions of the General Standard for Food Additives (GSFA).
• Codex *General Requirements for Natural Flavourings*
• Codex *Specifications for Identity and Purity of Food Additives.*
• Draft and Proposed Draft Food Additive Provisions of the General Standard for Food Additives (GSFA).
Responsible Agency: HHS/FDA.
U.S. Participation: Yes.

Codex Committee on Pesticide Residues

The Codex Committee on Pesticide Residues recommends to the Codex Alimentarius Commission establishment of maximum limits for pesticide residues for specific food items or in groups of food. A Codex Maximum Residue Limit for Pesticide (MRLP) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. Foods derived from commodities that comply with the respective MRLPs are intended to be toxicologically acceptable, that is, consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI*, should indicate that foods complying with Codex MRLPs are safe for human consumption.

Codex MRLPs are primarily intended to apply in international trade and are derived from reviews conducted by the Joint Meeting on Pesticide Residues (JMPR).

(a) Review of residue data from supervised trials and supervised uses, including those reflecting national good agricultural practices (GAP). Data from supervised trials conducted at the highest nationally recommended, authorized, or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLPs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

(b) Toxicological assessments of the pesticide and its residue. The 40th Session of the Committee met in Hangzhou, China, on April 14–19, 2008. The relevant document is ALINORM 08/31/24. The following items will be considered by the Commission at its 31st Session in June 2008.

To be considered at Step 8:
• Draft and Revised Draft Maximum Residue Limits.

To be considered at Step 5/8:
• Proposed Draft and Revised Draft Maximum Residue Limits.

To be considered at Step 5:
• Proposed Draft Maximum Residue Limits.

The committee is continuing work on:
• Proposed Draft and Draft Maximum Residue Limits Retained at Steps 7 and 4.
• Draft Maximum Residue Limits returned to Step 6.
• Proposed Draft Revision of the Codex Classification of Foods and Animal Feeds.

New Work:
• Achieving Globally Harmonized Maximum Residue Limits through Codex.
• Priority List of Pesticides (New Pesticides and Pesticides under Periodic Review).
• The Estimation of Measurement Uncertainty.
• Revision of the CCPR Risk Analysis Principles.
• Establishing a CCPR working group on Minor Uses and Specialty Crops.

Discontinued work:
• Discontinuation of work on the Proposed Draft and Draft Maximum Residues Limits for Pesticides.
• Codex Maximum Residue Limits Recommended for Revocation.
Responsible Agencies: EPA; USDA/AMS.
U.S. Participation: Yes.

Codex Committee on Methods of Analysis and Sampling

The Codex Committee on Methods of Analysis and Sampling:

(a) Defines the criteria appropriate to Codex Methods of Analysis and Sampling;

(b) Serves as a coordinating body for Codex with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories;

(c) Specifies, on the basis of final recommendations submitted to it by the other bodies referred to in (b) above, Reference Methods of Analysis and Sampling appropriate to Codex Standards which are generally applicable to a number of foods;

(d) Considers, amends if necessary, and endorses as appropriate methods of analysis and sampling proposed by Codex (Commodity) Committees, except that methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives do not fall within the terms of reference of this Committee;

(e) Elaborates sampling plans and procedures, as may be required;

(f) Considers specific sampling and analysis problems submitted to it by the Commission or any of its Committees; and

(g) Defines procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.

The 29th Session of the Committee met in Budapest, Hungary, on March 10–14, 2008. The relevant document is ALINORM 08/31/23. The following items will be considered by the 31st Session of the Commission in June 2008:

To be adopted:

- Proposed Amendment to the Working Instructions for the Implementation of the Criteria Approach in Codex.
- Endorsement of Methods of Analysis in Draft Standards and Existing Standards.

To be adopted at Step 5:

- Proposed Draft Guidelines on Analytical Terminology.

The Committee will continue to work on:

- Draft Guidelines for Evaluating Acceptable Methods of Analysis.
- Draft Guidelines for Settling of Disputes on Analytical (Test) Results.
- Guidance on Uncertainty from Sampling.
- Consideration of Methods of Analysis for Dioxins and Dioxin-like PCBs.
- Conformity Assessment in the Presence of Significant Measurement Error (Question referred by the Committee on Milk and Milk Products).

New Work:

- Proposed Draft Guidelines for Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology.
- Guidance on measurement uncertainty and uncertainty of sampling (Proposed Draft Revision of the Guidelines on Measurement Uncertainty).
- Guidelines for establishing methods criteria for identification of relevant analytical methods.

Responsible Agencies: HHS/FDA; USDA/GIPSA.

U.S. Participation: Yes.

Codex Committee on Food Import and Export Inspection and Certification Systems

The Codex Committee on Food Import and Export Inspection and Certification Systems is charged with developing principles and guidelines for food import and export inspection and certification systems to protect consumers and to facilitate trade. Additionally, the Committee develops principles and guidelines for the application of measures by competent authorities to provide assurance that foods comply with essential requirements, especially statutory health requirements. This encompasses work on equivalence of food inspection systems, including equivalence agreements, processes and procedures to ensure that sanitary measures are implemented; guidelines on food import control systems; and guidelines on food product certification and information exchange. The development of guidelines for the appropriate utilization of quality assurance systems to ensure that foodstuffs conform to requirements and to facilitate trade also are included in the Committee's terms of reference. The Committee met November 26–30, 2007. The reference document is ALINORM 08/31/30. The following will be considered for adoption by the Commission at its 31st Session in June 2008.

To be considered at step 5/8:

- Proposed Draft Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (N04–2004).

Certificates

The committee is continuing work on:

- Proposed Draft Guidelines for the Conduct of Foreign Audit Team Inspections.
- Proposed Draft Generic Template for Health Certificates.
- Discussion Paper on the Need for Guidance for National Food Inspection Systems.
- Discussion Paper on the Need for Guidance on Traceability/Product Tracing.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on General Principles

The Codex Committee on General Principles deals with procedure and general matters as are referred to it by the Codex Alimentarius Commission. The 25th Session is tentatively scheduled to be held in Paris, France, in April 2009. The Committee will continue to work on the following items:

- Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments.
- Proposed Draft Revised Code of Ethics for International Trade in Food.
- Recommendations from CCFICS related to the code of ethics.

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Labelling

The Codex Committee on Food Labelling drafts provisions on labeling applicable to all foods; considers, amends, and endorses draft specific provisions on labeling prepared by the Codex Committees drafting standards, codes of practice and guidelines; and studies specific labeling problems assigned by the Codex Alimentarius Commission. This Committee also studies problems associated with the advertisement of food with particular reference to claims and misleading descriptions. The Committee held its 36th Session in Ottawa, Canada, on April 28–May 2, 2008. The reference document is ALINORM 08/31/22. The following items are to be considered by the 31st Session of the Commission from June 30–July 4, 2008.

To be considered at Step 8:

- Draft Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Annex 1 (inclusion of Ethylene for Kiwifruit and Bananas).
- Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients.
- Draft Definition of Advertising in Relation to Nutrition and Health Claims (Draft Amendment to the Guidelines for Use of Nutrition and Health Claims).

The Committee will continue to work on:

- Draft Amendment to the Guidelines for the Production, Processing, Labelling

and Marketing of Organically Produced Foods: Annex 1 (inclusion of Ethylene for Other Products).

• Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of GM/GE): Definitions.

• Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of GM/GE.

The Committee agreed to undertake new work on:

• Amendment to the Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods (rotenone).

• Revision of the Guidelines on Nutrition Labelling (Implementation of the Global Strategy for Diet, Physical Activity and Health).

The Committee agreed to discontinue work on:

• Draft Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Annex 2—Permitted Substances: Table 3.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Hygiene

The Codex Committee on Food Hygiene has four primary responsibilities. The first is to draft basic provisions on food hygiene applicable to all food. These provisions normally take the form of Codes of Hygienic Practice for a specific commodity (e.g. bottled water) or group of commodities (e.g., milk and milk products). The second is to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to consider microbiological risk management matters in relation to food hygiene and in relation to the risk assessment activities of FAO and WHO. The third is to consider, amend if necessary, and endorse food hygiene provisions that are incorporated into specific Codex commodity standards by the Codex Commodity Committees. The fourth and final responsibility is to provide such other general guidance to the Commission on matters relating to food hygiene as may be necessary. The 39th Session of the Committee met in New Delhi, India, on October 30–November 4, 2007. The relevant document is ALNORM 08/31/13.

The following items related to the activities of the Codex Committee on Food Hygiene will be considered by the Commission at its 31st Session in June 2008.

To be considered for adoption at Step 5/8:

• Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.

• Proposed Draft Guidelines for the Validation of Food Safety Control Measures.

• Annex II: Guidance on Microbiological Risk Management Metrics (annex to the Principles and Guidelines for the Conduct of Microbiological Risk Management).

To be considered for approval as New Work:

• Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs (annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables).

• Proposed Draft Code of Hygienic Practice for *Vibrio* spp. in Seafood.

To be considered for discontinuance of work:

• Application of Food Safety Metrics in Risk Management Decision Making—Pasteurized Liquid Whole Eggs (Annex to the Code of Hygienic Practice for Egg and Egg Products).

The Committee will continue or begin work on:

• Annex on the Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-eat Foods (Annex to the Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods).

• Annex II: Microbiological Criteria for Powdered Follow-up Formula and Formula for Special Medical Purposes for Young Children (Annex to the Code of Hygienic Practice for Powdered Formulae for Infants and Children).

• Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat.

• Risk Analysis Policy of the Codex Committee on Food Hygiene.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Fresh Fruits and Vegetables

The Codex Committee on Fresh Fruits and Vegetables is responsible for elaborating world-wide standards and codes of practice for fresh fruits and vegetables. The 14th Session of the Committee met in Mexico City, Mexico on May 12–17, 2008. The relevant document is ALINORM 08/31/35. The following items will be considered by the Commission at its 31st Session in June 2008.

To be considered at Step 8:

• Draft Codex Standard for Tomatoes.

• Draft Codex Standard for Bitter Cassava.

To be considered at Step 5:

• Draft Codex Standard for Apples.

The Committee will continue working on:

• Layout for Codex Standards on Fresh Fruits and Vegetables.

• Amendments to the Priority List for the Standardization of Fresh Fruits and Vegetables.

New Work:

• Revision of the Codex Standard for Avocado.

• Proposed New Codex Standard for Durian.

• Proposed New Codex Standard for Chili Pepper.

• Proposed New Codex Standard for Tree Tomatoes.

Discontinued Work:

• Draft Codex Guidelines for the Inspection and Certification of Fresh Fruits and Vegetables for Conformity to Quality Standards.

Responsible Agencies: USDA/AMS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Nutrition and Foods for Special Dietary Uses

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is responsible for studying nutrition issues referred by the Codex Alimentarius Commission. The Committee also drafts general provisions, as appropriate, on nutritional aspects of all foods and develops standards, guidelines, or related texts for foods for special dietary uses. The Committee met November 12–16, 2007, in Bad Neuenahr-Ahrweiler, Germany. The relevant document is ALINORM 08/31/26. The following items will be considered by the 31st Session of the Commission in June 2008.

To be adopted at Step 8:

• Draft Revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten.

• Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children.

To be adopted at Step 5:

• Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Codex Committee on Nutrition and Foods for Special Dietary Uses.

The Committee will continue work on:

• Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B Containing Provisions on Dietary Fibre).

• Draft Advisory Lists of Nutrient Compounds for Use in Foods for Special

Dietary Uses Intended for Infants and Young Children: Part D Advisory List of Food Additives for Special Nutrient Forms: Provisions on gum arabic (gum acacia).

• Proposed Draft Recommendations on the Scientific Basis of Health Claims.

• Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09–1987).

• Proposal for New Work to Establish a Standard for Processed Cereal-based Foods for Underweight Infants and Young Children.

New Work:

• Additional or Revised Nutrient Reference Values (NRVs) for Labelling Purposes; project document is available in Appendix VII of ALINORM 08/31/26.

Responsible Agencies: HHS/FDA; USDA/ARS.

U.S. Participation: Yes.

Codex Committee on Fish and Fishery Products

The Fish and Fishery Products Committee is responsible for elaborating standards for fresh, frozen and otherwise processed fish, crustaceans, and molluscs. The Committee met on February 18–23, 2008 in Trondheim, Norway. The relevant document is ALINORM 08/31/18. The following items will be considered by the 31st Session of the Commission in June 2008.

To be considered at Step 8:

• Draft Code of Practice for Fish and Fishery Products (Live and Raw Bivalve Molluscs, Lobsters and Relevant Definitions).

• Draft Standard for Live and Raw Bivalve Molluscs.

The Committee will continue to work on:

• Draft Code of Practice for Fish and Fishery Products (Crabs and Relevant Definitions).

• Draft Standard for Sturgeon Caviar.

• Proposed Draft List of Methods for the Determination of Biotoxins in the Draft Standard for Raw and Live Bivalve Molluscs.

• Proposed Draft Code of Practice for Fish and Fishery Products (other sections).

• Proposed Draft Standard for Quick Frozen Scallop Adductor Muscle Meat.

• Proposed Draft Code of Practice on the Processing of Scallop Meat.

• Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish.

• Revision of the Procedure for the Inclusion of Additional Species in Standards for Fish and Fishery Products.

• Proposed Draft Standard for Fish Sauce.

• Amendment to the Standard for Quick Frozen Fish Sticks (Nitrogen Factors).

• Proposed Draft Standard for Fresh/Live and Frozen Abalone.

Responsible Agencies: HHS/FDA; USDC/NOAA/NMFS.

U.S. Participation: Yes.

Codex Committee on Milk and Milk Products

The Codex Committee on Milk and Milk Products is responsible for establishing international codes and standards for milk and milk products. The Committee held its 8th Session February 4–8, 2008, in Queenstown, New Zealand. The relevant document is ALINORM 08/31/11. The following items will be considered by the 31st Session of the Commission in June 2008.

To be considered for adoption:

• Maximum levels for annatto extracts in Codex Standards for Milk and Milk Products, including consequential changes to the provision for beta carotene (vegetable).

• Food additive listings of the Standard for Fermented Milks.

• Methods of Analysis and Sampling for Milk and Milk Products Standards.

At Step 8:

• Draft Model Export Certificate for Milk and Proposed Milk Products.

At Step 5/8:

• Proposed Draft Amendment to the List of Additives of the Codex Standard for Creams and Prepared Creams.

At Step 5:

• Proposed Draft Amendment to the Codex Standard for Fermented Milks pertaining to Drinks based on Fermented Milk .

Other Committee Work:

• Proposed Draft Standard for Processed Cheese.

• Maximum levels for annatto extracts in Codex individual cheese standards.

• Methods of Analysis and Sampling for Milk and Milk Products Standards, including AOAC standards.

Responsible Agencies: USDA/AMS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Fats and Oils

The Codex Committee on Fats and Oils is responsible for elaborating standards for fats and oils of animal, vegetable, and marine origin. The Committee will hold its 21st Session in Kota Kinabalu, Malaysia, on February 16–20, 2009. The Committee is working on:

• Proposed Draft List of Acceptable Previous Cargoes.

• Proposed Draft Criteria (Code of Practice for the Storage and Transport of Fats and Oils in Bulk).

• Proposed Draft Amendments to the Standard for Named Vegetable Oils: Total carotenoids in unbleached palm oil.

• Proposed Draft Amendment to the Standard for Olive Oils and Olive Pomace Oils: Linolenic acid.

• Proposed Draft Amendments to the Standard for Named Vegetable Oils: Inclusion of palm kernel olein and palm kernel stearin.

Responsible Agencies: HHS/FDA; USDA/ARS.

U.S. Participation: Yes.

Codex Committee on Processed Fruits and Vegetables

The Codex Committee on Processed Fruits and Vegetables is responsible for elaborating standards for processed fruits and vegetables. The Committee will hold its 24th Session in Washington, DC, on September 15–19, 2008. The Committee is working on:

• Proposed Draft Codex Standard for Jams, Jellies and Marmalades.

• Proposed Draft Codex Standard for Certain Canned Vegetables.

• Proposed draft annexes specific to the draft Codex Standard for certain canned vegetables (proposed draft for Codex Standard for Certain Canned Vegetables).

• Project Document on Sampling Plan Including Metrological Provisions for Controlling Minimum Drained Weight of Canned Fruits and Vegetables.

• Proposed Layout for Codex Standards for Processed Fruits and Vegetables.

• Proposals for Amendments to the Priority List for Standardization of Processed Fruits and Vegetables.

• Methods of Analysis for Processed Fruits and Vegetables—Aqueous Coconut Products.

• Food Additives Provisions for Processed Fruits and Vegetables.

Responsible Agencies: USDA/AMS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Natural Mineral Waters

The Codex Committee on Natural Mineral Waters is responsible for elaborating standards for all types of natural mineral water products. The Committee was reactivated by the 30th Session of the Codex Alimentarius Commission to address discrepancies of the health-related limits of certain substances between the Codex Standard for Natural Mineral Waters (CODEX STAN 108–1981) and the current version of the WHO Guidelines for

Drinking Water Quality. The Committee should complete the task in no more than two sessions and should propose a revised Section 3.2, ''Health-related limits for certain substances,'' of the Codex Standard for Natural Mineral Waters for final adoption by the Commission at its Session in 2009. The 8th Session of the Committee for Natural Mineral Waters was held on February 11–15, 2008, in Lugano, Switzerland. The following items will be considered by the Commission at its 31st Session in June 2008.

To be considered at Step 5/8:

• Proposed Draft Amendment to Sections 3.2 and 6.3.2 of the Codex Standard for Natural Mineral Waters (CODEX STAN 108–1981).

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Certain Codex Commodity Committees

Several Codex Alimentarius Commodity Committees have adjourned *sine die*. The following Committees fall into this category:

• *Cocoa Products and Chocolate.*
Responsible Agency: HHS/FDA.
U.S. Participation: Yes.
• *Meat Hygiene.*
Responsible Agency: USDA/FSIS.
U.S. Participation: Yes.
• *Sugars.*
Responsible Agencies: USDA/ARS; HHS/FDA.
U.S. Participation: Yes.
• *Vegetable Proteins.*
Responsible Agencies: USDA/ARS; HHS/FDA.
U.S. Participation: Yes.
• *Cereals, Pulses and Legumes.*
Responsible Agencies: HHS/FDA; USDA/GIPSA.
U.S. Participation: Yes.

Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance

The *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance was created by the 29th Session of the Commission. The Task Force, hosted by the Republic of Korea, has a time frame of four sessions, which started with its first meeting in October 2007. Its objective is to develop science-based guidance to assess the risks to human health associated with the presence in food and feed, including aquaculture, of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk. The first session of the Committee met in Seoul, Republic of Korea, on October 23–26, 2007. The relevant document is Alinorm 08/31/42. The following items will be considered by the Commission at its 31st Session in June 2008:

To be considered for approval:

• Proposed Amendments to the Terms of Reference of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance.

The Committee will continue to work on:

• Proposed Draft Risk Assessment Guidance Regarding Foodborne Antimicrobial Resistant Microorganisms.

• Proposed Draft Risk Management Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms.

• Proposed Draft Guidance on Creating Risk Profiles for Antimicrobial Resistant Foodborne Microoganisms for Setting Risk Assessment and Management Priorities.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology

The Commission established this task force to develop standards, guidelines, or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. The Task Force, established by the 23rd Session of the Codex Alimentarius Commission for a four-year period of time, completed its work, but was re-established at the 27th Session of the Commission. The relevant document is ALINORM 08/31/34. The Committee held its 7th Session in Chiba, Japan, September 24–28, 2007. The following are to be considered at Step 5/8 by the Commission at its 31st Session in June 2008.

• Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant–DNA Animals.

• Proposed Draft Annex: Food Safety Assessment of Foods Derived from Recombinant–DNA Plants Modified for Nutritional or Health Benefits.

• Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant–DNA Plant Material in Foods.

Responsible Agencies: HHS/FDA; USDA/APHIS.

U.S. Participation: Yes.

Ad Hoc Intergovernmental Task Force on the Processing and Handling of Quick Frozen Foods

The *Ad hoc* Intergovernmental Task Force on the Processing and Handling of Quick Frozen Foods was created by the 29th Session of the Codex Alimentarius Commission to resolve all outstanding issues, including the quality and safety provisions, of the *Code of Practice for the Processing and Handling of Quick Frozen Foods.* The Task Force, hosted by Thailand, was given two years to finalize the Code. Thailand and the United States prepared a Circular Letter requesting comments on a revised Code. The resulting document prepared from these comments served as the basis for discussion at the Session of the Task Force that took place on February 25–29, 2008. The following item will be considered by the 31st Session of the Commission in June 2008:

To be considered at Step 5/8:

• Proposed draft Recommended International Code of Practice for the Processing and Handling of Quick Frozen Foods.

Responsible Agencies: FDA/HHS, USDA/AMS.

U.S. Participation: Yes.

FAO/WHO Regional Coordinating Committees

The Codex Alimentarius Commission is made up of an Executive Committee, as well as approximately 30 subsidiary bodies. Included in these subsidiary bodies are coordinating committees for groups of countries located in proximity to each other who share common concerns. There are currently six Regional Coordinating Committees:

• Coordinating Committee for Africa.
• Coordinating Committee for Asia.
• Coordinating Committee for Europe.
• Coordinating Committee for Latin America and the Caribbean.
• Coordinating Committee for the Near East.
• Coordinating Committee for North America and the South-West Pacific.

The United States participates as an active member of the Coordinating Committee for North America and the South-West Pacific, and is informed of the other coordinating committees through meeting documents, final reports, and representation at meetings. Each regional committee:

• Defines the problems and needs of the region concerning food standards and food control;

• Promotes within the committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from

food control and stimulates the strengthening of food control infrastructures;

• Recommends to the Commission the development of world-wide standards for products of interest to the region, including products considered by the committee to have an international market potential in the future; and

• Serves a general coordinating role for the region and performs such other functions as may be entrusted to it by the Commission.

Codex Coordinating Committee for North America and the South-West Pacific

The Coordinating Committee (CCNASWP) is responsible for defining problems and needs concerning food standards and food control of all Codex member countries of the region. The next session of the committee is tentatively scheduled for October 27–30, 2008 in Tonga. Items on the agenda for the next meeting may include:

• Draft new Strategic Plan for CCNASWP.

• Report of the Electronic Working Group on Objective 6 of the Strategic Plan (on promoting the development of standards for food products produced in Pacific Island countries).

• Discussion Paper on the Development of a Standard for Kava.

• Discussion Paper on the Development of a Standard for Nonu (Noni) Products.

• *Progress Report:* Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards.

• Evaluation of the effectiveness of the Trust Fund for the participation of developing countries in Codex.

• Nomination of regional coordinator.

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

Attachment 2—U.S. Codex Alimentarius Officials

Codex Committee Chairpersons

Codex Committee on Food Hygiene

Dr. Karen Hulebak, Chief Scientist, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 4861, South Building, Washington, DC 20250–3700, Phone: (202) 205–7760, Fax: (202) 720–3157, E-mail: *karen.hulebak@fsis.usda.gov.*

Codex Committee on Processed Fruits and Vegetables

Mr. Terry Bane, Branch Chief, Processed Products Branch, Fruit and Vegetable Programs, AMS, Room 0709, South Building, Stop 9247, 1400 Independence Avenue, SW., Washington, DC 20250–0247, Phone: (202) 720–4693, Fax: (202) 690–1087, E-mail: *terry.bane@usda.gov.*

Codex Committee on Residues of Veterinary Drugs in Foods

Dr. Bernadette Dunham, Director, Center for Veterinary Medicine, U.S. Department of Health and Human Services, Food and Drug Administration, 7519 Standish Place (MPN4), Rockville, MD 20855, Phone: (240) 276–9000, Fax: (240) 276–9001, E-mail: *Bernadette.dunham@fda.hhs.gov.*

Codex Committee on Cereals, Pulses and Legumes (adjourned *sine die*)

Vacant.

Listing of U.S. Delegates and Alternates Worldwide General Subject Codex Committees

Codex Committee on Residues of Veterinary Drugs in Foods

(Host Government—United States)

U.S. Delegate, Steven D. Vaughn, D.V.M., Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855, Phone: (301) 827–1796, Fax: (301) 594–2297, E-mail: *SVaughn@cvm.fda.gov.*

Alternate Delegate, Emilio Esteban, PhD, Laboratory Director, Food Safety and Inspection Service, Department of Agriculture, 950 College Station Road, Athens, Georgia 30605, Phone: (706) 546–3429, Fax: (706) 546–3428, *Emilio.Esteban@fsis.usda.gov.*

Codex Committee on Food Additives

(Host Government—China)

U.S. Delegate, Dennis M. Keefe, PhD, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–200), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (202) 418–3113, Fax: (202) 418–3131, E-mail: *dennis.keefe@fda.hhs.gov.*

Alternate Delegate, Susan E. Carberry, PhD, Supervisory Chemist, Division of Petition Review, Office of Food Additive Safety (HFS–265), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436–1269, Fax: (301) 436–2972, E-mail: *Susan.Carberry@fda.hhs.gov.*

Codex Committee on Contaminants in Foods

(Host Government—the Netherlands)

U.S. Delegate, Nega Beru, PhD, Director, Office of Plant and Dairy Foods (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436–1700, Fax: (301) 436–2651, E-mail: *Nega.Beru@fda.hhs.gov.*

Alternate Delegate, Kerry Dearfield, PhD, Scientific Advisor for Risk Assessment, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 380, Aerospace Center, Washington, DC 20250, Phone: (202) 690–6451, Fax: (202) 690–6337, E-mail: *Kerry.Dearfield@fsis.usda.gov.*

Codex Committee on Pesticide Residues

(Host Government—China)

U.S. Delegate, Lois Rossi, Director of Registration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, Phone: (703) 305–5035, Fax: (703) 305–5147, E-mail: *rossi.lois@epa.gov.*

Alternate Delegate, Robert Epstein, PhD, Associate Deputy Administrator, Science and Technology, Agricultural Marketing Service, USDA, P.O. Box 96456, Room 3522S, Mail Stop 0222, 1400 Independence Avenue, SW., Washington, DC 20090, Phone: (202) 720–2158, Fax: (202) 720–1484, E-mail: *robert.epstein@usda.gov.*

Codex Committee on Methods of Analysis and Sampling

(Host Government—Hungary)

U.S. Delegate, Gregory Diachenko, PhD, Director, Division of Product Manufacture and Use, Office of Premarket Approval, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (HFS–300), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–2387, Fax: (301) 436–2364, E-mail: *gregory.diachenko@fda.hhs.gov.*

Alternate Delegate, Donald C. Kendall, Technical Services Division, Grain, Inspection, Packers & Stockyards Administration, U.S. Department of Agriculture, 10383

N. Ambassador Drive, Kansas City, MO 64153–1394, Phone: (816) 891–0463, Fax: (816) 891–0478, E-mail: *Donnald.C.Kendall@usda.gov.*

Codex Committee on Food Import and Export Inspection and Certification Systems

(Host Government—Australia)

U.S. Delegate, Catherine Carnevale, D.V.M, Director, International Affairs Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–550), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–2380, Fax: (301) 436–2612, E-mail: *catherine.carnevale@fda.hhs.gov.*

Alternate Delegate, Mary Stanley, Director, Import Inspection Division, Office of International Affairs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 2147-South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720–0287, Fax: (202) 720–6050, E-mail: *Mary.Stanley@fsis.usda.gov.*

Codex Committee on General Principles

(Host Government—France)

U.S.Delegate.

Note: A member of the Steering Committee heads the delegation to meetings of the General Principles Committee.

Codex Committee on Food Labeling

(Host Government—Canada)

U.S. Delegate, Barbara O. Schneeman, PhD, Director, Office of Nutritional Products, Labelling and Dietary Uses, Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Parkway (HFS–800), College Park, MD 20740, Phone: (301) 436–2373, Fax: (301) 436–2636, E-mail: *barbara.schneeman@fda.hhs.gov.*

Alternate Delegate, Heejeong Latimer, Risk Analyst, Risk Assessment Division, Food Safety and Inspection Service, USDA, 1400 Independence Avenue, SW., Rm. 333, Aerospace Center, Washington, DC 20250, Phone: (202) 690–0823, Fax: (202) 205–3625, E-mail: *Heejeong.Latimer@fsis.usda.gov.*

Codex Committee on Food Hygiene

(Host Government—United States)

U.S. Delegate, Robert L. Buchanan, PhD, Lead Scientist, Food Safety Initiative, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–006), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–2369, Fax: (301) 436–2360, E-mail: *robert.buchanan@fda.hhs.gov.*

Alternate Delegates, Kerry Dearfield, PhD, Scientific Advisor for Risk Assessment, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 380, Aerospace Center, Washington, DC 20250, Phone: (202) 690–6451, Fax: (202) 690–6337, E-mail: *Kerry.Dearfield@fsis.usda.gov.*

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Codex Committee on Nutrition and Food for Special Dietary Uses

(Host Government—Germany)

U.S. Delegate, Barbara O. Schneeman, PhD, Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Highway (HFS–800), College Park, MD 20740, Phone: (301) 436–2373, Fax: (301) 436–2636, E-mail: *barbara.schneeman@fda.hhs.gov.*

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Worldwide Commodity Codex Committees Codex Committee on Fresh Fruits and Vegetables

(Host Government—Mexico)

U.S. Delegate, Dorian LaFond, International Standards Coordinator, Fruit and Vegetables Program, Agricultural Marketing Service, USDA, Room 2086, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 690–4944, Fax: (202) 720–4722, E-mail: *dorian.lafond@usda.gov.*

Alternate Delegate, Michelle Smith, PhD, Interdisciplinary Scientist, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–306), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–2024, Fax: (301) 436–2651, E-mail: *Michelle.Smith@fda.hhs.gov.*

Codex Committee on Fish and Fishery Products

(Host Government—Norway)

U.S. Delegate, Donald Kraemer, Acting Director, Office of Seafood, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–2300, Fax: (301) 436–2599, E-mail: *donald.kraemer@fda.hhs.gov.*

Alternate Delegate, Timothy Hansen, Director, Seafood Inspection Program, National Oceanic and Atmospheric Administration, Department of Commerce, Room 10837, 1315 East West Highway, Silver Spring, MD 20910, Phone: (301) 713–2355, Fax: (301) 713–1081, E-mail: *Timothy.Hansen@noaa.gov.*

Codex Committee on Cereals, Pulses and Legumes (adjourned—sine die)

(Host Government—United States

U.S. Delegate, Henry Kim, PhD, Supervisory Chemist, Division of Plant Product Safety, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436–2023, Fax: (301) 436–2651, E-mail: *henry.kim@fda.hhs.gov.*

Codex Committee on Milk and Milk Products

(Host Government—New Zealand)

U.S. Delegate, Duane Spomer, Food Defense Advisor, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2750, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720–1861, Fax: (202) 205–5772, E-mail: *duane.spomer@usda.gov.*

Alternate Delegate, John F. Sheehan, Director, Division of Dairy and Egg Safety, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–306), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436–1488, Fax: (301) 436–2632, E-mail: *john.sheehan@fda.hhs.gov.*

Codex Committee on Fats and Oils

(Host Government—United Kingdom)

U.S. Delegate, Dennis M. Keefe, PhD, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–200), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–1284, Fax: (301) 436–2972, E-mail: *dennis.keefe@fda.hhs.gov.*

Alternate Delegate, Kathleen Warner, Agricultural Research Service, USDA, 1815 N. University Street, Peoria, IL 61604, Phone: (309) 681–6584, Fax: (309) 681–6668, E-mail: *warnerk@ncaur.usda.gov.*

Codex Committee on Cocoa Products and Chocolate

(Host Government—Switzerland)

U.S. Delegate, Michelle Smith, PhD, Food Technologist, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–306), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–2024, Fax: (301) 436–2651, E-mail: *michelle.smith@fda.hhs.gov.*

Codex Committee on Sugars

(Host Government—United Kingdom)

U.S. Delegate, Martin Stutsman, J.D., Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–306), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–1642, Fax: (301) 436–2651, E-mail: *martin.stutsman@fda.hhs.gov.*

Codex Committee on Processed Fruits and Vegetables

(Host Government—United States)

U.S. Delegate, Dorian LaFond, International Standards Coordinator, Fruit and Vegetable Division, Agricultural Marketing Service, USDA, Room 2086, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 690–4944, Fax: (202) 720–0016, E-mail: *dorian.lafond@usda.gov.*

Alternate Delegate, Paul South, PhD, Division of Plant Product Safety, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: (301) 436–1640, Fax: (301) 436–2561, E-mail: *paul.south@fda.hhs.gov.*

Codex Committee on Vegetable Proteins (Adjourned—sine die)

(Host Government—Canada)

U.S. Delegate, Dr. Wilda H. Martinez, Area Director, ARS North Atlantic Area, Agricultural Research Service, USDA, 600 E. Mermaid Lane, Wyndmoor, PA 19038, Phone: (215) 233–6593, Fax: (215) 233–6719, E-mail: *wmartinez@ars.usda.gov.*

Codex Committee on Meat Hygiene (Adjourned—sine die)

(Host Government—New Zealand)

U.S. Delegate, Perfecto Santiago, D.V.M., Deputy Assistant Administrator, Office of Food Security and Emergency Preparedness, Room 3130, South Building, Food Safety and Inspection Service, USDA, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 205–0452, Fax: (202) 690–5634, E-mail: *perfecto.santiago@fsis.usda.gov.*

Codex Committee on Natural Mineral Waters

(Host Government—Switzerland)

U.S. Delegate, Lauren Robin, PhD, Review Chemist, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–1639, Fax: (301) 436–2651, E-mail: *Lauren.Robin@fda.hhs.gov.*

Ad Hoc Intergovernmental Task Forces—Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology (Adjourned—sine die)

(Host Government—Japan)

U.S. Delegate, Eric Flamm, PhD, Senior Advisor, Office of the Commissioner, Food and Drug Administration, Room 1561, Parklawn Building, Rockville, MD 20857, Phone: (301) 827–0591, Fax: (301) 827–4774, E-mail: *eflamm@oc.fda.gov.*

Alternate Delegate, Cindy Smith, Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Unit 98, Ste. 5B05, 4700 River Road, Riverdale, MD 20737, Phone: (301) 734–7324, Fax: (301) 734–6352, E-mail: *Cindy.J.Smith@aphis.usda.gov.*

Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance

(Host Government—Republic of Korea)

Delegate, David G. White, D.V.M., Director, National Antimicrobial Resistance, Monitoring System (NARMS), U.S. Food and Drug Administration, Center for Veterinary Medicine, Office of Research, 8401 Muirkirk Rd., Laurel, MD 20708, Phone: (301) 210–4181, Fax: (301) 210–4685, E-mail: *David.White@fda.hhs.gov.*

Alternate Delegate, Neena Anandaraman, D.V.M., Veterinary Medical Officer, Zoonotic Diseases & Residue Surveillance Division, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 343, Aerospace Center, Washington, DC 20250, Phone: (202) 690–6429, Fax: (202) 690–6565, E-mail: *neena.anandaraman@fsis.usda.gov.*

Ad Hoc Intergovernmental Task Force on Quick Frozen Foods

(Host Government—Thailand)

Delegate, Donald Zink, PhD, Senior Scientist, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–302), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740–3835, Phone: (301) 436–1692, Fax: (301) 436–2632, E-mail: *Donald.Zink@fda.hhs.gov.*

There are six regional coordinating committees:

Coordinating Committee for Africa

Coordinating Committee for Asia

Coordinating Committee for Europe

Coordinating Committee for Latin America and the Caribbean

Coordinating Committee for the Near East

Coordinating Committee for North America and the South-West Pacific.

Contact: Paulo Almeida, Associate Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue, SW., Washington, DC 20250–3700, Phone: (202) 205–7760, Fax: (202) 720–3157, E-mail: *paulo.almeida@fsis.usda.gov.*

[FR Doc. E8–12563 Filed 6–4–08; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Meeting; Federal Lands Recreation Enhancement Act, (Title VIII, Pub. L. 108–447)

AGENCY: Pacific Northwest Region, USDA Forest Service.

ACTION: Notice of Meeting.

SUMMARY: The Pacific Northwest Recreation Resource Advisory Committee (RAC) will meet in Portland, Oregon. The purpose of the meeting is to review and provide recommendations concerning recreation fee proposals for facilities and services offered on lands managed by the Forest Service and Bureau of Land Management in Oregon and Washington. Proposals for this meeting include the jurisdictions of the Bureau of Land Management Salem, Vail, and Spokane Districts, the Okanogan-Wenatchee, Olympic, Rogue River-Siskiyou, Umatilla, Wallowa-Whitman, and Willamette National Forests. Other items of interest related to the Federal Lands Recreation Enhancement Act of 2004 may be discussed.

DATES: The meeting will be held on June 26, 2008, from 8:15 a.m. to 5 p.m. and June 27, 2008, from 8:15 a.m. to 4:30 p.m. A public input time is provided at 9 a.m. on both days. Comments will be limited to three minutes per person. The Designated Federal Official has the discretion to adjourn the meeting early if business is completed.

ADDRESSES: The meeting will be at the Red Lion Hotel, located at 1021 NE Grand Ave., Portland, Oregon, 97232. Send written comments to Dan Harkenrider, Designated Federal Official for the Pacific Northwest Recreation RAC, Columbia River Gorge National Scenic Area, 902 Wasco Ave, Suite 200, Hood River, Oregon 97031, or *dharkenrider@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Dan Harkenrider, Designated Federal Official, Columbia River Gorge National Scenic Area, 902 Wasco Ave, Suite 200, Hood River, Oregon 97031, 541–308–1700.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The agenda for June 26, 2008, includes fee proposals from the Rogue River-Siskiyou, Wallowa Whitman, and Umatilla Forests and the Salem, Vail, and Spokane Districts of the Bureau of Land Management. The agenda for June 27, 2008, includes fee proposals from the Okanogan-Wenatchee, Olympic, and Willamette Forests. Individuals from the public will have the opportunity to address the Committee at 9 a.m. both days. Committee discussion is limited to Forest Service and Bureau of Land Management staff and Recreation Resource Advisory Committee members. However; persons who wish to bring recreation fee matters to the attention of the Committee may address the committee at 9 a.m. both days. The agenda and proposals can be found at *http://www.fs.fed.us/r6/passespermits/rrac.shtml* on the internet.

The Recreation RAC is authorized by the Federal Land Recreation Enhancement Act, which was signed into law by President Bush in December 2004.

Dated: May 28, 2008.

Liz Agpaoa,

Acting Regional Forester, Pacific Northwest Region, USDA Forest Service.

[FR Doc. E8–12306 Filed 6–4–08; 8:45 am]

BILLING CODE 3410–11–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Kansas Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Kansas Advisory Committee to the Commission will convene on Wednesday, July 23, 2008 at 1 p.m and adjourn at 3 p.m at the Ogletree, Deakins, Nash, Smoak, & Stewart Law Firm, 4717 Grand Avenue, Suite 300, Kansas City, MO 64108. The purpose of the meeting is to conduct orientation and program planning for future SAC activities.

Members of the public are entitled to submit written comments; the comments must be received in the Central Regional Office by July 8, 2008. The address is 400 State Avenue, Suite 908, Kansas City, Kansas 66101. Persons wishing to e-mail their comments, or to present their comments verbally at the meeting, or who desire additional information should contact Farella E. Robinson, Regional Director, Central Regional Office, at (913) 551–1400 or by e-mail *frobinson@usccr.gov.*

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Central Regional Office, as they become available, both before and after the meeting. Persons interested in the work of the advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Central Regional Office at the above e-mail or street address.

The meetings will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, May 30, 2008.

Christopher Byrnes,

Chief, Regional Programs Coordination Unit.

[FR Doc. E8–12557 Filed 6–4–08; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–820]

Certain Hot-Rolled Carbon Steel Flat Products From India: Notice of Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 31, 2007, the Department of Commerce (the Department) published the preliminary results of the antidumping duty administrative review for certain hot-rolled carbon steel flat products from India. *See Certain Hot-Rolled Carbon Steel Flat Products From India: Notice of Preliminary Results of Antidumping Duty Administrative Review*, 72 FR 74267 (December 31, 2007) (*Preliminary Results*). This review covers four [1] manufacturers and exporters (respondents) of the subject merchandise: Ispat, Tata, JSW, and Essar. The period of review (POR) is December 1, 2005 through November 30, 2006.

Based on our analysis of the comments received, we have made changes to the margin calculations. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled ''Final Results of Review.''

EFFECTIVE DATE: June 5, 2008.

FOR FURTHER INFORMATION CONTACT: Christopher Hargett (Ispat), Joy Zhang (Tata Steel), Stephanie Moore (JSW) or

[1] Ispat Industries Limited (Ispat), Essar Steel Limited (Essar), JSW Steel Limited (JSW), and Tata Steel Limited (Tata Steel) (collectively, respondents).

Victoria Cho (Essar), AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4161, (202) 482–1168, (202) 482–3692, and (202) 482–5075, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 31, 2007, the Department published the *Preliminary Results.* Since the *Preliminary Results,* the following events have occurred. From January 28 through February 1, 2008, we verified the sales questionnaire responses of Tata, JSW and Ispat. From February 4 through 8, 2008, we verified Ispat's cost questionnaire response. On March 12 and 13, 2008 the Department issued its verification reports. We provided the interested parties an opportunity to comment on the *Preliminary Results* and the Department's verification findings.

On April 4, 2008, United States Steel Corporation (U.S. Steel) and Nucor Corporation (Nucor) (collectively, petitioners) filed case briefs. On April 4, 2008, Essar and JSW filed case briefs. On April 11, 2008, petitioners filed rebuttal briefs. Also, on April 11, 2008, Ispat, Essar, JSW, and Tata filed rebuttal briefs.

On April 7, 2008, the Department published the notice of extension of final results of the antidumping administrative review of certain hot-rolled carbon steel flat products from India, extending the deadline for these final results to no later than May 14, 2008. *See Certain Hot-Rolled Carbon Steel Flat Products From India: Extension of Time Limits for the Final Results of Antidumping Duty Administrative Review,* 73 FR 18753 (April 7, 2008). The Department published a second notice extending the deadline for these final results to no later than May 30, 2008. *See Certain Hot-Rolled Carbon Steel Flat Products From India: Extension of Time Limits for the Final Results of Antidumping Duty Administrative Review,* 73 FR 28100 (May 15, 2008).

Scope of the Order

The merchandise subject to this order is hot-rolled carbon steel products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers), regardless of thickness, and in straight lengths, of a thickness of less than 4.75 mm and of a width measuring at least 10 times the thickness. Universal mill plate (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm, but not exceeding 1250 mm, and of a thickness of not less than 4 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of this order.

Specifically included in the scope of this order are vacuum-degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high-strength low-alloy (HSLA) steels, and the substrate for motor lamination steels. IF steels are recognized as low-carbon steels with micro-alloying levels of elements such as titanium or niobium (also commonly referred to as columbium), or both, added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum.

Steel products included in the scope of this order, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTS), are products in which: (i) iron predominates, by weight, over each of the other contained elements; (ii) the carbon content is 2 percent or less, by weight; and (iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

1.80 percent of manganese, or
2.25 percent of silicon, or
1.00 percent of copper, or
0.50 percent of aluminum, or
1.25 percent of chromium, or
0.30 percent of cobalt, or
0.40 percent of lead, or
1.25 percent of nickel, or
0.30 percent of tungsten, or
0.10 percent of molybdenum, or
0.10 percent of niobium, or
0.15 percent of vanadium, or
0.15 percent of zirconium.

All products that meet the physical and chemical description provided above are within the scope of this order unless otherwise excluded. The following products, by way of example, are outside or specifically excluded from the scope of this order:

- Alloy hot-rolled carbon steel products in which at least one of the chemical elements exceeds those listed above (including, *e.g.*, American Society for Testing and Materials (ASTM) specifications A543, A387, A514, A517, A506)).
- Society of Automotive Engineers (SAE)/American Iron & Steel Institute (AISI) grades of series 2300 and higher.
- Ball bearings steels, as defined in the HTS.
- Tool steels, as defined in the HTS.
- Silico-manganese (as defined in the HTS) or silicon electrical steel with a silicon level exceeding 2.25 percent.
- ASTM specifications A710 and A736.
- United States Steel (USS) Abrasion-resistant steels (USS AR 400, USS AR 500).
- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507).
- Non-rectangular shapes, not in coils, which are the result of having been processed by cutting or stamping and which have assumed the character of articles or products classified outside chapter 72 of the HTS.

The merchandise subject to this order is currently classifiable in the HTS at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, and 7211.19.75.90. Certain hot-rolled carbon steel covered by this order, including: vacuum-degassed fully stabilized; high-strength low-alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers: 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Subject merchandise may also enter under 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7212.40.10.00, 7212.40.50.00, and 7212.50.00.00. Although the HTS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise subject to this order is dispositive.

Affiliation

As stated in the *Preliminary Results,* Nucor alleged that JSW is affiliated with the O.P. Jindal Group, pursuant to section 771(33) of the Tariff Act of 1930, as amended (the Act), and that they should be collapsed. The Department preliminarily determined that JSW is affiliated with the O.P. Jindal Group under sections 771(33)(A) and (F) of the Act, as they are under the common control of a family group. *See Preliminary Results,* at 74268. However, the evidence on the record did not indicate that the other companies in the O.P. Jindal Group have production facilities which would not require substantial retooling for producing similar or identical products. Thus, we did not find that the criteria for collapsing JSW into the O.P. Jindal Group had been satisfied.

We continue to find that JSW is affiliated with the O.P. Jindal Group, but there still is no evidence on the record that indicates that any of the other companies in the group produces the subject merchandise at its own facility or could produce the merchandise without substantially retooling their facilities, or that any other company in the group besides JSW sells the subject merchandise.

Regarding JSW's affiliation with another steel company as alleged by Nucor, the Department preliminarily determined that the companies are not affiliated. *See Preliminary Results,* at 74269. Although the Department finds that there is a long-standing business relationship between these entities, the Department does not find that control exists where one person is legally or operationally in a position to exercise restraint or direction over the other person and the relationship has the potential to impact decisions concerning the production, pricing, or cost of the subject merchandise or foreign like product. *See* section 771(33) of the Act and 19 CFR 351.102(b). Therefore, we continue to find that there is no affiliation between JSW and the other steel company.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this administrative review are addressed in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues which parties have raised, and to which we have responded in the Issues and Decision Memorandum, is attached to this notice as an Appendix. 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.* The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Review:

We determine that the following weighted-average margins exist:

Producer/manufacturer	Weighted-average margin
Ispat	0.00%.
Tata Steel	0.09% (*de minimis*).
JSW	0.24% (*de minimis*).
Essar	5.22%.

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b)(1), where the rate is above *de minimis*, we will issue importer-specific assessment instructions for entries of subject merchandise during the POR. The Department will issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of review.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003 (68 FR 23954). This clarification will apply to entries of subject merchandise during the POR produced by Tata, JSW, Ispat and Essar for which they did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate any unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of hot-rolled carbon steel flat products from India entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by sections 751(a)(1) and (a)(2)(C) of the Act: (1) for companies covered by this review, the cash deposit rate will be the rate listed above; (2) for previously reviewed or investigated companies other than those covered by this review, the cash deposit rate will be the company-specific rate established for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the producer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the subject merchandise; and (4) if neither the exporter nor the manufacturer has its own rate, the cash deposit rate will be 38.72 percent, the all-others rate published in the *Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Hot-Rolled Carbon Steel Flat Products from India,* 66 FR 60194 (December 3, 2001).[2] These deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this period of review. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping and or countervailing duties.

Notification Regarding APOs

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO as explained in the APO itself. See 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 sanctionable violation.

We are publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: May 30, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

APPENDIX I

List of Comments in the Accompanying Issues and Decision Memorandum

Tata Steel Limited

Comment 1: Application of Partial Adverse

[2] The all-others cash deposit rate, applied by CBP, is reduced to account for the export subsidy rate found in the countervailing duty investigation. The adjusted all-others rate is 23.87 percent.

Facts Available (AFA) to Tata's Reported Costs
Comment 2: Sales of Overruns in the Home Market
Comment 3: U.S. Credit Expense Calculations
Comment 4: Procurement Expenses
Comment 5: Deduction of DINDIRSU from CEP
Comment 6: Deduction of CEP Profit
Comment 7: Home Market Indirect Selling Expense Calculations

JSW Steel

Comment 8: Home Market Deduction of Taxes
Comment 9: Deduction of Antidumping and Countervailing Duty Deposits
Comment 10: Application of AFA for JSW
Comment 11: Finding Affiliation Based on AFA for JSW
Comment 12: Collapsing of the O.P. Jindal Group

Ispat Steel Limited

Comment 13: Date of Sale
Comment 14: Freight Charges in Home Market Sales
Comment 15: Treatment of Inland Freight
Comment 16: Calculation of Indirect Selling Expense
Comment 17: Calculation of General and Administrative Expenses

Essar Steel Co. Ltd.

Comment 18: Duty Drawback
Comment 19: Level of Trade
Comment 20: Countervailing Duty Offset
Comment 21: Treatment U.S. Date of Sale
Comment 22: Treatment of U.S. Credit Expense
Comment 23: Treatment of Sales Tax
Comment 24: U.S. Indirect Selling Expenses
Comment 25: DINDIRSU for CEP Sales
Comment 26: CEP Offset
Comment 27: Treatment of Rebates
Comment 28: Home Market Indirect Selling Expenses
Comment 29: Treatment of Commission

[FR Doc. E8–12603 Filed 6–4–08; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–901]

Certain Lined Paper Products From the People's Republic of China: Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 5, 2008.

FOR FURTHER INFORMATION CONTACT: Christopher Hargett, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482–4161.

SUPPLEMENTARY INFORMATION:

Background

On October 31, 2007, the U.S. Department of Commerce (''Department'') published a notice of initiation of the administrative review of the antidumping duty order on certain lined paper products from the People's Republic of China, covering the period April 17, 2006 to August 31, 2007. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 72 FR 61621 (October 31, 2007). The preliminary results of this review are currently due no later than June 1, 2008.

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue preliminary results within 245 days after the last day of the anniversary month of an order for which a review is requested. Section 751(a)(3)(A) of the Act further states that if it is not practicable to complete the review within the time period specified, the administering authority may extend the 245-day period to issue its preliminary results to up to 365 days.

We determine that completion of the preliminary results of this review within the 245-day period is not practicable for the following reasons. The mandatory respondent has complex cost allocation issues which require the Department to gather and analyze a significant amount of information associated with the factors of production and manufacturing costs. In addition, petitioner, Association of American School Paper Suppliers, has raised other issues which require the collection of additional information and has requested that the Department extend the preliminary results to allow more time to analyze these issues. Given the number and complexity of issues in this case and the Department's resource constraints, and in accordance with section 751(a)(3)(A) of the Act, we are extending the time period for issuing the preliminary results of review by 120 days. Therefore, the preliminary results are now due no later than September 29, 2008. The final results continue to be due 120 days after publication of the preliminary results.

This notice is issued and published pursuant to section 751(a)(3)(A) and 771(i)(1) of the Act.

Dated: May 30, 2008.

Stephan J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–12605 Filed 6–4–08; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–924, A–351–841, A–549–825

Postponement of Final Determinations of Antidumping Duty Investigations: Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China, Brazil, and Thailand

AGENCY: Import Administration, International Trade Administration, Department ofCommerce

EFFECTIVE DATE: June 5, 2008.

FOR FURTHER INFORMATION CONTACT: Erin Begnal or Toni Dach for the People's Republic of China, Mike Heaney for Brazil, and Stephen Bailey for Thailand, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1442, (202) 482–1655, (202) 482–4475, and (202) 482–0193, respectively.

SUPPLEMENTARY INFORMATION:

Postponement of Final Determination

On October 18, 2007, the Department of Commerce (''Department'') initiated the antidumping duty investigations of polyethylene terephthalate film, sheet, and strip (''PET Film'') from the People's Republic of China (''PRC''), Brazil, Thailand, and the United Arab Emirates (''UAE''). *See Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Brazil, the People's Republic of China, Thailand, and the United Arab Emirates: Initiation of Antidumping Duty Investigations*, 72 FR 60801 (October 26, 2007) (''*Initiation Notice*''). On May 5, 2008, the Department published the *Preliminary Determinations* in the antidumping duty investigations of PET Film from the PRC, Brazil, and Thailand.[1] *See Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value*, 73 FR 24552 (May 5, 2008), *Notice of Preliminary Determination of Sales at*

[1] The Department postponed the final determination of the investigation of PET Film from the UAE on May 5, 2008. See Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination, 73 FR 24547 (May 5, 2008).

Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, 73 FR 24560 (May 5, 2008), and *Notice of Preliminary Determination of Sales at Not Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip from Thailand*, 73 FR 24565 (May 5, 2008) (collectively, ''*Preliminary Determinations*''). The final determinations of the antidumping duty investigations are currently due on July 9, 2008.[2]

Section 735(a)(2) of the Tariff Act of 1930 (''the Act'') provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by petitioner. In addition, the Department's regulations, at Section 351.210(e)(2), require that requests by respondents for postponement of a final determination be accompanied by a request for extension of provisional measures from a four–month period to not more than six months. *See* 19 CFR 351.210(e)(2).

On May 2, 2008, DuPont Teijin Films China Limited, the sole active mandatory respondent in the PRC investigation, along with its affiliates DuPont Teijin Hongji Films Ningbo Co., Ltd., and DuPont–Hongji Films Foshan Co., Ltd., and Terphane Ltda., the sole mandatory respondent in the Brazil investigation, requested extension of the final determinations and extension of the provisional measures.[3] Thus, because the preliminary determinations in the PRC and Brazil investigations are affirmative, and the respondents requesting extension of the final determinations and extension of the provisional measures account for significant proportions of exports of the subject merchandise, and no compelling reasons for denial exist, we are extending the due date for the final determination in the PRC and Brazil investigations to no later than 135 days after the date of the publication of the preliminary determination.

On May 2, 2008, DuPont Teijin Films, Mitsubishi Polyester Film of America, Inc., SKC, Inc. and Toray Plastics (America), Inc. (collectively, ''petitioners''), requested an extension of the final determination in the Thailand investigation. Thus, as the request for extension in the Thailand investigation was made by petitioners because the preliminary determination in the Thailand investigation is negative, and no compelling reasons for denial exist, we are extending the due date for the final determination in the Thailand investigation to no later than 135 days after the date of the publication of the preliminary determination.

For the reasons identified above, we are postponing the final determinations in the PRC, Brazil, and Thailand investigations until September 17, 2008.

This notice is issued and published pursuant to sections 777(i) and 735(a)(2) of the Act and 19 CFR 351.210(g).

Dated: May 29, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–12612 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–DS–S

[2] The Department inadvertently stated in the PRC preliminary determination that it would make its final determination no later than 75 days after the date of publication of the preliminary determination, instead of no later than 75 days after the date of the preliminary determination.

[3] Terphane Ltda.'s original request did not mention its agreement to the extension of provisional measures, as required by 19 CFR 351.210(e)(2) . However, on May 19, 2008, Terphane Ltda. submitted a letter agreeing to the extension of the provisional measures.

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Upcoming Sunset Reviews

Background

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended, the Department of Commerce (''the Department'') and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for July 2008

The following Sunset Reviews are scheduled for initiation in July 2008 and will appear in that month's Notice of Initiation of Five-year Sunset Reviews.

Antidumping Duty Proceedings	*Department Contact*
Certain Frozen Fish Fillets from Vietnam (A–522–801)	Alex Villanueva (202) 482–3208
Crawfish Tailmeat from the PRC (A–570–848)	Lyn Johnson (202) 482–5287
Countervailing Duty Proceedings.	
Dynamic Random Access Memory Semiconductors from Korea (C–580–851)	Nancy Decker(202) 482–0196

Suspended Investigations

No Sunset Review of suspended investigations are scheduled for initiation in July 2008.

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in the Department's Policy Bulletin 98.3--Policies Regarding the Conduct of Five–year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin, 63 FR 18871 (April 16, 1998) . The Notice of Initiation of Five–year (''Sunset'') Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to

participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: May 30, 2008.

Stephen J. Claeys

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–12609 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–911]

Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Affirmative Determination of Critical Circumstances

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the ''Department'') has determined that countervailable subsidies are being provided to producers and exporters of circular welded carbon quality steel pipe (''CWP'') from the People's Republic of China (''PRC''). For information on the estimated countervailing duty rates, please see the ''Suspension of Liquidation'' section, below.

EFFECTIVE DATE: June 5, 2008.

FOR FURTHER INFORMATION CONTACT: Shane Subler, Damian Felton or Salim Bhabhrawala, 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) 482–0189, (202) 482–0133 or (202) 482–1784 respectively.

SUPPLEMENTARY INFORMATION:

Petitioner

The Petitioners in this investigation are the Ad Hoc Coalition for Fair Pipe Imports from the People's Republic of China and the United States Steel Workers (collectively, ''Petitioners'').

Period of Investigation

The period for which we are measuring subsidies, or period of investigation, is January 1, 2006, through December 31, 2006.

Case History

The following events have occurred since the announcement of the preliminary determination published in the **Federal Register** on November 13, 2007. *See Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination; Preliminary Affirmative Determination of Critical Circumstances; and Alignment of Final Countervailing Duty Determination with Final Antidumping Duty Determination*, 72 FR 63875 (November 13, 2007) (''*Preliminary Determination*'').

On November 13, 2007, the Department issued questionnaires to Weifang East Steel Pipe Co., Ltd. (''East Pipe''); Zhejiang Kingland Pipeline and Technologies Co., Ltd., Kingland Group Co., Ltd., Beijing Kingland Century Technologies Co., Ltd., Zhejiang Kingland Pipeline Industry Co., Ltd., and Shanxi Kingland Pipeline Co., Ltd. (collectively, ''Kingland'') and, the Government of the People's Republic of China (''GOC'') regarding new subsidy allegations made by petitioners on October 3, 2007. We received responses to these questionnaires from Kingland on November 22, 2007, and from the GOC and East Pipe on December 5, 2007.

We issued supplemental questionnaires to East Pipe and Kingland on November 16, 2007, and to the GOC on November 19, 2007. We received responses to these questionnaires from Kingland on December 4, 2007, from East Pipe on December 12, 2007, and from the GOC on December 17, 2007. We issued additional supplemental questionnaires to Kingland on December 14, 2007, and East Pipe on December 17, 2007. We received responses to these questionnaires from Kingland and East Pipe on December 27, 2007.

The GOC, East Pipe, Kingland, Petitioners, and interested parties also submitted factual information, comments, and arguments at numerous instances prior to the final determination based on various deadlines for submissions of factual information and/or arguments established by the Department subsequent to the *Preliminary Determination*.

From January 14 through January 23, 2008, we conducted verification of the questionnaire responses submitted by the GOC, Kingland, and East Pipe.

On April 9, 2008, we issued our post–preliminary determination regarding the provision of land for less than adequate remuneration and new subsidy allegations. We addressed our preliminary findings in an April 9, 2008, memorandum to David M. Spooner, Assistant Secretary for Import Administration, entitled *Post–Preliminary Findings for the Provision of Land for Less Than Adequate Remuneration and New Subsidy Allegations*, which is on file in the Central Records Unit (''CRU'').

We received case briefs from the GOC, East Pipe, Kingland, Petitioners, certain members of the Specialty Steel Industry of North America (''SSINA''), United States Steel Corporation (''US Steel''), Western International Forest Products, LLC (''Western''), MAN Ferrostaal, Inc., Commercial Metals Company and QT Trading LP (collectively, ''MAN Ferrostaal''), and SeAH Steel America (''SSA'') on April 17, 2008. The same parties submitted rebuttal briefs on April 22 and April 29, 2008. We held a hearing for this investigation on May 5, 2008.

Scope of the Investigation

The scope of this investigation covers certain welded carbon quality steel pipes and tubes, of circular cross–section, and with an outside diameter of 0.372 inches (9.45 mm) or more, but not more than 16 inches (406.4 mm), whether or not stenciled, regardless of wall thickness, surface finish (*e.g.*, black, galvanized, or painted), end finish (*e.g.*, plain end, beveled end, grooved, threaded, or threaded and coupled), or industry specification (*e.g.*, ASTM, proprietary, or other), generally known as standard pipe and structural pipe (they may also be referred to as circular, structural, or mechanical tubing).

Specifically, the term ''carbon quality'' includes products in which (a) iron predominates, by weight, over each of the other contained elements; (b) the carbon content is 2 percent or less, by weight; and (c) none of the elements listed below exceeds the quantity, by weight, as indicated:

(i) 1.80 percent of manganese;
(ii) 2.25 percent of silicon;
(iii) 1.00 percent of copper;
(iv) 0.50 percent of aluminum;
(v) 1.25 percent of chromium;
(vi) 0.30 percent of cobalt;
(vii) 0.40 percent of lead;
(viii) 1.25 percent of nickel;
(ix) 0.30 percent of tungsten;
(x) 0.15 percent of molybdenum;
(xi) 0.10 percent of niobium;
(xii) 0.41 percent of titanium;
(xiii) 0.15 percent of vanadium; or
(xiv) 0.15 percent of zirconium.

Standard pipe is made primarily to American Society for Testing and Materials (''ASTM'') specifications, but

can be made to other specifications. Standard pipe is made primarily to ASTM specifications A–53, A–135, and A–795. Structural pipe is made primarily to ASTM specifications A–252 and A–500. Standard and structural pipe may also be produced to proprietary specifications rather than to industry specifications. This is often the case, for example, with fence tubing. Pipe multiple–stenciled to a standard and/or structural specification and to any other specification, such as the American Petroleum Institute (''API'') API–5L specification, is also covered by the scope of this investigation when it meets the physical description set forth above and also has one or more of the following characteristics: is 32 feet in length or less; is less than 2.0 inches (50 mm) in outside diameter; has a galvanized and/or painted surface finish; or has a threaded and/or coupled end finish. (The term ''painted'' does not include coatings to inhibit rust in transit, such as varnish, but includes coatings such as polyester.)

The scope of this investigation does not include: (a) pipe suitable for use in boilers, superheaters, heat exchangers, condensers, refining furnaces and feedwater heaters, whether or not cold drawn; (b) mechanical tubing, whether or not cold–drawn; (c) finished electrical conduit; (d) finished scaffolding; (e) tube and pipe hollows for redrawing; (f) oil country tubular goods produced to API specifications; and (g) line pipe produced to only API specifications.

The pipe products that are the subject of this investigation are currently classifiable in HTSUS statistical reporting numbers 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, 7306.30.50.90, 7306.50.10.00, 7306.50.50.50, 7306.50.50.70, 7306.19.10.10, 7306.19.10.50, 7306.19.51.10, and 7306.19.51.50. However, the product description, and not the Harmonized Tariff Schedule of the United States (''HTSUS'') classification, is dispositive of whether merchandise imported into the United States falls within the scope of the investigation.

Scope Comments

The scope listed above has changed from the *Preliminary Determination*.

On December 19, 2007, Petitioners requested that the Department clarify the scope of this investigation and the companion antidumping duty investigation of CWP from the PRC. We have analyzed the request and comments of the interested parties regarding the scope of this investigation. Our position on these comments is discussed in the final determination in the companion antidumping duty investigation of CWP from the PRC.

Injury Test

Because the PRC is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Tariff Act of 1930, as amended, (the Act), section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from the PRC materially injure, or threaten material injury to a U.S. industry. On August 3, 2007, the ITC published its preliminary determination that there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury by reason of imports from China of circular welded carbon–quality steel pipe. 72 FR 43295.

Critical Circumstances

In the *Preliminary Determination*, the Department determined that critical circumstances exist with respect to imports of circular welded pipe from certain PRC exporters, pursuant to section 703(e) of the Act and 19 CFR 351.206. *Preliminary Determination*, 72 FR at 63879–80. The Department continues to find critical circumstances in this final determination. For further discussion on this issue, see ''Issues and Decision Memorandum for the Final Determination,'' from Stephen J. Claeys, Deputy Assistant Secretary for Import Administration, to David M. Spooner, Assistant Secretary for Import Administration, dated May 29, 2008 (''*Decision Memorandum*'') at Comments 10, 11, and 12, and Memorandum to the File Re ''Critical Circumstances Analysis for Zhejiang Kingland Pipeline and Technologies Co., Ltd. Import Shipment Analysis for Zhejiang Kingland Pipeline and Technologies Co., Ltd. and ''All Others'' (May 29, 2008) (''Final Critical Circumstances Memorandum'') (this memorandum is on file in the Department's CRU).

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this investigation are addressed in the *Decision Memorandum*, which is hereby adopted by this notice. Attached to this notice as an Appendix is a list of the issues that parties have raised and to which we have responded in the *Decision Memorandum*. Parties can find a complete discussion of all issues raised in this investigation and the corresponding recommendations in this public memorandum, which is on file in the CRU. In addition, a complete version of the *Decision Memorandum* can be accessed directly on the Internet at http://ia.ita.doc.gov/frn/. The paper copy and electronic version of the *Decision Memorandum* are identical in content.

Use of Adverse Facts Available

Sections 776(a)(1) and (2) of the Act provide that the Department shall apply ''facts otherwise available'' if, *inter alia*, necessary information is not on the record or an interested party or any other person: (A) withholds information that has been requested; (B) fails to provide information within the deadlines established, or in the form and manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act; (C) significantly impedes a proceeding; or (D) provides information that cannot be verified as provided by section 782(i) of the Act.

Where the Department determines that a response to a request for information does not comply with the request, section 782(d) of the Act provides that the Department will so inform the party submitting the response and will, to the extent practicable, provide that party the opportunity to remedy or explain the deficiency. If the party fails to remedy the deficiency within the applicable time limits and subject to section 782(e) of the Act, the Department may disregard all or part of the original and subsequent responses, as appropriate. Section 782(e) of the Act provides that the Department ''shall not decline to consider information that is submitted by an interested party and is necessary to the determination but does not meet all applicable requirements established by the administering authority'' if the information is timely, can be verified, is not so incomplete that it cannot be used, and if the interested party acted to the best of its ability in providing the information. Where all of these conditions are met, the statute requires the Department to use the information if it can do so without undue difficulties.

Section 776(b) of the Act further provides that the Department may use an adverse inference in applying the facts otherwise available when a party has failed to cooperate by not acting to the best of its ability to comply with a request for information. Section 776(b) of the Act also authorizes the Department to use as adverse facts available (''AFA'') information derived from the petition, the final determination, a previous

administrative review, or other information placed on the record.

Section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation or review, it shall, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal. Secondary information is defined as ''{i}nformation derived from the petition that gave rise to the investigation or review, the final determination concerning the subject merchandise, or any previous review under section 751 concerning the subject merchandise.'' *See Statement of Administrative Action* (''SAA'') accompanying the Uruguay Round Agreements Act, attached to H.R. Rep. No. 103–316, Vol. I at 870 (1994), *reprinted in* 1994 U.S.C.C.A.N. 3773, 4163 (''SAA''). Corroborate means that the Department will satisfy itself that the secondary information to be used has probative value. *See* SAA at 870. To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used. The SAA emphasizes, however, that the Department need not prove that the selected facts available are the best alternative information. *See* SAA at 869.

The Department has concluded that it is appropriate to base the final determination for Tianjin Shuangjie Steel Pipe Group Co., Ltd. (''Shuangjie'') on facts otherwise available. Shuangjie failed to respond at all to the Department's October 24, 2007, request for shipment data relating to the allegation of critical circumstances, did not respond to the Department's October 25, 2007, supplemental questionnaire, and finally, on October 31, 2007, withdrew all of its proprietary information from the record.

Consequently, the use of facts otherwise available is warranted under section 776(a)(2)(A) of the Act.

In selecting from among the facts available, the Department has determined that an adverse inference is warranted, pursuant to section 776(b) of the Act because, in addition to not fully responding to all of our requests for information, Shuangjie withdrew from all participation in the investigation and did not provide the Department with the opportunity to verify the information it did submit. Thus, Shuangjie failed to cooperate by not acting to the best of its ability, and our final determination is based on total AFA.

We have also determined that it is appropriate to apply facts available with respect to certain information that the GOC failed to provide, or information that could not be verified. Specifically, despite the Department's requests to submit sub–national government plans relating to the steel industry in the PRC, the GOC stated that none existed. However, at verification the Department discovered the existence of the Shandong Provincial Steel Plan. Additionally, the Department was unable to verify information regarding the level of state ownership in the HRS industry in the PRC because the GOC misrepresented the source of the data. In both instances, the GOC failed to act to the best of its ability and, consequently, application of AFA is warranted.

Selection of the Adverse Facts Available

In deciding which facts to use as AFA, section 776(b) of the Act and 19 CFR 351.308(c)(1) authorize the Department to rely on information derived from (1) the petition, (2) a final determination in the investigation, (3) any previous review or determination, or (4) any information placed on the record. It is the Department's practice to select, as AFA, the highest calculated rate in any segment of the proceeding. *See, e.g., Certain In–shell Roasted Pistachios from the Islamic Republic of Iran: Final Results of Countervailing Duty Administrative Review*, 71 FR 66165 (November 13, 2006), and accompanying Issues and Decision Memorandum at ''Analysis of Programs'' & Comment 1.

The Department's practice when selecting an adverse rate from among the possible sources of information is to ensure that the margin is sufficiently adverse ''as to effectuate the purpose of the facts available role to induce respondents to provide the Department with complete and accurate information in a timely manner.'' *See Notice of Final Determination of Sales at Less than Fair Value: Static Random Access Memory Semiconductors From Taiwan*, 63 FR 8909, 8932 (February 23, 1998). The Department's practice also ensures ''that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *See* SAA at 870. In choosing the appropriate balance between providing a respondent with an incentive to respond accurately and imposing a rate that is reasonably related to the respondent's prior commercial activity, selecting the highest prior margin ''reflects a common sense inference that the highest prior margin is the most probative evidence of current margins, because, if it were not so, the importer, knowing of the rule, would have produced current information showing the margin to be less.'' *See Rhone Poulenc, Inc. v. United States*, 899 F. 2d 1185, 1190 (Fed. Cir. 1990).

Therefore, for every program based on the provision of goods at less than adequate remuneration, the Department used the Kingland rate for the provision of hot–rolled steel for less than adequate remuneration. For value added tax (''VAT'') programs, we are unable to utilize company–specific rates from this proceeding because neither respondent received any countervailable subsidies from these subsidy programs. Therefore, for VAT programs we are also applying the highest subsidy rate for any program otherwise listed, which in this instance is Kingland's rate for the provision of hot–rolled steel for less than adequate remuneration.

Similarly, for the grant programs, we are not relying on the highest calculated final rate because it is *de minimis*. Instead, we are applying the highest calculated final subsidy rate, which in this instance is Kingland's rate for the provision of hot–rolled steel for less than adequate remuneration.

Finally, for the six alleged income tax programs pertaining to either the reduction of the income tax rates or exemption from income tax, we have applied an adverse inference that Shuangjie paid no income tax during the period of investigation (*i.e.*, calendar year 2006). The standard income tax rate for corporations in the PRC is 30 percent, plus a 3 percent provincial income tax rate. Therefore, the highest possible benefit for these six income tax rate programs is 33 percent. We are applying the 33 percent AFA rate on a combined basis (*i.e.*, the six programs combined provided a 33 percent benefit). This 33 percent AFA rate does not apply to income tax deduction or credit programs. For income tax deduction or credit programs, we are applying the highest subsidy rate for any program otherwise listed, which in this instance is Kingland's rate for the provision of hot–rolled-steel at less than adequate remuneration.

In a change from the *Preliminary Determination*, we are not assigning rates for alleged provincial subsidy programs where record evidence shows that Tianjin Shuangjie was not located in those provinces. *See Decision Memorandum* at Comment 15.

We do not need to corroborate these rates because they are not considered secondary information as they are based on information obtained in the course of this investigation, pursuant to section 776(c) of the Act. *See also* SAA at 870.

Regarding the application of adverse facts available to the GOC, we have treated companies as state–owned

where the GOC did not provide information regarding the companies' ownership. Also, where the provincial steel plan was not provided, we are finding that policy lending existed in that province. *See Decision Memorandum* at ''Analysis of Programs;'' Comment 3; and Comment 8.

Suspension of Liquidation

In accordance with section 705(c)(1)(B)(i)(I) of the Act, we have calculated an individual rate for the companies under investigation, East Pipe, Kingland and Shuangjie. 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. As Shuangjie's rate was calculated under section 776 of the Act, it is not included in the ''all others'' rate.

Nothwithstanding the language of section 705(c)(1)(B)(i)(I) of the Act, we have not calculated the ''all others'' rate by weight averaging the rates of East Pipe and Kingland, because doing so risks disclosure of proprietary information. Therefore, we have calculated a simple average of the two responding firms' rates. Since there were either no or *de minimis* countervailable export subsidies for Kingland and East Pipe and because the ''all others'' rate is a simple average based on the individually investigated exporters and producers, the ''all others'' rate does not include export subsidies.

Exporter/Manufacturer	Net Subsidy Rate
Weifang East Steel Pipe Co., Ltd.	29.57%
Zhejiang Kingland Pipeline and Technologies Co., Ltd., and affiliated companies.	44.86 %
Tianjin Shuangjie Steel Pipe Co., Ltd.; Tianjin Shuangjie Steel Pipe Group Co., Ltd.; Tianjin Wa Song Imp. & Exp. Co., Ltd.; and Tianjin Shuanglian Galvanizing Products Co., Ltd.	615.92%
All Others	37.22%

Because we preliminarily determined that critical circumstances exist for entries of CWP manufactured/exported by Kingland, Shuangjie and ''all other'' Chinese manufacturers/exporters and pursuant to sections 703(d)(1)(B) and (2) and 703(e)(2)(A) of the Act, we instructed the U.S. Customs and Border Protection (''CBP'') to suspend liquidation of entries of CWP manufactured/exported by Kingland, Shuangjie and ''all other'' Chinese exports of CWP which were entered or withdrawn from warehouse, for consumption on or after November 13, 2007, and to apply the suspension of liquidation to any unliquidated entries entered, or withdrawn from warehouse for consumption, on or after August 15, 2007 (90 days before the date of publication of the *Preliminary Determination*. Also, in accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation for countervailing duty purposes for subject merchandise entered on or after March 12, 2008, but to continue the suspension of liquidation of entries made from August 15, 2007, through March 12, 2008. *Preliminary Determination*, 72 FR at 6386.

For entries of CWP manufactured/exported by East Pipe, we did not instruct CBP to suspend liquidation because we preliminarily determined that East Pipe did not receive any countervailable subsidies.

We will issue a countervailing duty order and reinstate the suspension of liquidation under section 706(a) of the Act (for all companies including East Pipe) if the International Trade Commission (''ITC'') issues a final affirmative injury determination, and 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 non–proprietary 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 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 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 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 published pursuant to sections 705(d) and 777(i) of the Act.

Dated: May 29, 2008.

David M. Spooner,

Assistant Secretaryfor Import Administration.

Appendix

List of Comments and Issues in the Decision Memorandum

Comment 1: The Department's Authority to Apply the Countervailing Duty Law to China
Comment 2: Subsidies Prior to China's Accession to the World Trade Organization

Comment 3: Adverse Facts Available (''AFA'')

Comment 4: Attribution of Subsidies Received by Affiliates of Zhejiang Kingland Pipeline and Technologies Co., Ltd.
Comment 5: Scope of the Investigation
Comment 6: Sales Denominator for Weifang East Steel Pipe Company Ltd.
Comment 7: Provision of Hot–rolled Steel for Less Than Adequate Remuneration

Comment 8: Government Policy Lending

Comment 9: Provision of Electricity for Less Than Adequate Remuneration
Comment 10: Critical Circumstances on an Importer Specific Basis
Comment 11: Base and Comparison Period for Critical Circumstances
Comment 12: Kingland Export Subsidy and Finding of Critical Circumstances
Comment 13: East Pipe Debt Forgiveness

Comment 14: Discount Rate
Comment 15: Programs Included in AFA Rate for Tianjin Shuangjie Steel Pipe Co., Ltd.

Comment 16: Double Remedy

[FR Doc. E8–12606 Filed 6–4–08; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

A–570–910

Notice of Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 5, 2008.

SUMMARY: The Department of Commerce (''the Department'') has determined that circular welded carbon quality steel pipe (''CWP'') from the People's Republic of China (''PRC'') is being, or is 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 final dumping margins for this investigation are listed in the ''Final Determination Margins'' section below.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Maisha Cryor, 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) 482–5831, respectively.

SUPPLEMENTARY INFORMATION:

Case History

On January 15, 2008, the Department published in the **Federal Register** its preliminary determination that CWP from PRC is being, or is likely to be, sold in the United States at LTFV, as provided in the Act. *See Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 73 FR 2445, 2451 (January 15, 2008) (''*Preliminary Determination*''). For the *Preliminary Determination*, the Department calculated a zero percent dumping margin for Jiangsu Yulong Steel Pipe Co., Ltd. (''Yulong''). On March 12, 2008, Petitioners,[1] mandatory respondent Yulong, separate rate applicants Weifang East Steel Pipe Co., Ltd., Tianjin Baloai International Trade Co., Ltd., Shijiazhuang Zhongqing Import and Export Co., Ltd., and Shandong Fubo Group Co. (collectively, ''Weifang East Pipe''), and two U.S. importers of subject merchandise, SeAH Steel America, Ltd. (''SeAH'') and Western International Forest Products, LLC (''Western''), filed case briefs pursuant to the *Preliminary Determination*.[2] On March 20, 2008, Petitioners, Yulong, and one U.S. importer, MAN Ferrostaal Inc., Commercial Metals Company, and QT Trading LP (collectively, ''MAN Ferrostaal''), filed rebuttal briefs.[3] On March 24, 2008, the Department held a public hearing. Subsequent to the submission of briefs and the hearing, the Department received an allegation that a PRC pipe company involved in the investigation submitted falsified documents to the Department. Following the Department's request for comments on this allegation, on April 7, 2008, Yulong withdrew from the investigation and stated that it did not contest the allegation. *See Amended Preliminary Determination of Sales at Less Than Fair Value: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China*, 73 FR 22130, 22131 (April 24, 2008) (''*Amended Preliminary Determination*'') In light of Yulong's withdrawal from the investigation, on April 24, 2008, the Department published its *Amended Preliminary Determination*, in which the Department applied total adverse facts available (''AFA'') to Yulong and denied Yulong a separate rate, treating it as part of the PRC–wide entity. In addition, the Department assigned a new rate to the PRC–wide entity and provided parties with the opportunity to submit a second set of case briefs and rebuttal briefs. On April 28, 2008, Weifang East Pipe submitted a case brief pursuant to the *Amended Preliminary Determination*.[4] On April 30, 2008, Petitioners submitted a rebuttal brief in response to Weifang East Pipe's April Case Brief.[5]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by the parties to this investigation are addressed in the ''Issues and Decision Memorandum for the Final Determination of Sales at Less than Fair Value: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China,'' dated concurrently with this notice, which is hereby adopted by this notice in its entirety (''Issues and Decision Memorandum''). A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file in the Central Records Unit (''CRU''), Main Commerce Building, Room 1117, and is accessible on the Web at http://www.trade.gov/ia. The paper copy and electronic version of the memorandum are identical in content.

Period of Investigation

The period of investigation (''POI'') is October 1, 2006, through March 31, 2007.

Changes Since the Amended Preliminary Determination

Based on our analysis of comments received, we have made no changes in our margin calculations since the Department's *Amended Preliminary Determination*.

Scope of Investigation

The scope of this investigation covers certain welded carbon quality steel pipes and tubes, of circular cross-section, and with an outside diameter of 0.372 inches (9.45 mm) or more, but not more than 16 inches (406.4 mm), whether or not stenciled, regardless of wall thickness, surface finish (*e.g.*, black, galvanized, or painted), end finish (*e.g.*, plain end, beveled end, grooved, threaded, or threaded and coupled), or industry specification (*e.g.*, ASTM, proprietary, or other), generally known as standard pipe and structural pipe (they may also be referred to as circular, structural, or mechanical tubing).

[1] Petitioners in this investigation are Allied Tube & Conduit, Sharon Tube Company, IPSCO Tubulars, Inc., Western Tube & Conduit Corporation, Northwest Pipe Company, Wheatland Tube Co., *i.e.*, the Ad Hoc Coalition For Fair Pipe Imports From China, and the United Steelworkers.

[2] Petitioners' March 12, 2008, case brief is hereinafter referred to as the ''Petitioners' March Case Brief.'' The Yulong March 12, 2008, case brief is hereinafter referred to as the ''Yulong March Case Brief.'' The Weifang East Pipe March 12, 2008, case brief is hereinafter referred to as the ''Weifang East Pipe March Case Brief.'' The SeAH March 12, 2008, case brief is hereinafter referred to as the ''SeAH March Case Brief.'' The Western March 12, 2008, case brief is hereinafter referred to as the ''Western March Case Brief.''

[3] Petitioners' March 20, 2008, rebuttal brief is hereinafter referred to as the ''Petitioners' March Rebuttal Brief.'' The Yulong March 20, 2008, rebuttal brief is hereinafter referred to as the ''Yulong March Rebuttal Brief.'' The MAN Ferrostaal March 20, 2008, rebuttal brief is hereinafter referred to as the ''MAN Ferrostaal March Rebuttal Brief.''

[4] The Weifang East Pipe April 28, 2008, case brief is hereinafter referred to as the ''Weifang East Pipe April Case Brief.''

[5] Petitioners' April 30, 2008, rebuttal brief is hereinafter referred to as the ''Petitioners' April Rebuttal Brief.''

Specifically, the term ''carbon quality'' includes products in which (a) iron predominates, by weight, over each of the other contained elements; (b) the carbon content is 2 percent or less, by weight; and (c) none of the elements listed below exceeds the quantity, by weight, as indicated:
(i)1.80 percent of manganese;
(ii)2.25 percent of silicon;
(iii)1.00 percent of copper;
(iv)0.50 percent of aluminum;
(v)1.25 percent of chromium;
(vi) 0.30 percent of cobalt;
(vii) 0.40 percent of lead;
(viii) 1.25 percent of nickel;
(ix) 0.30 percent of tungsten;
(x) 0.15 percent of molybdenum;
(xi) 0.10 percent of niobium;
(xii) 0.41 percent of titanium;
(xiii) 0.15 percent of vanadium; or
(xiv) 0.15 percent of zirconium.

Standard pipe is made primarily to American Society for Testing and Materials (''ASTM'') specifications, but can be made to other specifications. Standard pipe is made primarily to ASTM specifications A–53, A–135, and A–795. Structural pipe is made primarily to ASTM specifications A–252 and A–500. Standard and structural pipe may also be produced to proprietary specifications rather than to industry specifications. This is often the case, for example, with fence tubing. Pipe multiple–stenciled to a standard and/or structural specification and to any other specification, such as the American Petroleum Institute (''API'') API–5L specification, is also covered by the scope of this investigation when it meets the physical description set forth above and also has one or more of the following characteristics: is 32 feet in length or less; is less than 2.0 inches (50 mm) in outside diameter; has a galvanized and/or painted surface finish; or has a threaded and/or coupled end finish. (The term ''painted'' does not include coatings to inhibit rust in transit, such as varnish, but includes coatings such as polyester.)

The scope of this investigation does not include: (a) pipe suitable for use in boilers, superheaters, heat exchangers, condensers, refining furnaces and feedwater heaters, whether or not cold drawn; (b) mechanical tubing, whether or not cold–drawn; (c) finished electrical conduit; (d) finished scaffolding; (e) tube and pipe hollows for redrawing; (f) oil country tubular goods produced to API specifications; and (g) line pipe produced to only API specifications.

The pipe products that are the subject of this investigation are currently classifiable in HTSUS statistical reporting numbers 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, 7306.30.50.90, 7306.50.10.00, 7306.50.50.50, 7306.50.50.70, 7306.19.10.10, 7306.19.10.50, 7306.19.51.10, and 7306.19.51.50. However, the product description, and not the Harmonized Tariff Schedule of the United States (''HTSUS'') classification, is dispositive of whether merchandise imported into the United States falls within the scope of the investigation.

Scope Comments

In its March case brief, Petitioners argued that the Department should revise; 1) the scope of the investigation to be based upon end–use application, and 2) the definition of ''painted.'' For the reasons discussed in the Issues and Decision Memorandum, we have not revised the scope of the investigation. However, we have revised the definition of the term ''painted,'' and have updated the scope accordingly. *See* Issues and Decision Memorandum at Comment 1.

Non–Market Economy Treatment

In the *Preliminary Determination* and *Amended Preliminary Determination*, the Department considered the PRC to be a non–market economy (''NME'') country. In accordance with section 771(18)(C)(i) of the Act, any determination that a country is an NME country shall remain in effect until revoked by the administering authority. *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Results of 2001–2002 Administrative Review and Partial Rescission of Review*, 68 FR 7500 (February 14, 2003), unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Final Results of 2001–2002 Administrative Review and Partial Rescission of Review*, 68 FR 70488 (December 18, 2003). In its March case brief, Weifang East Pipe argued that the PRC should be granted market economy status. *See* Weifang East Pipe March Case Brief, at 6. For the reasons discussed in the Issues and Decision Memorandum, we disagree with Weifang East Pipe and have continued to treat the PRC as an NME. *See* Issues and Decision Memorandum at Comment 2.

Separate Rates

In proceedings involving NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an investigation in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. *See Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20588 (May 6, 1991) (''*Sparklers*''), as amplified by *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*''), and Section 351.107(d) of the Department's regulations.

In the *Preliminary Determination*, we found that the following separate rate applicants demonstrated their eligibility for separate–rate status: Wai Ming (Tianjin) Int'l Trading Co., Ltd.; Weifang East Steel Pipe Co., Ltd.; Wuxi Fastube Industry Co., Ltd.; Wuxi Eric Steel Pipe Co., Ltd.; Beijing Sai Lin Ke Hardware Co., Ltd.; Wah Cit Enterprises; Guangdong Walsall Steel Pipe Industrial Co., Ltd.; Shijiazhuang Zhongqing Imp & Exp Co., Ltd.; Tianjin Baolai Int'l Trade Co., Ltd.; Dalian Brollo Steel Tubes Ltd.; Benxi Northern Pipes Co., Ltd.; Shanghai Metals & Minerals Import & Export Corp.; Huludao Steel Pipe Industrial Co., Ltd.; Tianjin Xingyuda Import & Export Co. Ltd.; Jiangyin Jianye Metal Products Co., Ltd.; Rizhao Xingye Import & Export Co., Ltd.; Kunshan Hongyuan Machinery Manufacture Co., Ltd.; Tianjin No. 1 Steel Rolled Co., Ltd.; Qingdao Yongjie Import & Export Co., Ltd.; Jiangsu Guoqiang Zinc–Plating Industrial Company, Ltd.; Qingdao Xiangxing Steel Pipe Co., Ltd.; Hengshui Jinghua Steel Pipe Co., Ltd.; Zhangjiagang Zhongyuan Pipe–Making Co., Ltd.; Kunshan Lets Win Steel Machinery Co., Ltd.; and Shenyang BOYU M/E Co., Ltd.

No party has commented on the eligibility of these companies for separate–rate status. For the final determination, we continue to find that the evidence placed on the record of this investigation by these companies demonstrates both a *de jure* and *de facto* absence of government control with respect to their respective exports of the merchandise under investigation. Thus, we continue to find that they are eligible for separate–rate status. Normally the separate rate is determined based on the estimated weighted–average dumping margins established for exporters and producers individually investigated, excluding *de minimis* margins or margins based entirely on AFA. *See* section 735(c)(5)(A) of the Act. In this case, given the absence of participating

respondents and having calculated no margins, we have assigned to the separate rate companies the simple average of the margins alleged in the petition. *See Amended Preliminary Determination*, 73 FR at 22133.

We determined in the *Preliminary Determination* that Shandong Fubo Group Co. (''Fubo'') and Tianjin Youcheng Galvanized Steel Pipe Co., Ltd. (''Youcheng'') are not entitled to a separate rate. We received no comments on this denial of separate rates and, for the final determination, continue to find that Fubo and Youcheng are not entitled to a separate rate.

The PRC–Wide Rate

In the *Preliminary Determination*, the Department found that certain companies did not respond to our requests for information. See Preliminary Determination, 73 FR at 2451. In the *Preliminary Determination* we treated these PRC producers/exporters as part of the PRC–wide entity because they did not demonstrate that they operate free of government control over their export activities. In addition, in the *Amended Preliminary Determination*, the Department applied total AFA to Jiangsu Yulong Steel Pipe Co., Ltd. (''Yulong''). We determined, as AFA, that Yulong was not eligible for a separate rate, and, for the final determination, we are treating Yulong as part of the PRC–wide entity. No additional information was placed on the record with respect to any of these companies after the *Preliminary Determination* or the *Amended Preliminary Determination*. Therefore, pursuant to section 776(a)(2)(A) of the Act, the Department continues to find that the use of facts available is appropriate to determine the PRC–wide rate.

Section 776(b) of the Act provides that, in selecting from among the facts otherwise available, the Department may employ an adverse inference if an interested party fails to cooperate by not acting to the best of its ability to comply with requests for information. *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold–Rolled Flat–Rolled Carbon–Quality Steel Products from the Russian Federation*, 65 FR 5510, 5518 (February 4, 2000). *See also ''Statement of Administrative Action''* accompanying the URAA, H.R. Rep. No. 103–316, vol. 1, at 870 (1994) (''SAA''). We determined that, because the PRC–wide entity did not respond to our request for information, it has failed to cooperate to the best of its ability. Therefore, the Department finds that, in selecting from among the facts otherwise available, an adverse inference is appropriate for the PRC–wide entity.

Because we begin with the presumption that all companies within a NME country are subject to government control and because only the companies listed under the ''Final Determination Margins'' section below have overcome that presumption, we are applying a single antidumping rate (*i.e.*, the PRC–wide entity rate) to all other exporters of subject merchandise from the PRC. Such companies did not demonstrate entitlement to a separate rate. *See, e.g., Synthetic Indigo from the People's Republic of China: Notice of Final Determination of Sales at Less Than Fair Value*, 65 FR 25706 (May 3, 2000). The PRC–wide entity rate applies to all entries of subject merchandise except for entries from the respondents which are listed in the ''Final Determination Margins'' section below.

In the *Amended Preliminary Determination*, we assigned to the PRC–wide entity the highest margin alleged in the petition, as revised in Petitioners' supplemental responses, 85.55 percent. *See Amended Preliminary Determination*, 73 FR at 22133. We received no comments on this rate. Therefore, for the final determination, we have continued to assign to the PRC–wide entity the rate of 85.55 percent.

Corroboration

Section 776(c) of the Act provides that, when the Department relies on secondary information in using the facts otherwise available, it must, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal. We have interpreted ''corroborate'' to mean that we will, to the extent practicable, examine the reliability and relevance of the information submitted. *See Certain Cold–Rolled Flat–Rolled Carbon–Quality Steel Products From Brazil: Notice of Final Determination of Sales at Less Than Fair Value*, 65 FR 5554, 5568 (February 4, 2000); *see, e.g., Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, from Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews*, 61 FR 57391, 57392 (November 6, 1996).

Because there are no cooperating mandatory respondents, to corroborate the 85.55 percent margin used as adverse facts available for the PRC–wide entity, we relied upon our pre–initiation analysis of the adequacy and accuracy of the information in the petition. *See* Antidumping Investigation Initiation Checklist: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China, (Initiation Checklist) (''Initiation Checklist'') (July 5, 2007). During the initiation stage, we examined evidence supporting the calculations in the petition and the supplemental information provided by Petitioners to determine the probative value of the margins alleged in the petition. During our pre–initiation analysis, we examined the information used as the basis of export price and NV in the petition, and the calculations used to derive the alleged margins. Also during our pre–initiation analysis, we examined information from various independent sources provided either in the petition or, based on our requests, in supplements to the petition, which corroborated key elements of the export price and NV calculations. *Id.* We received no comments as to the relevance or probative value of this information. Therefore, for the final determination, the Department finds that the rates derived from the petition for purposes of initiation have probative value for the purpose of being selected as the AFA rate assigned to the PRC–wide entity.

Final Critical Circumstances Determination

On December 11, 2007, the Department preliminarily found that critical circumstances existed for all PRC exporters of subject merchandise, including the separate rate applicant companies and companies subject to the PRC–wide rate. The Department affirmed this preliminary finding in the *Preliminary Determination* and the *Amended Preliminary Determination*. Pursuant to the *Preliminary Determination*, we received comments on this issue from SeAH and Western. *See* SeAH March Case Brief, at 3; *see also* Western March Case Brief, at 1. These companies argued that we should no longer find that critical circumstances exist for certain importers that had placed information on the record of the proceeding to support claims that their imports were not part of the ''massive'' imports found by the Department, pursuant to 19 CFR 351.206. We also received comments from Petitioners, who support the preliminary finding of critical circumstances for all PRC exporters, but who recommend certain modifications to the Department's analysis. *See* Petitioners' March Rebuttal Brief, at 19.

Based on the comments from interested parties, we have revised our analysis, but continue to find that critical circumstances exist with regard

to all imports of CWP from the PRC. For further details, *see* the Issues and Decision Memorandum at Comments 11–13; *see also*, Memorandum from Abdelali Elouaradia, Office Director, to Stephen J. Claeys, Deputy Assistant Secretary, ''Antidumping Duty Investigation of Circular Welded Carbon Quality Steel Pipe (''CWP'') from the People's Republic of China (''PRC'') - Final Affirmative Determination of Critical Circumstances,'' dated May 29, 2008.

Combination Rates

In *Initiation of Antidumping Duty Investigation: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China*, 72 FR 36663 (July 5, 2007) (''*Initiation Notice*''), the Department stated that it would calculate combination rates for respondents that are eligible for a separate rate in this investigation. *See Initiation Notice*. This change in practice is described in *Policy Bulletin 05.1*, available at http://ia.ita.doc.gov/. *Policy Bulletin 05.1*, 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 Policy Bulletin 05.1*, ''Separate Rates Practice and Application of Combination Rates in Antidumping Investigations Involving Non–Market Economy Countries.''

Final Determination Margins

We determine that the following percentage weighted–average margins exist for the POI:

Exporter	Producer	Weighted–Average Margin
Beijing Sai Lin Ke Hardware Co., Ltd.	Xuzhou Guang Huan Steel Tube Products Co., Ltd.	69.20
Wuxi Fastube Industry Co., Ltd.	Wuxi Fastube Industry Co., Ltd.	69.20
Jiangsu Guoqiang Zinc–Plating Industrial.Co.,Ltd.[6]	Jiangsu Guoqiang Zinc–Plating Industrial Co., Ltd.	69.20
Wuxi Eric Steel Pipe Co., Ltd.	Wuxi Eric Steel Pipe Co., Ltd.	69.20
Qingdao Xiangxing Steel Pipe Co., Ltd.	Qingdao Xiangxing Steel Pipe Co., Ltd.	69.20
Wah Cit Enterprises	Guangdong Walsall Steel Pipe Industrial Co., Ltd.	69.20
Guangdong Walsall Steel Pipe Industrial Co., Ltd.	Guangdong Walsall Steel Pipe Industrial Co.,.Ltd.	69.20
Hengshui Jinghua Steel Pipe Co., Ltd.	Hengshui Jinghua Steel Pipe Co.,Ltd.	69.20
Zhangjiagang Zhongyuan Pipe–Making Co., Ltd.	Zhangjiagang Zhongyuan Pipe–Making Co, Ltd.	69.20
Weifang East Steel Pipe Co., Ltd.	Weifang East Steel Pipe Co., Ltd.	69.20
Shijiazhuang Zhongqing Imp & Exp Co., Ltd.	Bazhou Zhuofa Steel Pipe Co., Ltd.	69.20
Tianjin Baolai Int'l Trade Co., Ltd.	Tianjin Jinghai County Baolai Business and Industry Co., Ltd.	69.20
Wai Ming (Tianjin) Int'l Trading Co., Ltd.	Bazhou Dong Sheng Hot–dipped Galvanized Steel Pipes Co., Ltd.	69.20
Kunshan Lets Win Steel MachineryCo., Ltd.	Kunshan Lets Win Steel Machinery Co., Ltd.	69.20
Shenyang Boyu M/E Co., Ltd.	Bazhou Dong Sheng Hot–dipped Galvanized Steel Pipes Co., Ltd.	69.20
Dalian Brollo Steel Tubes Ltd.	Dalian Brollo Steel Tubes Ltd.	69.20
Benxi Northern Pipes Co., Ltd.	Benxi Northern Pipes Co., Ltd.	69.20
Shanghai Metals & Minerals Import & Export Corp.	Huludao Steel Pipe Industrial Co.	69.20
Shanghai Metals & Minerals Import & Export Corp.	Benxi Northern Pipes Co., Ltd.	69.20
Huludao Steel Pipe Industrial Co.	Huludao Steel Pipe Industrial Co.	69.20
Tianjin Xingyuda Import & Export Co., Ltd.	Tianjin Lifengyuanda Steel Group	69.20
Tianjin Xingyuda Import & Export Co., Ltd.	Tianjin Xingyunda Steel Pipe Co.	69.20
Tianjin Xingyuda Import & Export Co., Ltd.	Tianjin Lituo Steel Products Co.	69.20
Tianjin Xingyuda Import & Xinlida Export Co., Ltd.	Tangshan Fengnan District Steel Pipe Co., Ltd.	69.20
Jiangyin Jianye Metal Products Co., Ltd.	Jiangyin Jianye Metal Products Co., Ltd.	69.20
Rizhao Xingye Import & Export Co., Ltd.	Shandong Xinyuan Group Co., Ltd.	69.20
Tianjin No. 1 Steel Rolled Co., Ltd.	Tianjin Hexing Steel Co., Ltd.	69.20
Tianjin No. 1 Steel Rolled Co., Ltd.	Tianjin Ruitong Steel Co., Ltd.	69.20
Tianjin No. 1 Steel Rolled Co., Ltd.	Tianjin Yayi Industrial Co.	69.20
Kunshan Hongyuan Machinery Manufacture Co., Ltd.	Kunshan Hongyuan Machinery Manufacture Co., Ltd.	69.20
Qingdao Yongjie Import & Export Co., Ltd.	Shandong Xinyuan Group Co., Ltd.	69.20
PRC–Wide Entity[7]		85.55

[6] In the *Preliminary Determination*, the Department incorrectly identified Jiangsu Guoqiang Zinc-Plating Industrial Company, Ltd., as Jiangsu Guoqiang Zinc-Plating Co., Ltd. We note, however, that in the Department's subsequent instructions to CBP to suspend liquidation and require cash deposits for CWP from PRC, the Department correctly identified Jiangsu Guoqiang Zinc-Plating Industrial Company, Ltd.

[7] In the *Preliminary Determination*, the Department found that the Tianjin Shuangjie Group is part of the PRC-wide entity. In the *Amended Preliminary Determination*, the Department found that Yulong is part of the PRC-wide entity.

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).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we are directing

U.S. Customs and Border Protection (''CBP'') to continue to suspend liquidation of all imports of subject merchandise as described in the ''Scope of Investigation'' section, that are entered or withdrawn from warehouse, for consumption on or after October 17, 2007, which is 90 days prior to the date of publication of the preliminary determination in the **Federal Register**, except for imports from Yulong. In specific regard to Yulong, we are directing CBP to continue to suspend liquidation of all entries of subject merchandise as described in the ''Scope of Investigation'' section, entered, or withdrawn from warehouse, for consumption on or after January 25, 2008, which is 90 days prior to the date of publication of the amended preliminary determination in the **Federal Register**. *See Amended Preliminary Determination*. We will instruct CBP to continue to require a cash deposit or the posting of a bond for all companies based on the estimated weighted–average dumping margins shown above. The suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (''ITC'') of our final determination of sales at LTFV. As our final determination is affirmative, in accordance with section 735(b)(2) of the Act, within 45 days the ITC will determine whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that material injury or threat of material 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, upon further instruction by the Department, 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.

Notification Regarding APO

This notice also serves as a reminder to the parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return or 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.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: May 29, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

Appendix

Comment 1: Whether the Scope Language Should Include End–Use Definition and Reference to End–Use Applications
Comment 2: Whether the Department Should Graduate the People's Republic of China to Market Economy Status
Comment 3: Whether the Department Should Calculate a Company–Specific Separate Rate for Weifang East Pipe
Comment 4: Whether the Department Should Find Weifang East Pipe to be a Market–Oriented Enterprise
Comment 5: Whether the Department Should Utilize Weifang East Pipe's Actual Hot–Rolled Costs When Calculating an AD Margin Due to the Existence of the Companion Countervailing Duty Investigation
Comment 6: Whether a Double–Remedy Results from the Simultaneous Application of Non–Market Economy AD and Countervailing Duty Methodologies
Comment 7: Whether the Department's Amended Preliminary Determination Violated Legal Principles
Comment 8: Whether the Department Should Employ Weifang East Pipe's Suggested Analytical Approach For Calculating Its Company–Specific Margin
Comment 9: Whether the Department Should Assign Weifang East Pipe's Company–Specific AD Rate to All Cooperative Separate Rate Respondents
Comment 10: Whether the Department Should Make an Adjustment for Countervailable Export Subsidies
Comment 11: Whether the Department Should Use the Highest Petition Margin as the Adverse Facts Available Rate
Comment 12: Whether the Department Should Find That Critical Circumstances Do Not Exist for Yulong
Comment 13: Whether the Department Should Analyze Critical Circumstances on an Importer–Specific Basis in its Critical Circumstances Analysis
Comment 14: Whether the Department Should Include June 2007 in the Base Period Rather than the Comparison Period in its Critical Circumstances Analysis

[FR Doc. E8–12608 Filed 6–4–08; 8:45 am]

Billing Code: 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating a five-year review (''Sunset Review'') of the antidumping duty orders listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same orders.

EFFECTIVE DATE: June 2, 2008.

FOR FURTHER INFORMATION CONTACT: The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Ave., NW., Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing *Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in the Department's Policy Bulletin 98.3—*Policies Regarding the Conduct of Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders: Policy Bulletin,* 63 FR 18871 (April 16, 1998).

Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating the Sunset Review of the following antidumping duty orders:

DOC Case No.	ITC Case No.	Country	Product	Department Contact
A–570–879	731–TA–1014	PRC	Polyvinyl Alcohol	Brandon Farlander, (202) 482–0182.
A–588–861	731–TA–1016	Japan	Polyvinyl Alcohol	Brandon Farlander, (202) 482–0182.
A–580–850	731–TA–1017	Korea	Polyvinyl Alcohol	Brandon Farlander, (202) 482–0182.
A–570–878	731–TA–1013	PRC	Saccharin	Andrea Berton, (202) 482–4037.

Filing Information

As a courtesy, we are making information related to Sunset proceedings, including copies of the pertinent statute and Department's regulations, the Department schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's sunset Internet Web site at the following address: ''*http://ia.ita.doc.gov/sunset/*.'' All submissions in this Sunset Review must be filed in accordance with the Department's regulations regarding format, translation, service, and certification of documents. These rules can be found at 19 CFR 351.303.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for this proceeding. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties to apply for access to proprietary information under administrative protective order (''APO'') immediately following publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii) as set forth below.

Information Required From Interested Parties

Domestic interested parties defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b)) wishing to participate in this Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review. *See* 19 CFR 351.218(d)(1)(iii).

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that all parties wishing to participate in the Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Please consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews.[1] Please consult the Department's regulations at 19 CFR Part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: May 30, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–12611 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–DS–P

[1] In comments made on the interim final sunset regulations, a number of parties stated that the proposed five-day period for rebuttals to substantive responses to a notice of initiation was insufficient. This requirement was retained in the final sunset regulations at 19 CFR 351.218(d)(4). As provided in 19 CFR 351.302(b), however, the Department will consider individual requests of that five-day deadline based upon a showing of good cause.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Gray's Reef National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DCC).

ACTION: Notice and request for applications.

SUMMARY: The Gray's Reef National Marine Sanctuary (GRNMS or sanctuary) is seeking applicants for the following vacant seats on its Sanctuary Advisory Council (council) Charter/Commercial Fishing and University Education. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve three-year terms, pursuant to the council's Charter.

DATES: Applications are due by July 15, 2008.

ADDRESSES: Application kits may be obtained from Becky Shortland, Council Coordinator (*becky.shortland@noaa.gov*), 10 Ocean Science Circle, Savannah, GA 31411; 912–598–2381). Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Becky Shortland, Council Coordinator (*becky.shortland@noaa.gov*), 10 Ocean Science Circle, Savannah, GA 31411; 912–598–2381.

SUPPLEMENTARY INFORMATION: The sanctuary advisory council was established in August 1999 to provide advice and recommendations on management and protection of the sanctuary. The advisory council, through its members, also serves as

liaison to the community regarding sanctuary issues and represents community interests, concerns, and management needs to the sanctuary and NOAA.

Authority: 16 U.S.C. Section 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429, Marine Sanctuary Program)

May 27, 2008.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. E8–12283 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XI28

Caribbean Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council will hold a meeting of its Annual Catch Limit Plan Development Group (ACLG)

DATES: The ACLG will meet on June 24–25, 2008.

ADDRESSES: The meeting will be held at the Best Western San Juan Airport Hotel and Casino, located at the Luis Munoz Marin Airport, in Carolina, Puerto Rico.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 268 Munoz Rivera Avenue, Suite 1108, San Juan, Puerto Rico 00918; telephone: (787) 766–5926.

SUPPLEMENTARY INFORMATION: The ACLG will meet to discuss the items contained in the following agenda:

•Call to Order

•Overview of ACLG (Annual Catch Limit Plan Development Group) Tasks

•Report from the Technical Monitoring and Compliance Team (TMCT) on:

-Fisheries Overfished and undergoing overfishing

-Other fisheries

•Determination of ACLs and AMs

-By Fishery (SFA Units: Groupers Unit 4, Parrotfishes, Queen Conch. etc.)

-By Species

-By Area

-By Gear

•Recommendations to the SSC

•Other Business

•Next Meeting

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. For more information or request for sign language interpretation and/other auxiliary aids, please contact Mr. Miguel A. Rolon, Executive Director, Caribbean Fishery Management Council, 268 Munoz Rivera Avenue, Suite 1108, San Juan, Puerto Rico 00918, telephone (787) 766–5926, at least 5 days prior to the meeting date.

Dated: June 2, 2008

Tracey L. Thompson,

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

[FR Doc. E8–12593 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XI27

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public committee meeting.

SUMMARY: The North Pacific Fishery Management Council's (Council) Crab Socioeconomic Data Collection Committee will meet in Anchorage, AK.

DATES: The meeting will be held on June 24, 2008, from 8 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at Anchorage Hilton Hotel, Iliamna Room, 500 West 3rd Avenue, Anchorage, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Mark Fina, NPFMC, telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The committee will have discussions concerning the collection of social and economic fisheries data, and potential analytical uses of those data. These data include revenue, cost, crew, labor, and community information, which may be collected from vessels and processing plants participating in the fisheries, as well as data from other sources.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, (907) 271–2809, at least 5 working days prior to the meeting date.

Dated: June 2, 2008.

Tracey L. Thompson,

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

[FR Doc. E8–12592 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XI29

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Groundfish Management Team (GMT) will hold a working meeting, which is open to the public.

DATES: The GMT meeting will be held Monday, June 23, 2008 from 1 p.m. until business for the day is completed. The GMT meeting will reconvene Tuesday, June 24 through Friday, June 27, from 8:30 a.m. until business for each day is completed.

ADDRESSES: The GMT meeting will be held at the Pacific Fishery Management

Council office, Large Conference Room, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Groundfish Management Coordinator; telephone: (503) 820–2280.

SUPPLEMENTARY INFORMATION: The purpose of the GMT working meeting is to complete analyses for the 2009–10 Groundfish Harvest Specifications and Management Measures Environmental Impact Statement (EIS). The main task will be completing any analysis of the Council's preferred alternative for groundfish harvest specifications and management measures for the next biennium.

Although non-emergency issues not contained in the meeting agenda may come before the GMT for discussion, those issues may not be the subject of formal GMT action during this meeting. GMT action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the GMT's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820–2280 at least 5 days prior to the meeting date.

Dated: June 2, 2008.

Tracey L. Thompson,

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

[FR Doc. E8–12594 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XI23

Nominations to the Marine Fisheries Advisory Committee

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

ACTION: Notice; request for nominations.

SUMMARY: Nominations are being sought for appointment by the Secretary of Commerce (Secretary) to serve on the Marine Fisheries Advisory Committee (MAFAC or Committee) beginning in October 2008. MAFAC is the only Federal advisory committee with the responsibility to advise the Secretary on all matters concerning living marine resources that are the responsibility of the Department of Commerce. The Committee makes recommendations to the Secretary to assist in the development and implementation of Departmental regulations, policies and programs critical to the mission and goals of the NMFS. Nominations are encouraged from all interested parties involved with or representing interests affected by NMFS actions in managing living marine resources. Nominees should possess demonstrable expertise in a field related to the management of living marine resources and be able to fulfill the time commitments required for two annual meetings. Individuals serve for a term of three years for no more than two consecutive terms if re-appointed. NMFS is seeking qualified nominees to fill upcoming vacancies being created by the expiration of existing appointments this October, thereby bringing the Committee to its full complement of 21 members.

DATES: Nominations must be received by July 21, 2008.

ADDRESSES: Nominations must be sent to Dr. Mark Holliday, Executive Director, MAFAC, Office of Policy, NMFS F–14451, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Mark Holliday, MAFAC Executive Director; (301) 713–2239 x120; e-mail: *Mark.Holliday@noaa.gov*.

SUPPLEMENTARY INFORMATION: The establishment of MAFAC was approved by the Secretary on December 28, 1970, and subsequently chartered under the Federal Advisory Committee Act, 5 U.S.C. App. 2, on February 17, 1971. The Committee meets twice a year with supplementary subcommittee meetings as determined necessary by the Committee Chairperson. No less that 15 and no more than 21 individuals may serve on the Committee. Membership is comprised of highly qualified individuals representing commercial and recreational fisheries interests, environmental organizations, academic institutions, governmental, tribal and consumer groups from a balance of U.S. geographical regions, including Puerto Rico and the Western Pacific and the U.S. Virgin Islands.

A MAFAC member cannot be a Federal employee or a member of a Regional Fishery Management Council. Selected candidates must pass security checks and submit financial disclosure forms. Membership is voluntary, and except for reimbursable travel and related expenses, service is without pay.

Each submission should include the submitting person or organization's name and affiliation, a cover letter describing the nominee's qualifications and interest in serving on the Committee, a curriculum vitae and or resume of the nominee, and no more than three supporting letters describing the nominee's qualifications and interest in serving on the Committee. Self-nominations are acceptable. The following contact information must accompany each nominee's submission: name, address, phone number, fax number, and e-mail address (if available).

Nominations should be sent to (see **ADDRESSES**) and must be received by (see **DATES**). The full text of the Committee Charter and its current membership can be viewed at the NMFS's web page at *www.nmfs.noaa.gov/mafac.htm*.

Dated: May 30, 2008.

James W. Balsiger,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. E8–12602 Filed 6–5–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Estuarine Research Reserve System

AGENCY: Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of public comment period for the Revised Management Plan for the Sapelo Island National Estuarine Research Reserve.

SUMMARY: Notice is hereby given that the Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce is announcing a thirty-day public comment period on the Sapelo Island National Estuarine Research Reserve Management Plan Revision.

The Sapelo Island Reserve (Georgia) was designated in 1976 pursuant to Section 315 of the Coastal Zone

Management Act of 1972, as amended, 16 U.S.C. 1461. The Reserve has been operating under a management plan approved in 1999. Pursuant to 15 CFR 921.33(c), a state must revise their management plan every five years. The submission of this plan fulfills this requirement and sets a course for successful implementation of the goals and objectives of the Reserve. New facilities and updated programmatic objectives are notable revisions to the 1999 approved management plan.

The mission of the Sapelo Island Reserve is to perpetuate the protection of the Sapelo Island National Estuarine Research Reserve and to provide a platform for conservation-based research, education and stewardship through the Reserve. The revised management plan identifies priority resource issues that are addressed through active management. These priority issues include addressing public access and visitor impact on Reserve uplands and marsh areas, addressing impacts related to activities on the Reserve by the island's population and addressing the projected increase in development and population growth on the Georgia coast. By addressing these priority resource issues, the Sapelo Island Reserve aims to fulfill its mission.

The revised plan establishes goals and objectives for the Reserve's various programmatic activities, including scientific biological research; water quality monitoring; education, training, and outreach programs; and stewardship programs. It also outlines the plans for future facility development to support reserve operations.

Since 1999, the reserve has realized some aspects of the 1999 plan, including the contributions toward the completion of the Barrier Island Research and Learning Center, a joint research dormitory and lab shared with the University of Georgia.

FOR FURTHER INFORMATION CONTACT: Amy N. Clark at (301) 563–1137 or Laurie McGilvray at (301) 563–1158 of NOAA's National Ocean Service, Estuarine Reserves Division, 1305 East-West Highway, N/ORM5, 10th floor, Silver Spring, MD 20910. For copies of the revised Management Plan for the Sapelo Island National Estuarine Research Reserve visit *http://www.sapelonerr.org.*

Dated: May 22, 2008.

David M. Kennedy,

Director, Office of Ocean and Coastal Resource Management, National Oceanic and Atmospheric Administration.

[FR Doc. E8–12541 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Privacy Act of 1974; System of Records

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed new Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the United States Patent and Trademark Office (USPTO) gives notice of a proposed new system of records entitled ''COMMERCE/PAT–TM–22 Patent e-Commerce Database.'' We invite the public to comment on the system announced in this publication.

DATES: Written comments must be received no later than July 7, 2008. The amendments will become effective as proposed on July 7, 2008, unless the USPTO receives comments that would result in a contrary determination.

ADDRESSES: You may submit written comments by any of the following methods:

E-mail: Susan.Fawcett@uspto.gov.

Fax: (571) 273–0112, marked to the attention of Susan Fawcett.

Mail: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Federal Rulemaking Portal: http://www.regulations.gov.

All comments received will be available for public inspection at the Federal rulemaking portal located at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, (571) 272–5429.

SUPPLEMENTARY INFORMATION: The United States Patent and Trademark Office (USPTO) is giving notice of a new system of records that is subject to the Privacy Act of 1974. The information in this system of records is used to maintain a list of customers who wish to receive patent e-Commerce updates or attend patent e-Commerce events.

The proposed new system of records, ''COMMERCE/PAT–TM–22 Patent e-Commerce Database,'' is published in its entirety below.

COMMERCE/PAT–TM–22

SYSTEM NAME:

Patent e-Commerce Database.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Search and Information Resources Administration (SIRA), United States Patent and Trademark Office, 600 Dulany Street, Alexandria, VA 22314.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals subscribing to receive patent e-Commerce updates or to attend a patent e-Commerce event.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name of subscriber, name of organization, and subscriber's electronic mail address.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

35 U.S.C. 2.

PURPOSE(S):

The information in this system of records is used to maintain a list of customers who wish to receive patent e-Commerce updates or attend patent e-Commerce events.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See Prefatory Statement of General Routine Uses Nos. 4–5, 9–10, and 13, as found at 46 FR 63501–63502 (December 31, 1981). The USPTO may use the information contained in this system of records to contact customers who have expressed an interest in patent e-Commerce events and updates.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Not applicable.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic records in a computer database stored on magnetic storage media.

RETRIEVABILITY:

Name of subscriber (first and/or last), name of organization, and subscriber's electronic mail address.

SAFEGUARDS:

The database is password-protected and can only be accessed by authorized personnel.

RETENTION AND DISPOSAL:

Records retention and disposal is in accordance with the series records schedules.

SYSTEM MANAGER(S) AND ADDRESS:

SIRA Customer Outreach Manager, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

NOTIFICATION PROCEDURE:

Information about the records contained in this system may be obtained by sending a request in writing, signed, to the SIRA Customer Outreach Manager at the address above. When requesting notification of or access to records covered by this notice, requesters should provide their name and electronic mail address in accordance with the inquiry provisions appearing in 37 CFR 102 subpart B.

RECORD ACCESS PROCEDURES:

Requests from individuals should be addressed to the SIRA Customer Outreach Manager at the address above.

CONTESTING RECORD PROCEDURES:

The general provisions for access, contesting contents, and appealing initial determinations by the individual concerned appear in 37 CFR 102 subpart B. Requests from individuals should be addressed to the SIRA Customer Outreach Manager at the address above.

RECORD SOURCE CATEGORIES:

Subject individuals and those authorized by the individual to furnish information.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: May 29, 2008.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E8–12564 Filed 6–4–08; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

RIN 3038–AC52

Exemptive Order for SPDR® Gold Futures Contracts

AGENCY: Commodity Futures Trading Commission.

ACTION: Final order.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is exempting certain transactions in physically delivered futures contracts based on SPDR® Gold Shares (SPDR® gold futures contracts) from those provisions of the Commodity Exchange Act (CEA or Act),[1] and the Commission's regulations thereunder, that are inconsistent with the trading and clearing of SPDR® gold futures contracts as security futures. The exemption is conditioned on the compliance of transactions in SPDR® gold futures contracts with the requirements established for the trading and clearing of security futures. The authority for the issuance of this exemption is found in Section 4(c) of the Act.[2]

DATES: Effective June 5, 2008.

FOR FURTHER INFORMATION CONTACT: Bruce Fekrat, Special Counsel, Office of the Director (telephone 202.418.5578, e-mail *bfekrat@cftc.gov*), Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

In correspondence dated October 26, 2007, OneChicago, LLC (OneChicago or the Exchange),[3] a board of trade designated with the Commission pursuant to Sections 5 and 6(a) of the Act, proposed and requested Commission approval to list for trading SPDR® gold futures contracts as security futures.[4] OneChicago is notice-registered with the Securities and Exchange Commission (SEC) as a national securities exchange under Section 6(g) of the Securities Exchange Act of 1934 ('34 Act) for the purpose of listing and trading security futures products. The approval request was filed pursuant to Section 5c(c)(2) of the Act and Commission Regulations 40.5 and 41.23.[5] OneChicago submitted its request for approval under the 45-day fast-track review period established by Commission Regulation 40.5. The fast-track review period for the Exchange's submission was scheduled to expire on December 10, 2007. The review period was extended by the Director of the Division of Market Oversight, pursuant to Regulations 40.5(c) and 40.7(a)(1), to January 24, 2008 on the grounds that the SPDR® gold futures contracts raised novel and complex issues that required additional time for review.[6] By letter dated January 23, 2008, the Exchange, upon the request of the Commission's staff, voluntarily extended the review period to March 17, 2008. By letter dated February 26, 2008, the Exchange voluntarily extended the review period to April 30, 2008.[7] By letter dated April 28, 2008, the Exchange further voluntarily extended the review period to May 30, 2008.

On March 14, 2008, the Commission published for pubic comment in the **Federal Register** a proposal to exempt, pursuant to Section 4(c) of the Act, SPDR® gold futures contracts from those provisions of the CEA, and the Commission's regulations thereunder, that are inconsistent with the trading and clearing of SPDR® gold futures contracts as security futures.[8] The Commission proposed to issue the exemption in order to facilitate the Exchange's request for contract approval. No formal comments were submitted in response to the Commission's publication.[9]

II. CEA Section 4(c) Exemptive Order

In accordance with the Memorandum of Understanding entered into between the CFTC and the SEC on March 11, 2008, and in particular the addendum thereto concerning *Principles Governing the Review of Novel Derivative Products*, the Commission believes that novel derivative products that implicate areas of overlapping regulatory concern should be permitted to trade in either or both a CFTC or SEC regulated environment, in a manner consistent with laws and regulations (including the appropriate use of all available exemptive and interpretive authority). The Commission has determined to use

[1] 7 U.S.C. 1 *et seq.*

[2] 7 U.S.C. 6(c).

[3] OneChicago is jointly owned by the CME Group, Inc., IB Exchange Corp., and the Chicago Board Options Exchange.

[4] In accordance with Section 2(a)(9)(B)(i) of the Act, Commission staff forwarded the new contract filing to the Securities and Exchange Commission, the U.S. Department of Treasury and the Board of Governors of the Federal Reserve System on October 29, 2007. No comments were received in response to this correspondence. On January 4, 2008, the Exchange filed a rule amendment concerning minimum price fluctuations to supplement its initial submission.

[5] 7 U.S.C. 7a–2(c)(2), 17 CFR 40.5, 41.23.

[6] Commission Regulations 40.5(c) and 40.7(a)(1) allow the Commission, and certain staff acting pursuant to delegated authority, to extend the 45-day fast-track review period by an additional 45 days if a product raises novel or complex issues requiring additional time for review. 17 CFR 40.5(c), 40.7(a)(1).

[7] Section 5c(c) of the Act requires the Commission to approve any designated contract market instrument submitted for approval within 90 days after the submission of the request unless (1) it finds that the trading or clearing of the instrument would violate the Act (or the Commission's regulations), or (2) the person submitting the request for approval agrees to extend the period of review beyond the 90 day time limitation.

[8] Proposed Exemptive Order for ST [SPDR®] Gold Futures Contracts, 73 FR 13876 (March 14, 2008) (Proposed Order). Effective May 21, 2008, the streetTRACKS® Gold Trust has been restyled as the SPDR® Gold Trust. Consequently, on May 22, 2008 the Exchange filed a rule amendment to reflect that change.

[9] A thorough summary of the Trust's operations is provided in the Proposed Order.

its authority under Section 4(c) of the Act, as proposed, to exempt transactions in SPDR® gold futures contracts from those provisions of the Act and the Commission's regulations thereunder that, if the underlying were considered to be a commodity that is not a security, would be inconsistent with the trading and clearing of SPDR® gold futures contracts as security futures.[10] Section 4(c)(1) of the CEA empowers the Commission to ''promote responsible economic or financial innovation and fair competition'' by exempting any transaction or class of transactions [11] from any of the provisions of the Act upon determining that the exemption would be consistent with the public interest.[12] Section 4(c)(2) of the Act provides that the Commission may grant exemptions only when it determines that the requirements for which an exemption is being provided should not be applied to the agreements, contracts or transactions at issue; that the exemption is consistent with the public interest and the purposes of the Act; that the agreements, contracts or transactions will be entered into solely between appropriate persons; and that the exemption will not have a material adverse effect on the ability of the Commission or any designated contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory responsibilities under the CEA.[13] With respect to the term ''appropriate persons,'' Section 4(c)(3) of the Act enumerates several categories of appropriate persons and provides in subparagraph (K) that the term shall include ''[s]uch other persons that the Commission determines to be appropriate in light of * * * the applicability of appropriate regulatory protections.''

In enacting Section 4(c) of the Act, Congress noted that the goal of the provision ''is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner.'' [14] SPDR® gold futures contracts are novel instruments and the Commission believes that this is an appropriate case for issuing an exemption, as proposed, without making a finding as to the nature of these particular instruments. Accordingly, given the potential usefulness of SPDR® gold futures contracts to the significant market for the Trust's Shares, as well as all gold-linked markets, the Commission herein exempts transactions in SPDR® gold futures contracts traded on OneChicago, and the clearing of such contracts as security futures, from the provisions of the Act, and the Commission's regulations thereunder, to the extent necessary to permit them to be so traded and cleared. In the Commission's opinion, the issuance of this exemptive order is in the public interest and is consistent with the purposes of the Act, because it will likely foster both financial innovation by bringing an innovative derivatives product to market, and competition by not potentially excluding other similarly innovative products from trading on regulated futures markets. In addition, SPDR® gold futures contracts, when traded as security futures pursuant to this exemption and the Commission's subsequent or concurrent approval of the Exchange's submissions, will be subject to regulation by both the SEC and the Commission.[15] The implementation of an exemption, under these circumstances, will not erode appropriate regulatory protections, and thus SPDR® gold futures contracts will be traded by appropriate persons. Nor will this exemption impair the ability of the Commission or OneChicago to discharge any regulatory or self-regulatory duty under the Act.

This Order is subject to termination or revision, on a prospective basis, if the Commission determines upon further information that this exemption is not consistent with the public interest. If the Commission believes such exemption becomes detrimental to the public interest, the Commission may revoke this Order on its own motion.

III. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) [16] 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. This exemptive order does not require a new collection of information from any entity that would be subject to the order.

B. Cost-Benefit Analysis

Section 15(a) of the CEA, as amended by Section 119 of the Commodity Futures Modernization Act of 2000,[17] requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA. Section 15(a) of the Act further specifies that costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. By its terms, Section 15(a) does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, Section 15(a) simply requires the Commission to ''consider the costs and benefits'' of its action. The Commission may give greater weight to any one of the five enumerated areas and could in its discretion determine

[10] The Commission recently issued a similar order with respect to exchange-traded credit default products. *See* Order Exempting the Trading and Clearing of Certain Credit Default Products Pursuant to the Exemptive Authority in Section 4(c) of the Commodity Exchange Act, 72 FR 32079 (June 11, 2007).

[11] Covered transactions are subject to certain exceptions not relevant here.

[12] Section 4(c)(1) of the CEA, 7 U.S.C. § 6(c)(1), provides in full that:

In order to promote responsible economic or financial innovation and fair competition, the Commission by rule, regulation, or order, after notice and opportunity for hearing, may (on its own initiative or on application of any person, including any board of trade designated or registered as a contract market or derivatives transaction execution facility for transactions for future delivery in any commodity under section 7 of this title) exempt any agreement, contract, or transaction (or class thereof) that is otherwise subject to subsection (a) of this section (including any person or class of persons offering, entering into, rendering advice or rendering other services with respect to, the agreement, contract, or transaction), either unconditionally or on stated terms or conditions or for stated periods and either retroactively or prospectively, or both, from any of the requirements of subsection (a) of this section, or from any other provision of this chapter (except subparagraphs (c)(ii) and (D) of section 2(a)(1) of this title, except that the Commission and the Securities and Exchange Commission may by rule, regulation, or order jointly exclude any agreement, contract, or transaction from section 2(a)(1)(D) of this title), if the Commission determines that the exemption would be consistent with the public interest.

[13] Section 4(c)(2) of the CEA, 7 U.S.C. 6(c)(2), provides in full that:

The Commission shall not grant any exemption under paragraph (1) from any of the requirements of subsection (a) of this section unless the Commission determines that—

(A) The requirement should not be applied to the agreement, contract, or transaction for which the exemption is sought and that the exemption would be consistent with the public interest and the purposes of this Act; and

(B) The agreement, contract, or transaction—

(i) Will be entered into solely between appropriate persons; and

(ii) Will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory duties under this Act.

[14] H.R. Conf. Rep. No. 102–978, 1992 U.S.C.C.A.N. 3179, at 3213 (H.R. Conf. Rep.).

[15] 7 U.S.C. 2(a)(1)(A). Security futures are subject to joint regulation by the CFTC and the SEC under Section 2(a)(1)(D) of the CEA, 7 U.S.C. 2(a)(1)(D).

[16] 44 U.S.C. 3507(d).

[17] 7 U.S.C. 19(a).

that, notwithstanding potential costs, a particular order is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

In the Proposed Order, the Commission analyzed the costs and benefits associated with the implementation of an exemption under Section 4(c) of the Act. The Commission invited public comment on its analysis of the costs and benefits associated with the issuance of an exemptive order under Section 4(c) of the Act.[18] No comments were submitted to the Commission.

After considering the factors presented in this release, the Commission has determined to issue this Order.

Issued in Washington, DC, on May 30, 2008 by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E8–12579 Filed 6–4–08; 8:45 am]

BILLING CODE 6351–01–P

[18] Proposed Order at 13870.

COMMODITY FUTURES TRADING COMMISSION

Order Exempting the Trading and Clearing of Certain Products Related to SPDR® Gold Trust Shares

AGENCY: Commodity Futures Trading Commission.

ACTION: Final Order.

SUMMARY: On April 23rd, 2008, the Commodity Futures Trading Commission (''CFTC'' or the ''Commission'') published for public comment in the **Federal Register** [1] a proposal to exempt the trading and clearing of products called options on streetTRACKS® Gold Trust Shares (''ST Gold Options''), proposed to be traded on national securities exchanges, and cleared by The Options Clearing Corporation (''OCC''), from the provisions of the Commodity Exchange Act (''CEA'') [2] and Commission regulations thereunder to the extent necessary for them to be so traded and cleared. The Commission has determined to issue this Order essentially as proposed. Authority for this exemption is found in Section 4(c) of the CEA.[3]

DATES: *Effective Date:* May 30, 2008.

FOR FURTHER INFORMATION CONTACT: Robert B. Wasserman, Associate Director, 202–418–5092, *rwasserman@cftc.gov,* Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

[1] 73 FR 21917 (April 23, 2008)

[2] 7 U.S.C. 1 *et seq.*

[3] 7 U.S.C. 6(c).

SUPPLEMENTARY INFORMATION:

I. Introduction

The OCC is both a Derivatives Clearing Organization (''DCO'') registered pursuant to Section 5b of the CEA,[4] and a securities clearing agency registered pursuant to Section 17A of the Securities Exchange Act of 1934 (''the '34 Act'').[5]

OCC filed with the CFTC, pursuant to Section 5c(c) of the CEA and Commission Regulations 39.4(a) and 40.5 thereunder,[6] requests for approval of rules and rule amendments that would enable OCC to clear and settle ST Gold Options [7] traded on national securities exchanges in its capacity as a registered securities clearing agency regulated by the Securities and Exchange Commission (''SEC'') (and not in its capacity as a DCO).[8] Section 5c(c)(3) provides that the CFTC must approve any such rules and rule amendments submitted for approval unless it finds that the rules or rule amendments would violate the CEA.

II. Section 4(c) of the Commodity Exchange Act

Section 4(c)(1) of the CEA empowers the CFTC to ''promote responsible economic or financial innovation and fair competition'' by exempting any transaction or class of transactions from any of the provisions of the CEA (subject to exceptions not relevant here) where the Commission determines that the exemption would be consistent with the public interest. The Commission may grant such an exemption by rule, regulation or order, after notice and opportunity for hearing, and may do so on application of any person or on its own initiative.

In enacting Section 4(c), Congress noted that the goal of the provision ''is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner.'' [9] Permitting ST Gold Options to trade on national securities exchanges and be cleared on OCC as discussed above appears likely to foster both financial innovation and competition. In accordance with the Memorandum of Understanding entered into between the CFTC and the Securities and Exchange Commission (''SEC'') on March 11, 2008, and in particular the addendum thereto concerning *Principles Governing the Review of Novel Derivative Products,* the Commission believes that novel derivative products that implicate areas of overlapping regulatory concern should be permitted to trade in either or both a CFTC- or SEC-regulated environment, in a manner consistent with laws and regulations (including the appropriate use of all available exemptive and interpretive authority).

ST Gold Options are novel instruments and, given their potential usefulness to the market, the Commission believes that this is an appropriate case for issuing an exemption without making a finding as to the nature of these particular instruments.

Section 4(c)(2) provides that the Commission may grant exemptions only when it determines that the requirements for which an exemption is being provided should not be applied to the agreements, contracts or transactions at issue, and the exemption is consistent with the public interest and the purposes of the CEA; that the agreements, contracts or transactions will be entered into solely between appropriate persons; and that the exemption will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory responsibilities under the CEA.

In the April 23, 2008 **Federal Register** Release, the Commission requested public comment on the matters discussed above and all issues raised by its proposed exemptive order. No comments were received.

[4] 7 U.S.C. 7a–1.

[5] 15 U.S.C. 78q–l.

[6] 7 U.S.C. 7a–2(c), 17 CFR 39.4(a), 40.5.

[7] streetTRACKS® Gold Trust Shares, which underlie ST Gold Options, are described in greater detail in the ''Proposed Exemptive Order for ST Gold Futures Contracts,'' 73 FR 13867, 13868 (March 14, 2008). On May 20, 2008, streetTRACKS® Gold Trust Shares were renamed SPDR® Gold Trust Shares. *See* Prospectus for SPDR® Gold Trust, *available at http://www.spdrgoldshares.com/pdf/SPDRGoldTrustProspectus.pdf* (reviewed May 22, 2008).

[8] The request for approval concerning the ST Gold Options was filed effective February 4, 2008, and Amendment No. 1 thereto was filed effective March 7, 2008. *See* SR–OCC–2008–04 and Amendment No. 1. OCC has also filed these proposed rule changes with the SEC. *See* SEC Release No. 34–57695; File No. SR–OCC–2008–07 (April 21, 2008), 73 FR 22452 (April 25, 2008). On May 22, 2008, OCC filed Amendment No. 2 to the request for approval, reflecting the change in the name of streetTRACKS® Gold Trust Shares.

[9] House Conf. Report No. 102–978, 1992 U.S.C.C.A.N. 3179, 3213 (''4(c) Conf. Report'').

III. Findings and Conclusions

After considering the complete record in this matter, the Commission has determined that the requirements of Section 4(c) have been met. First, the exemption is consistent with the public interest and with the purposes of the CEA, including ''promot[ing] responsible innovation and fair competition among boards of trade, other markets and market participants.'' [10] It appears to be consistent with these and the other purposes of the CEA, with the public interest, with the CFTC-SEC Memorandum of Understanding of March 11, 2008, and with the addendum thereto, for the mode of trading of these transactions—whether it is to be through CFTC-regulated markets and clearing organizations or SEC-regulated markets and clearing agencies—to be determined by competitive market forces.

Second, the ST Gold Options will be entered into solely between appropriate persons. Section 4(c)(3) includes within the term ''appropriate persons'' a number of specified categories of persons, but also in subparagraph (K), ''such other persons that the Commission determines to be appropriate in light of * * * the applicability of appropriate regulatory protections.'' National securities exchanges, OCC and broker-dealers who will intermediate transactions in ST Gold Options are subject to extensive and detailed oversight by the SEC and, in the case of the intermediaries, the securities self-regulatory organizations. Given that the products will be traded on national securities exchanges, the regulatory protections available under the securities laws, and the goal of promoting fair competition, the ST Gold Options will be traded by appropriate persons.

Third, the exemption would not have a material adverse effect on the ability of the Commission or any designated contract market to carry out their regulatory responsibilities under the CEA. There is no reason to believe that granting an exemption here would interfere with the Commission's or a designated contract market's ability to oversee the trading of similar products or otherwise carry out their duties.

Therefore, upon due consideration, pursuant to its authority under Section 4(c) of the CEA, the Commission hereby issues this Order and exempts the trading of ST Gold Options on national securities exchanges and clearing of ST Gold Options by OCC in its capacity as a registered securities clearing agency from the CEA and the Commission's Regulations thereunder to the extent necessary to permit them to be so traded and cleared.

This Order is subject to termination or revision, on a prospective basis, if the Commission determines upon further information that this exemption is not consistent with the public interest. If the Commission believes such exemption becomes detrimental to the public interest, the Commission may revoke this Order on its own motion.

IV. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') [11] 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. The exemptive order will not require a new collection of information from any entities.

B. Cost-Benefit Analysis

Section 15(a) of the CEA, as amended by Section 119 of the Commodity Futures Modernization Act of 2000 (''CFMA''),[12] requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA. By its terms, Section 15(a) as amended does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, Section 15(a) simply requires the Commission to ''consider the costs and benefits'' of its action.

Section 15(a) of the CEA further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular order was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

The Commission has considered the costs and benefits of the order in light of the specific provisions of Section 15(a) of the CEA, as follows:

1. *Protection of market participants and the public.* National securities exchanges, OCC and their members who will intermediate ST Gold Options are subject to extensive regulatory oversight.

2. *Efficiency, competition, and financial integrity.* The exemptive order appears likely to enhance market efficiency and competition since it could encourage potential trading of ST Gold Options on markets other than designated contract markets or derivative transaction execution facilities. Financial integrity will not be affected since the ST Gold Options will be cleared by OCC, a DCO and SEC-registered clearing agency, and intermediated by SEC-registered broker-dealers.

3. *Price discovery.* Price discovery may be enhanced through market competition.

4. *Sound risk management practices.* The ST Gold Options will be subject to OCC's current risk-management practices including its margining system.

5. *Other public interest considerations.* The exemptive order appears likely to encourage development of derivative products through market competition without unnecessary regulatory burden.

The Commission requested comment on its application of these factors in the proposing release. No comments were received.

After considering these factors, the Commission has determined to issue this Order.

Issued in Washington, DC, on May 30, 2008 by the Commission.

David A. Stawick,

Secretary of the Commission.

Dissenting in Part and Concurring in Part to Exemptive Order Under Section 4(c) of the Commodity Exchange Act (CEA) To Exempt Certain Products Related to SPDR ® Gold Trust Shares Traded on a National Securities Exchange and Cleared by the Options Clearing Corporation (OCC) From Provisions of the CEA, and Approval of OCC's Request for Approval of Rules

I applaud the agencies' efforts today to enhance cooperation and coordination in approving innovative and novel products. I respectfully dissent, however, from the Commission's issuance of the above-referenced order. In the promulgation of such an exemptive order in furtherance of the approval process, I believe the Commission should have adequate basis

[10] CEA Section 3(b), 7 U.S.C. 5(b).

[11] 44 U.S.C. 3507(d).

[12] 7 U.S.C. 19(a).

for confidence that the Securities and Exchange Commission will similarly fully exercise its broad statutory exemptive authority under the securities laws to permit futures exchanges to trade products that are economically equivalent to those that are or may be approved for trading on national securities exchanges, and to allow derivatives clearing organizations to clear such products, to ensure that the futures markets are not competitively disadvantaged with regard to such products. I dissent from today's action, because I do not believe this exemptive order provides sufficient basis for or assurance of such reciprocity in the future. Given the issuance of today's orders, I concur in the approval of the Options Clearing Corporation's above-referenced request for approval of rules.

Bart Chilton,

Commissioner, Commodity Futures Trading Commission.

[FR Doc. E8–12624 Filed 6–4–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 08–55]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 08–55 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: May 28, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY
WASHINGTON, DC 20301-2800

MAY 16 2008
In reply refer to:
USP004663-08

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515-6501

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 08-55, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Romania for defense articles and services estimated to cost $4.5 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

Richard J. Millies
Deputy Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Same ltr to:

House	Senate
Committee on Foreign Affairs	Committee on Foreign Relations
Committee on Armed Services	Committee on Armed Services
Committee on Appropriations	Committee on Appropriations

Transmittal No. 08-55

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) Prospective Purchaser: Romania

(ii) Total Estimated Value:

Major Defense Equipment*	$2.5 billion
Other	$2.0 billion
TOTAL	$4.5 billion

(iii) (Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: 24 F-16C/D Block 50/52 aircraft with either the F100-PW-229 or F110-GE-129 Increased Performance Engines (IPE) and APG 68(V)9 radars; refurbishment and upgrades of 24 F-16C/D Block 25 aircraft being provided as Excess Defense Articles (grant EDA notification is being submitted separately) with the F100-PW-220 Increased Performance Engines (IPE) and APG-68(V)1 radars; 4 F100-PW-229 or F110-GE-129 IPE spare engines; 5 F100-PW-220 IPE spare engines; 4 APG-68(V)9 spare radar sets 60 LAU-129/A Launchers; 30 LAU-117 Launchers; 6 Joint Helmet Mounted Cueing Systems; 4 AN/ARC-238 Single Channel Ground and Airborne Radio Systems (SINCGARS) with HAVE QUICK I/II; 24 Conformal Fuel Tanks (pairs); 4 Link-16 Multifunctional Information Distribution System-Low Volume Terminals; 2 Link-16 Ground Stations; 4 Global Positioning Systems (GPS) and Embedded GPS/ Inertial Navigation Systems (INS); 12 AN/AAQ-33 SNIPER or AN/AAQ-28 LITENING Targeting Pods; 4 Tactical Air Reconnaissance Systems or DB-110 Reconnaissance Pods (RECCE); 4 AN/APX-113 Advanced Identification Friend or Foe (AIFF) Systems; 28 AN/ALQ-213 Electronic Warfare Management System; 28 AN/ALQ 211 Advanced Integrated Defensive Electronic Warfare Suite (AIDEWS); AN/ALQ-187 Advanced Countermeasures Electronic Systems (ACES), or AN/ALQ-178 Self-Protection Electronic Warfare Suites (SPEWS)

*** as defined in Section 47(6) of the Arms Export Control Act.**

Also included: support equipment, software development/integration, tanker support, ferry services, Cartridge Actuated Devices/Propellant Actuated Devices (CAD/PAD), repair and return, modification kits, spares and repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics support.

(iv) Military Department: Air Force (SAC)

(v) Prior Related Cases, if any: None.

(vi) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None.

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached.

(viii) Date Report Delivered to Congress: MAY 16 2008

POLICY JUSTIFICATION

Romania - F-16C/D Block 50/52 Aircraft

The Government of Romania has requested a possible sale of 24 F-16C/D Block 50/52 aircraft with either the F100-PW-229 or F110-GE-129 Increased Performance Engines (IPE) and APG 68(V)9 radars; refurbishment and upgrades of 24 F-16C/D Block 25 aircraft being provided as Excess Defense Articles (grant EDA notification is being submitted separately) with the F100-PW-220 Increased Performance Engines (IPE) and APG-68(V)1 radars; 4 F100-PW-229 or F110-GE-129 IPE spare engines; 5 F100-PW-220 IPE spare engines; 4 APG-68(V)9 spare radar sets; 60 LAU-129/A Launchers; 30 LAU-117 Launchers; 6 Joint Helmet Mounted Cueing Systems; 4 AN/ARC-238 Single Channel Ground and Airborne Radio Systems (SINCGARS) with HAVE QUICK I/II; 24 Conformal Fuel Tanks (pairs); 4 Link-16 Multifunctional Information Distribution System-Low Volume Terminals; 2 Link-16 Ground Stations; 4 Global Positioning Systems (GPS) and Embedded GPS/ Inertial Navigation Systems (INS); 12 AN/AAQ-33 SNIPER or AN/AAQ-28 LITENING Targeting Pods; 4 Tactical Air Reconnaissance Systems or DB-110 Reconnaissance Pods (RECCE); 4 AN/APX-113 Advanced Identification Friend or Foe (AIFF) Systems; 28 AN/ALQ-213 Electronic Warfare Management Systems; 28 AN/ALQ- 211 Advanced Integrated Defensive Electronic Warfare Suite (AIDEWS); or AN/ALQ-187 Advanced Countermeasures Electronic Systems (ACES), or AN/ALQ-178 Self-Protection Electronic Warfare Suites (SPEWS). Also included: support equipment, software development/integration, tanker support, ferry services, CAD/PAD, repair and return, modification kits, spares and repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics support. The estimated cost is $4.5 billion.

The proposed sale will contribute to the foreign policy and national security objectives of the United States by enhancing the capability of Romania, a NATO ally. Delivery of this weapon system will greatly enhance Romania's interoperability with the U.S. and other NATO nations, making it a more valuable partner in an important area of the world, as well as supporting Romania's legitimate need for its own self-defense.

The proposed sale will allow the Romanian Air Force to modernize its aging air force by acquiring both new and used fighter aircraft, thereby enabling Romania to support both its own air defense needs and coalition operations. The country will have no difficulty absorbing this new capability into its armed forces.

The proposed sale of this weapon system will not affect the basic military balance in the region.

The principal contractors will be:

BAE Advanced Systems	**Greenlawn, New York**
Boeing Corporation	**Seattle, Washington**
Boeing Integrated Defense Systems	**St Louis, Missouri**
(three locations)	**Long Beach, California**
	San Diego, California
Raytheon Company	**Lexington, Massachusetts**
(two locations)	**Goleta, California**
Raytheon Missile Systems	**Tucson, Arizona**
Lockheed Martin Aeronautics Company	**Fort Worth, Texas**
Lockheed Martin Missile and Fire Control	**Dallas, Texas**
Northrop-Grumman Electro-Optical Systems	**Garland, Texas**
Northrop-Grumman Electronic Systems	**Baltimore, Maryland**
Pratt & Whitney United Technology Company	**East Hartford, Connecticut**
General Electric Aircraft Engines	**Cincinnati, Ohio**
Goodrich ISR Systems	**Danbury, Connecticut**
L3 Communications	**Arlington, Texas**

There are no known offset agreements in connection with this proposed sale.

Implementation of this proposed sale will require multiple trips to Romania involving U.S. Government and contractor representatives for technical reviews/support, program management, and training over a period of 15 years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 08-55

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

Annex
Item No. vii

(vii) Sensitivity of Technology:

1. This sale will involve the release of sensitive technology to Romania. The F-16C Block 25 and F-16C/D Block 50/52 weapon systems are unclassified, except as noted below. The aircraft utilizes the F-16 airframe and features advanced avionics and systems. The Block 25 aircraft have the Pratt and Whitney F-100-PW-220 engine, AN/APG-68 radar, digital flight control systems, external electronic warfare equipment, Advanced IFF, situational awareness datalink, operational flight trainer, and software computer programs. The Block 50/52 aircraft have the Pratt and Whitney F-100-PW-229 or the General Electric F-110-GE-129 engine, AN/APG-68(V)9 radar, digital flight control system, internal and external electronic warfare equipment, Advanced IFF, Link-16 datalink, operational flight trainer, and software computer programs.

2. Sensitive and/or classified (up to Secret) elements of the proposed F-16C/D include hardware, accessories, components, and associated software: AN/APG-68(V)1 Radar, AN/APG-68V(9) Radar, Have Quick I/II Radios, AN/APX-113 Advanced Identification Friend or Foe (AIFF) with Mode IV capability, AN/ALE-47 Countermeasures (Chaff and Flare) set, SNIPER Targeting Pod and/or LITENING Advanced Targeting (AT) Pod Capabilities, TARS and/or DB-110 RECCE Pods, LINK-16 Advanced Data Link Group A provision only, Embedded Global Positioning System/Inertial Navigation System, Joint Helmet-Mounted Cueing System, AN/ALR-56M Radar Warning Receiver, AN/ALQ-213 Electronic Warfare Management System, AN/ALQ-187 Advanced Countermeasures Electronic System (ACES) or Self Protection Electronic Warfare Suite (SPEWS), Modular Mission Computer, Have Glass I/II without Infrared top coat, Digital Flight Control System, F-100 or F-110 engine infrared signature, and Advanced Interference Blanker Unit. Additional sensitive areas include operating manuals and maintenance technical orders containing performance information, operating and test procedures, and other information related to support operations and repair. The hardware, software, and data identified are classified to protect vulnerabilities, design and performance parameters, and other similar critical information.

3. The AN/APG-68(V)9 radar is the latest model of the APG-68 radar and was specifically designed for foreign military sales. This model contains the latest digital technology available for a mechanically scanned antenna, including higher processor power, higher transmission power, more sensitive receiver electronics, and an entirely new capability, Synthetic Aperture Radar (SAR), which creates higher-resolution ground maps from a much greater distance than previous versions of the APG-68. The AN/APG-68(V)1 radar was designed in the early 1980s and is currently flying on the Block 25 aircraft. The upgrade features a 30% increase in detection range of air targets, a five-fold increase in processing speed, a ten-fold increase in memory, as well as significant improvements in all modes, jam resistance and false alarm rates. Complete hardware is classified Confidential; major components and subsystems are classified Confidential; software is classified Secret; and technical data and documentation are classified up to Secret.

4. The AN/ARC-238 Single Channel Ground and Airborne Radio System (SINCGAR) radio with HAVE QUICK II is a voice communications radio system. HAVE QUICK II employs cryptographic technology that is classified Secret. Classified elements include operating characteristics, parameters, technical data, and keying material.

5. The SNIPER Targeting System (AN/AAQ-33) is Unclassified but contains state-of-the-art technology. Information on performance and inherent vulnerabilities is classified Secret. The software (object code) is classified Confidential. Sensitive elements include the Forward Looking Infrared (FLIR) sensors, Laser Pulse Interval Modulation (PIM) and doublet coding, the AGM-65 Missile Boresight Correlator (MBC), and ECCM features that increase capability in a jamming environment. The SNIPER system to be released will not include the Laser Pulse Interval Modulation (PIM), laser doublet coding, or the Lockheed Martin (LM)-proprietary XR image processing algorithm (no extended range capability).

6. The LITENING Targeting System (AN/AAQ-28) is Unclassified but contains state-of-the-art technology. Information on performance and inherent vulnerabilities is classified Secret. The software (object code) is classified Confidential. Sensitive elements include the Forward Looking Infrared (FLIR) sensors, the Laser Pulse Interval Modulation (PIM) and doublet coding, and the AGM-65 Missile Boresight Correlator (MBC), and ECCM features that increase capability in a jamming environment. The LITENING AT system to be released will not include laser PIM, or laser doublet coding (no extended range capability).

7. The AN/APX-113 Identification Friend or Foe (IFF) System is Unclassified unless Mode IV operational evaluator parameters are loaded into the equipment. Classified elements of the IFF system include software object code, operating characteristics, parameters, and technical data. Mode IV anti-jam performance specifications/data, software source code, algorithms, and tempest plans or reports will not be offered, released, discussed or demonstrated.

8. The Multifunctional Information Distribution System-Low Volume Terminal (MIDS-LVT) is an advanced Link-16 command, control, communications, and intelligence (C3I) system incorporating high-capacity, jam-resistant, digital communication links for exchange of near real-time tactical information, including both data and voice, among air, ground, and sea elements. MIDS-LVT is intended to support key theater functions such as surveillance, identification, air control, weapons engagement coordination, and direction for all Services and Allied forces. The system will provide jamming-resistant, wide-area communications on a Link-16 network among MIDS and Joint Tactical Information Distribution System (JTIDS) equipped platforms. The MIDS/LVT and MIDS On Ship Terminal hardware, publications, performance specifications, operational capability, parameters, vulnerabilities to countermeasures, and software documentation are classified Confidential. The communication security devices and data exchanged on Link-16 networks are classified Secret. The classified information to be provided consists of that which is necessary for the operation, maintenance, and repair (through intermediate level) of the data link terminal, installed systems, and related software. Only Group A provisions will be initially transferred. Transfer of Link-16 terminals will take place only after completion of the release process for communications security devices and U.S. Secret data.

9. The Joint Helmet Mounted Cueing System (JHMCS) is a modified HGU-55/P helmet that incorporates a visor-projected Heads-Up Display (HUD) to cue weapons and aircraft sensors to air and ground targets. In close combat, a pilot must currently align the aircraft to shoot at a target. JHMCS allows the pilot to simply look at a target to shoot. This system projects visual targeting and aircraft performance information on the back of the helmet's visor, enabling the pilot to monitor this information without interrupting his field of view through the cockpit canopy. The system uses a magnetic transmitter unit fixed to the pilot's seat and a magnetic field probe mounted on the helmet to define helmet pointing positioning. A Helmet Vehicle Interface (HVI) interacts with the aircraft system bus to provide signal generation for the helmet display. This provides significant improvement for close combat targeting and engagement. The Hardware is Unclassified; the technical data and documents are classified up to Secret.

10. The AN/ALQ-211 Advanced Integrated Defensive Electronic Warfare Suite (AIDEWS) provides passive radar warning, wide spectrum RF jamming, and control and management of the entire EW system. It is an internally mounted suite. The commercially developed system software and hardware is Unclassified. The system is classified Secret when loaded with a US-derived EW database.

11. The AN/ALQ-213 Electronic Warfare Management System integrates and controls the chaff and flare dispenser, jammer, and RWR self protection systems. The commercially developed system software and hardware are Unclassified. The system is classified Secret when loaded with a U.S.-derived EW database.

12. The AN/ALQ-178 Self-Protection Electronic Warfare Suite (SPEWS) II is an internal system composed of a fully integrated RWR, jammer, and ALE-47 variant chaff and flare dispenser. It incorporates updated digital receivers, provides a wide-variety of advanced jamming techniques, and Digital Radio Frequency Memory (DRFM) capability. The commercially developed system software and hardware are Unclassified. The system is classified Secret when loaded with a U.S.-derived EW database.

13. The AN/ALQ-187 Advanced Countermeasures Electronic System (ACES) is a fully automatic jammer system integrated with radar warning (AN/ALR-93V or ALR-69) and flare/chaff (AN/ALE-47) systems for tactical aircraft self-protection. It incorporates advanced signal processing including a DRFM capability. The highest classification of the system is Secret.

14. The AN/ALE-47 Countermeasures Dispensing System is a software reprogrammable dispenser of chaff and flares. It provides for either automatic (via integrated Missile Warning System input) or aircrew commanded response dispense capabilities. Specific dispense routines are sensitive. The export version uses a country unique "look-up decision tree" for determining dispense routines. This software when loaded in the ALE-47 is classified Confidential. Increased risk of exploitation is significantly reduced given that the software is in executable form only, i.e., binary code, and the actual dispense routines can be gained through visual observation.

15. The ALR-56M Radar Warning Receiver continuously detects and intercepts radio frequency (RF) signals. It provides improved performance in a dense signal environment and improved detection of modern threat signals as compared to the ALR-69. The highest classification for the hardware is Confidential and the software is Secret.

16. Software, hardware, and other data/information, which is classified or sensitive, are reviewed prior to release to protect system vulnerabilities, design data, and performance parameters. Some end-item hardware, software, and other data identified above are classified at the Confidential and Secret level. Potential compromise of these systems is controlled through management of the basic software programs of highly sensitive systems and software-controlled weapon systems on a case-by-case basis.

17. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software in this proposed sale, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of systems with similar or advance capabilities.

[FR Doc. E8–12456 Filed 6–4–08; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 08–61]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(l) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 08–61 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: May 28, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY
2800 DEFENSE PENTAGON
WASHINGTON, DC 20301-2800

MAY 21 2008

In reply refer to:
USP005720-08

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515-6501

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 08-61, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Australia for defense articles and services estimated to cost $100 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

Richard J. Millies
Deputy Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Same ltr to:

House	Senate
Committee on Foreign Affairs	Committee on Foreign Relations
Committee on Armed Services	Committee on Armed Services
Committee on Appropriations	Committee on Appropriations

Transmittal No. 08-61

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) **Prospective Purchaser:** Australia

(ii) **Total Estimated Value:**

Major Defense Equipment*	$ 60 million
Other	$ 40 million
TOTAL	$100 million

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:** Installation of AN/AAQ-24(V) Large Aircraft Infrared Countermeasures (LAIRCM) systems on 12 Australian C-130J aircraft, including the following Line Replaceable Units (LRUs): 12 Control Interface Units (CIU), 12 System Processors (SP), 12 AN/AAR-54(V) Missile Warning Systems (MWS), 12 Small Laser Transmitter Assemblies (SLTA), and Operational Flight Program (OFP) software. The sale includes the following spare LRUs: 6 Control Interface Units (CIU), 6 System Processors (SP), 7 individual MWS sensors, and 12 Small Laser Transmitter Assemblies (SLTA). Also included: installation support, engineering change proposals, minor modifications, support equipment, spare and repair parts, publications and technical documents, repair and return, depot maintenance, training and training equipment, U.S. Government and contractor technical assistance, and other related elements of logistics and program support.

(iv) **Military Department:** Air Force (QAE)

(v) **Prior Related Cases, if any:** FMS case SEN - $54 million – 17Sep07

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:** none

(vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:** See Annex attached

(viii) **Date Report Delivered to Congress:** MAY 2 1 2008

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Australia – Large Aircraft Infrared Countermeasures (LAIRCM) Systems

The Government of Australia has requested a possible sale of AN/AAQ-24(V) LAIRCM systems to be installed on C-130J aircraft, including the following Line Replaceable Units (LRUs): 12 Control Interface Units (CIU), 12 System Processors (SP), 12 AN/AAR-54(V) Missile Warning Systems (MWS), 12 Small Laser Transmitter Assemblies (SLTA), Operational Flight Program (OFP) software, and spare LRUs (6 Control Interface Units (CIU), 6 System Processors (SP), 7 individual MWS sensors, and 12 Small Laser Transmitter Assemblies (SLTA)). Also included: installation support, engineering change proposals, minor modifications, support equipment, spare and repair parts, publications and technical documents, repair and return, depot maintenance, training and training equipment, U.S. Government and contractor technical assistance, and other related elements of logistics and program support. The estimated cost is $100 million.

Australia is an important ally in the Western Pacific. The strategic location of this political and economic power contributes significantly to ensuring peace and economic stability in the region. Australia's efforts in peacekeeping and humanitarian operations have made a significant impact to regional political and economic stability and have served U.S. national security interests. This proposed sale is consistent with those objectives and facilitates burden sharing with our allies.

These systems will be integrated on Australia's C-130J aircraft. The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Northrop Grumman Corporation, Rolling Meadows, IL. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will require approximately five contractor representatives to provide training, installation, and maintenance support technical and logistics support in Australia for twelve weeks after delivery. U.S. Government and contractor representatives will also participate in program management and technical reviews for two-week intervals annually.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 08-61

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex
Item No. vii

(vii) Sensitivity of Technology:

1. The AN/AAQ-24(V) LAIRCM is a self-contained, directed energy countermeasures system designed to protect aircraft from infrared-guided surface-to-air missiles. The system features digital technology and micro-miniature solid-state electronics. The system operates in all conditions, detecting incoming missiles and jamming infrared-seeker equipped missiles with aimed bursts of laser energy. Major components and subsystems of the LAIRCM system are unclassified; technical data documentation, training, devices and services to be conveyed with the proposed sale are also unclassified.

2. LAIRCM system software, including Operational Flight Program and jam codes, are classified Secret. LAIRCM operational parameters, test report data, and specific capabilities and limitations are classified Secret and will not be conveyed with the proposed sale. This information is sensitive due to potential for system exploitation and development of effective counter-countermeasures or similar defensive systems.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software in this proposed sale, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advance capabilities.

[FR Doc. E8–12457 Filed 6–4–08; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2008–OS–0065]

Privacy Act of 1974; System of Records

AGENCY: National Security Agency/ Central Security Service, DoD.

ACTION: Notice to Amend a System of Records.

SUMMARY: The National Security Agency/Central Security Service proposes to amend a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action would be effective without further notice on July 7, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the National Security Agency/ Central Security Service, Office of Policy, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Hill at (301) 688–6527.

SUPPLEMENTARY INFORMATION: The National Security Agency's systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record system being amended is set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: May 28, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

GNSA 02

SYSTEM NAME:

NSA/CSS Applicants (February 22, 1993, 58 FR 10531).

CHANGES:

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete and replace with ''National Security Agency Act of 1959, 50 U.S.C. 402 note (Pub. L. 86–36); 5 U.S.C. Chapters 3 and 33; EO 10450, as amended and EO 9397 (SSN).''

* * * * *

ROUTINE USES OF RECORDS:

Replace last item with ''The DoD 'Blanket Routine Uses' published at the beginning of the NSA/CSS' compilation

of system of record notices apply to this system.''

STORAGE:

Delete entry and replace with ''Paper in file folders and electronic storage media.''

* * * * *

SAFEGUARDS:

Delete entry and replace with ''Buildings are secured by a series of guarded pedestrian gates and checkpoints. Access to facilities is limited to security-cleared personnel and escorted visitors only. Within the facilities themselves, access to paper and computer printouts are controlled by limited-access facilities and lockable containers. Access to electronic means is limited and controlled by computer password protection.''

* * * * *

SYSTEM MANAGER:

Delete entry and replace with ''The Associate Director, Human Resources, National Security Agency/Central Security Service, Ft. George G. Meade, MD 20755–6000.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/ Privacy Act Office, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The NSA/CSS rules for contesting contents and appealing initial determinations are published at 32 CFR Part 322 or may be obtained by written request addressed to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.''

* * * * *

GNSA 02

SYSTEM NAME:

NSA/CSS Applicants.

SYSTEM LOCATION:

National Security Agency/Central Security Service, Ft. George G. Meade, MD 20755–6000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for employment with NSA/CSS.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains forms, documents and correspondence providing personal and qualifications information submitted by individual applicants, educational institutions, past employers, references. Records include processing items, status reports, test results, interview reports, reports of reviewing organizations and other related information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Security Agency Act of 1959, 50 U.S.C. 402 note (Pub. L. 86–36); 5 U.S.C. Chapters 3 and 33; EO 10450, as amended and EO 9397 (SSN).

PURPOSE(S):

To support the recruitment, selection, hire and placement of applicants. The file is used to document applicant processing, as a basis for selection decisions by individual agency elements and the personnel organization, and such other related uses as required.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To contractor employees and other government entities to make determinations as noted in the purpose above.

The DoD 'Blanket Routine Uses' published at the beginning of the NSA/ CSS' compilation of system of record notices apply to this system.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Paper in file folders and electronic storage media.

RETRIEVABILITY:

By name, Social Security Number, and other appropriate data elements.

SAFEGUARDS:

Buildings are secured by a series of guarded pedestrian gates and checkpoints. Access to facilities is limited to security-cleared personnel and escorted visitors only. Within the facilities themselves, access to paper and computer printouts are controlled by limited-access facilities and lockable containers. Access to electronic means is limited and controlled by computer password protection.

RETENTION AND DISPOSAL:

For applicants who are subsequently hired, records are transferred to Personnel File or destroyed as appropriate. For applicants not hired, record are retained for a period not to exceed one year or until completion of legal proceedings involving issues pertaining to these records, whichever is later, unless employment requirements necessitate retention for a longer period.

SYSTEM MANAGER(S) AND ADDRESS:

The Associate Director, Human Resources, National Security Agency/ Central Security Service, Ft. George G. Meade, MD 20755–6000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/ Privacy Act Office, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.

CONTESTING RECORD PROCEDURES:

The NSA/CSS rules for contesting contents and appealing initial determinations are published at 32 CFR Part 322 or may be obtained by written request addressed to the National Security Agency/Central Security Service, Freedom of Information Act/ Privacy Act Office, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.

RECORD SOURCE CATEGORIES:

Applicant, educational institutions, references, former employers including other governmental entities, interviewing and reviewing individuals including possible gaining organization, security and medical authorities and other sources as relevant and appropriate.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Portions of this system may be exempt pursuant to 5 U.S.C. 552a(k)(1) and (k)(5), as applicable.

An exemption rule for this record system has been promulgated according to the requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR part 322. For additional information contact the system manager.

[FR Doc. E8–12581 Filed 6–4–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2008–OS–0064]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to amend a system of records notice.

SUMMARY: The Office of the Secretary of Defense is amending a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on July 7, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mrs. Cindy Allard at (703) 588–2386.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record systems being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: May 28, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

DMDC 02

SYSTEM NAME:

Defense Eligibility Records (February 11, 2008, FR 73 7716).

CHANGES:

* * * * *

Delete DMDC 02 and replace with ''DMDC 02 DoD.''

SYSTEM NAME:

Delete entry and replace with ''Defense Enrollment Eligibility Reporting System (DEERS).''

* * * * *

DMDC 02 DoD

SYSTEM NAME:

Defense Enrollment Eligibility Reporting System (DEERS).

SYSTEM LOCATION:

EDS—Service Management Center, 1075 West Entrance Drive, Auburn Hills, MI 48326–2723.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty members and other Uniform Servicemembers, i.e. Department of Defense (DoD), Coast Guard, NOAA and USPHS; Reserve Members; National Guard members; State National Guard Employees; Presidential Appointees of all Federal Government agencies; DoD and Uniformed Service civil service employees, except Presidential appointees; Disabled American veterans; DoD and Uniformed Service contract employees; Former members (Reserve service, discharged RR or SR following notification of retirement eligibility); Medal of Honor recipients; Non-DoD civil service employees; U.S. Military Academy Students; Non-appropriated fund DoD and Uniformed Service employees (NAF); Non-Federal Agency Civilian associates, i.e. American Red Cross Emergency Services paid employees, Non-DoD contract employees; Reserve retirees not yet eligible for retired pay; Retired military members eligible for retired pay; Foreign Affiliates; DoD OCONUS Hires; DoD Beneficiaries; Civilian Retirees; Dependents; Members of the general public treated for a medical emergency in a DoD Medical Facility; Emergency Contact Person; Care Givers; Prior Military Eligible for VA benefits.

CATEGORIES OF RECORDS IN THE SYSTEM:

Computer files containing beneficiary's name, Service or Social Security Number, enrollment number, relationship of beneficiary to sponsor, residence address of beneficiary or sponsor, date of birth of beneficiary, sex of beneficiary, branch of Service of sponsor, dates of beginning and ending eligibility, number of family members of sponsor, primary unit duty location of sponsor, race and ethnic origin of beneficiary, occupation of sponsor, rank/pay grade of sponsor, disability documentation, Medicare eligibility and enrollment data, primary and secondary fingerprints and photographs of beneficiaries, blood test results, dental care eligibility codes and dental x-rays.

Catastrophic Cap and Deductible (CCD) transactions, including monetary amounts; CHAMPUS/TRICARE claim records containing enrollee, participant and health care facility, provider data such as cause of treatment, amount of payment, name and Social Security or tax identification number of providers or potential providers of care; citizenship data/country of birth; civil service employee employment information (agency and bureau, pay plan and grade, nature of action code and nature of action effective date, occupation series, dates of promotion and expected return from overseas, service computation date); claims data; compensation data; contractor fee payment data; date of separation of former enlisted and officer personnel; demographic data (kept on others beyond beneficiaries) date of birth, home of record state, sex, race, education level; Department of Veterans Affairs disability payment records; digital signatures where appropriate to assert validity of data; email (home/work); emergency contact information; immunization data; Information Assurance (IA) Work Force information; language data; military personnel information (rank, assignment/deployment, length of service, military occupation, education, and benefit usage); pharmacy benefits; reason leaving military service or DoD civilian service; Reserve member's civilian occupation and employment information; education benefit eligibility and usage; special military pay information; SGLI/FGLI; stored documents for proofing identity and association; workforces information (e.g. Acquisition, First Responders); Privacy Act audit logs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. Chapters 53, 54, 55, 58, and 75; 10 U.S.C. 136; 31 U.S.C.

3512(c); 50 U.S.C. Chapter 23, Internal Security; DoD Directive 1341.1, Defense Enrollment/Eligibility Reporting System; DoD Instruction 1341.2, DEERS Procedures; 5 U.S.C. App. 3 (Pub. L. 95–452, as amended (Inspector General Act of 1978)); Public Law 106–265, Federal Long-Term Care Insurance; 10 U.S.C. 2358, Research and Development Projects; 42 U.S.C., Chapter 20, Subchapter I-G, Registration and Voting by Absent Uniformed Services Voters and Overseas Voters in Elections for Federal Office, Sec. 1973ff, Federal responsibilities; DoD Directive 1000.4, Federal Voting Assistance Program (FVAP); Homeland Security Presidential Directive 12, Policy for a Common Identification Standard for Federal Employees and Contractors; 38 CFR part 9.20, Traumatic injury protection, Servicemembers' Group Life Insurance and Veterans' Group Life Insurance; and E.O. 9397 (SSN).

PURPOSE(S):

The purpose of the system is to provide a database for determining eligibility to DoD entitlements and privileges; to support DoD health care management programs; to provide identification of deceased members; to record the issuance of DoD badges and identification cards, i.e. Common Access Cards (CAC) or beneficiary cards; and to detect fraud and abuse of the benefit programs by claimants and providers to include appropriate collection actions arising out of any debts incurred as a consequence of such programs.

To authenticate and identify DoD affiliated personnel (e.g., contractors); to assess manpower, support personnel and readiness functions; to perform statistical analyses; identify current DoD civilian and military personnel for purposes of detecting fraud and abuse of benefit programs; to register current DoD civilian and military personnel and their authorized dependents for purposes of obtaining medical examination, treatment or other benefits to which they are entitled; to ensure benefit eligibility is retained after separation from the military; information will be used by agency officials and employees, or authorized contractors, and other DoD Components for personnel and manpower studies; and to assist in recruiting prior-service personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To the Social Security Administration (SSA) to perform computer data matching against the SSA Wage and Earnings Record file for identifying employers of Department of Defense (DoD) beneficiaries eligible for health care. This employer data will in turn be used to identify those employed beneficiaries who have employment-related group health insurance, to coordinate insurance benefits provided by DoD with those provided by the other insurance. This information will also be used to perform computer data matching against the SSA Master Beneficiary Record file for identifying DoD beneficiaries eligible for health care who are enrolled in the Medicare Program, to coordinate insurance benefits provided by DoD with those provided by Medicare.

2. To other Federal agencies and state, local and territorial governments to identify fraud and abuse of the Federal agency's programs and to identify debtors and collect debts and overpayment in the DoD health care programs.

3. To each of the fifty states and the District of Columbia for the purpose of conducting an on going computer matching program with state Medicaid agencies to determine the extent to which state Medicaid beneficiaries may be eligible for Uniformed Services health care benefits, including CHAMPUS, TRICARE, and to recover Medicaid monies from the CHAMPUS program.

4. To provide dental care providers assurance of treatment eligibility.

5. To Federal agencies and/or their contractors, in response to their requests, for purposes of authenticating the identity of individuals who, incident to the conduct of official business, present the Common Access Card or similar identification as proof of identity to gain physical or logical access to government and contractor facilities, locations, networks, or systems.

6. To State and local child support enforcement agencies for purposes of providing information, consistent with the requirements of 29 U.S.C. 1169(a), 42 U.S.C. 666(a)(19), and E.O. 12953 and in response to a National Medical Support Notice (NMSN) (or equivalent notice if based upon the statutory authority for the NMSN), regarding the military status of identified individuals and whether, and for what period of time, the children of such individuals are or were eligible for DoD health care coverage. **Note:** Information requested by the States is not disclosed when it would contravene U.S. national policy or security interests (42 U.S.C. 653(e)).

7. To the Department of Health and Human Services (HHS):

a. For purposes of providing information, consistent with the requirements of 42 U.S.C. 653 and in response to an HHS request, regarding the military status of identified individuals and whether, and for what period of time, the children of such individuals are or were eligible for DoD healthcare coverage. **Note:** Information requested by HHS is not disclosed when it would contravene U.S. national policy or security interests (42 U.S.C. 653(e)).

b. For purposes of providing information so that specified Medicare determinations, specifically late enrollment and waiver of penalty, can be made for eligible (1) DoD military retirees and (2) spouses (or former spouses) and/or dependents of either military retirees or active duty military personnel, pursuant to section 625 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2002 (as codified at 42 U.S.C. 1395p and 1395r).

c. To the Office of Child Support Enforcement, Federal Parent Locator Service, pursuant to 42 U.S.C. 653 and 653a; to assist in locating individuals for the purpose of establishing parentage; establishing, setting the amount of, modifying, or enforcing child support obligations; or enforcing child custody or visitation orders; the relationship to a child receiving benefits provided by a third party and the name and SSN of those third party providers who have a legal responsibility. Identifying delinquent obligors will allow State Child Support Enforcement agencies to commence wage withholding or other enforcement actions against the obligors.

8. To the American Red Cross for purposes of providing emergency notification and assistance to members of the Armed Forces, retirees, family members or survivors.

9. To the Department of Veterans Affairs (DVA):

a. To provide military personnel and pay data for present and former military personnel for the purpose of evaluating use of veterans' benefits, validating benefit eligibility and maintaining the health and well being of veterans and their family members.

b. To provide identifying military personnel data to the DVA and its insurance program contractor for the purpose of notifying separating eligible Reservists of their right to apply for Veteran's Group Life Insurance coverage

under the Veterans Benefits Improvement Act of 1996 (38 U.S.C. 1968) and for DVA to administer the Traumatic Servicemember's Group Life Insurance (TSGLI) (Traumatic Injury Protection Rider to Servicemember's Group Life Insurance (TSGLI), 38 CFR part 9.20).

c. To register eligible veterans and their dependents for DVA programs.

d. Providing identification of former military personnel and survivor's financial benefit data to DVA for the purpose of identifying military retired pay and survivor benefit payments for use in the administration of the DVA's Compensation and Pension Program (38 U.S.C. 5106). The information is to be used to process all DVA award actions more efficiently, reduce subsequent overpayment collection actions, and minimize erroneous payments.

e. To conduct computer matching programs regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a), for the purposes of:

(1) Providing full identification of active duty military personnel, including full time National Guard/Reserve support personnel, for use in the administration of DVA's Compensation and Pension benefit program. The information is used to determine continued eligibility for DVA disability compensation to recipients who have returned to active duty so that benefits can be adjusted or terminated as required and steps taken by DVA to collect any resulting over payment (38 U.S.C. 5304(c)).

(2) Providing military personnel and financial data to the Veterans Benefits Administration, DVA for the purpose of determining initial eligibility and any changes in eligibility status to insure proper payment of benefits for GI Bill education and training benefits by the DVA under the Montgomery GI Bill (Title 10 U.S.C., Chapter 1606—Selected Reserve and Title 38 U.S.C., Chapter 30—Active Duty), the REAP educational benefit (Title 10 U.S.C, Chapter 1607), and the National Call to Service enlistment educational benefit (Title 10, Chapter 510). The administrative responsibilities designated to both agencies by the law require that data be exchanged in administering the programs.

(3) Providing identification of reserve duty, including full time support National Guard/Reserve military personnel, to the DVA, for the purpose of deducting reserve time served from any DVA disability compensation paid or waiver of VA benefit. The law (10 U.S.C. 12316) prohibits receipt of reserve pay and DVA compensation for the same time period, however, it does permit waiver of DVA compensation to draw reserve pay.

(4) Providing identification of former active duty military personnel who received separation payments to the DVA for the purpose of deducting such repayment from any DVA disability compensation paid. The law requires recoupment of severance payments before DVA disability compensation can be paid (10 U.S.C. 1174).

f. To provide identifying military personnel data to the DVA for the purpose of notifying such personnel of information relating to educational assistance as required by the Veterans Programs Enhancement Act of 1998 (38 U.S.C. 3011 and 3034).

10. To DoD Civilian Contractors and grantees for the purpose of performing research on manpower problems for statistical analyses.

11. To consumer reporting agencies to obtain current addresses of separated military personnel to notify them of potential benefits eligibility.

12. To Defense contractors to monitor the employment of former DoD employees and military members subject to the provisions of 41 U.S.C. 423.

13. To Federal and Quasi Federal agencies, territorial, state, and local governments to support personnel functions requiring data on prior military service credit for their employees or for job applications. To determine continued eligibility and help eliminate fraud and abuse in benefit programs and to collect debts and over payments owed to these programs. Information released includes name, Social Security Number, and military or civilian address of individuals. To detect fraud, waste and abuse pursuant to the authority contained in the Inspector General Act of 1978, as amended (Pub. L. 95–452) for the purpose of determining eligibility for, and/or continued compliance with, any Federal benefit program requirements.

14. To Federal and Quasi Federal agencies, territorial, state and local governments, and contractors and grantees for the purpose of supporting research studies concerned with the health and well being of active duty, reserve, and retired personnel or veterans, to include family members. DMDC will disclose information from this system of records for research purposes when DMDC:

a. Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

b. Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

c. Has required the recipient to (1) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (A) In emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;

d. Has secured a written statement attesting to the recipients' understanding of, and willingness to abide by these provisions.

15. To Federal and State agencies for purposes of obtaining socioeconomic information on Armed Forces personnel so that analytical studies can be conducted with a view to assessing the present needs and future requirements of such personnel.

16. To Federal and state agencies to validate demographic data (e.g., Social Security Number, citizenship status, date and place of birth, etc.) for individuals in DoD personnel and pay files so that accurate information is available in support of DoD requirements.

17. To the Bureau of Citizenship and Immigration Services, Department of Homeland Security, for purposes of facilitating the verification of individuals who may be eligible for expedited naturalization (Pub. L. 108–136, Section 1701, and E.O. 13269, Expedited Naturalization).

18. To the Federal voting program to provide unit and e-mail addresses for the purpose of notifying the military members where to obtain absentee ballots.

19. To the Department of Homeland Security for the conduct of studies related to the health and well-being of Coast Guard members and to

authenticate and identify Coast Guard personnel.

20. To Coast Guard recruiters in the performance of their assigned duties.

21. To the Office of Personnel Management:

To conduct computer matching programs regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a), for the purpose of:

(1) Providing to OPM all reserve military members eligible for TRICARE Reserve Select (TRS) to matched against the OPM Central Personnel Data File (OPM/GOVT–1) for providing those reserve military members that are also Federal civil service employees. This disclosure by OPM will provide the DoD with the FEHB eligibility and Federal employment information necessary to determine continuing eligibility for the TRS program. Only those reservists not eligible for FEHB are eligible for TRS (Section 1076d of title 10).

The DoD ''Blanket Routine Uses'' published at the beginning of OSD's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on magnetic tapes and disks, and are housed in a controlled computer media library.

RETRIEVABILITY:

Records about individuals are retrieved by an algorithm which uses name, Social Security Number, date of birth, rank, and duty location as possible inputs. Retrievals are made on summary basis by geographic characteristics and location and demographic characteristics. Information about individuals will not be distinguishable in summary retrievals. Retrievals for the purposes of generating address lists for direct mail distribution may be made using selection criteria based on geographic and demographic keys.

SAFEGUARDS:

Computerized records are maintained in a controlled area accessible only to authorized personnel. Entry to these areas is restricted to those personnel with a valid requirement and authorization to enter. Physical entry is restricted by the use of locks, guards, and administrative procedures (e.g., fire protection regulations).

Access to personal information is restricted to those who require the records in the performance of their official duties, and to the individuals who are the subjects of the record or their authorized representatives. Access to personal information is further restricted by the use of passwords, which are changed periodically. All individuals granted access to this system of records is to have received Information Assurance and Privacy Act training.

RETENTION AND DISPOSAL:

Data is destroyed when superseded or when no longer needed for operational purposes, whichever is later.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Director, Defense Manpower Data Center, DoD Center Monterey Bay, 400 Gigling Road, Seaside, CA 93955–6771.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Deputy Director, Defense Manpower Data Center, DoD Center Monterey Bay, 400 Gigling Road, Seaside, CA 93955–6771.

Written requests should contain the full name, Social Security Number (SSN), date of birth, and current address and telephone number of the individual.

Individuals should provide the name and number of this system of records notice so that your request can be tasked to the appropriate OSD/JS office. This section must also include a description of needed identifier so that the record may be retrieved.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the OSD/JS FOIA Requester Service Center, Office of the Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

Written requests should contain the full name, Social Security Number (SSN), date of birth, and current address and telephone number of the individual.

Individuals should provide the name and number of this system of records notice so that your request can be tasked to the appropriate OSD/JS office. This section must also include a description of needed identifier so that the record may be retrieved.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the Privacy Act Officer, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

RECORD SOURCE CATEGORIES:

Individuals, personnel, pay, and benefit systems of the military and civilian departments and agencies of the Defense Department, the Coast Guard, the Public Health Service, the National Oceanic and Atmospheric Administration, Department of Veterans Affairs, and other Federal agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–12582 Filed 6–4–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2008–0013]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to Add a System of Records.

SUMMARY: The Department of the Army is proposing to add a system of records to its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on July 7, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Department of the Army, Freedom of Information/ Privacy Division, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Dickerson at (703) 428–6513.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on May 27, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated

February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: May 28, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

A0635a AHRC

SYSTEM NAME:

Combat-Related Special Compensation Files.

SYSTEM LOCATION:

Combat-Related Special Compensation Branch, U.S. Army Human Resources Command, 200 Stovall Street, Alexandria, VA 22315.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Army Retirees who have applied for Combat-Related Special Compensation Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Full name, Social Security Number (SSN), military grade or rate, and claim number; DD Form 2860, Claim for Combat-Related Special Compensation (CRSC), may also contain: Medical reports and disability compensation information from the Department of Veterans Affairs; medical reports from civilian medical facilities; medical board reports; statements of findings of physical evaluation boards; military health records; military personnel records; records and reports from the Defense Finance and Accounting Service; retirement records; pay information; correspondences between applicants and agency; intra-agency and interagency correspondence concerning the case; members of Congress, attorneys, representatives, and other cognizant persons or parties; decisional documents; any additional supporting documentation; and/or copies of any of the foregoing documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Defense Authorization Act Section 636; Public Law 107–314, Bob Stump National Defense Authorization Act for Fiscal Year 2003; 10 U.S.C. 1413a, as amended, Combat Related Special Compensation; 10 U.S.C. Chapter 61, Retirement or Separation for Physical Disability; AR 635–40, Physical Evaluation for Retention, Retirement, or Separation and E.O. 9397 (SSN).

PURPOSE(S):

To determine whether Army Retirees are entitled to combat-related special compensation; as a management tool to effectuate payment of combat-related special compensation; and to respond to official inquiries concerning the applications of particular applicants. The file may also be referred to by the Board for Correction of Army Records in conjunction with their subsequent review of applications from applicants.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b)(3) as follows:

To officials and employees of the Department of Veterans Affairs to request and verify information of service-connected disabilities in order to evaluate applications for combat-related special compensation and effectuate pay.

Note: This system of records contains individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18–R) issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18–R may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Individual's name, Social Security Number (SSN) and/or claim number.

SAFEGUARDS:

Paper files are maintained in a secure room and are signed out as needed to appropriate representatives and are under the control of authorized personnel during working hours. Individual computerized system is password protected and access to the data base requires being afforded rights and being able to access AKO and authenticate using either a common access card (CAC) or AKO user name and password. System Administrators assign local access to database. The office is located in a secured building leased by the Army that has a 24-hour security force. All personnel are required to wear a badge to gain entrance. All staff are required to have annual HIPAA certification.

RETENTION AND DISPOSAL:

Paper copies are kept secured until digitization occurs. Once digitized and transferred to the Interactive Personnel Electronic Record Management System (iPERMS) the paper copy records are placed in burn bags and destroyed. iPERMS will destroy the electronic record 10 years after transfer.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Army Human Resources Command (AHRC), 200 Stovall Street, Alexandria, VA 22332.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to Army Human Resources Command (AHRC), Combat-Related Special Compensation (CRSC) Branch, 200 Stovall Street, Alexandria, VA 22332.

The request should contain the full name of the individual, military grade or rate, claim number, Social Security Number (SSN) and signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in the system should address written inquiries to the Army Human Resources Command (AHRC), Combat-Related Special Compensation (CRSC) Branch, 200 Stovall Street, Alexandria, VA 22332.

The request should contain the full name of the individual, military grade or rate, claim number, Social Security Number (SSN) and signed.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in AR 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Army retirees who apply for combat-related special compensation; military medical boards and medical facilities; Department of Veterans Affairs and civilian medical providers and facilities; physical evaluation boards and other activities of the disability evaluation system; the Judge Advocate General; Army local command activities; the Defense Finance and Accounting Service; of the Department of Defense activities; and correspondence from members of Congress, attorneys, representatives, and other cognizant persons or parties.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–12580 Filed 6–4–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before July 7, 2008.

ADDRESSES: Written comments should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Comments may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']''. Persons submitting comments electronically should not submit paper copies.

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 IC Clearance Official, 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.

Dated: May 30, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: Revision.

Title: National Assessment of Educational Progress 2008–2010 Operational and Pilot Surveys System Clearance—2009 Wave 1.

Frequency: One time.

Affected Public: Individuals or households.

Reporting and Recordkeeping Hour Burden:

Responses: 446,417.

Burden Hours: 111,604.

Abstract: This is a request for clearance of NAEP 2009 Wave 2 materials. These materials are questionnaires for 4th, 8th and 12th graders including pilot and core materials—science, reading, mathematics, civics, U.S. history and geography.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3700. 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. E8–12562 Filed 6–4–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Reading First Advisory Committee

AGENCY: Department of Education, Office of Elementary and Secondary Education.

ACTION: Notice of Open Meeting.

SUMMARY: This notice describes an open meeting of the Reading First Advisory Committee. Notice of the meeting is required by Section 10(a)(2) of the Federal Advisory Committee Act and is intended to notify the public of their opportunity to attend.

DATE AND TIME: Monday, June 23, 2008 from 1 p.m. to 5 p.m. Eastern Daylight Time.

ADDRESSES: Westin Washington DC City Center at 1400 M Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Deborah Spitz, Reading First Team Leader, Reading First Advisory Committee; 400 Maryland Avenue, SW., Washington, DC 20202; telephone: (202) 260–3793; fax: (202) 260–8969; e-mail: *Deborah.Spitz@ed.gov;* Committee Web site: *www.ed.gov/programs/readingfirst/advisory.html.*

SUPPLEMENTARY INFORMATION: The Reading First Advisory Committee is authorized by Sections 1203(c)(2)(a) and 1202(e)(2) of the Elementary and Secondary Education Act (ESEA) of 1965, as amended. The Committee is established within the Department of Education to evaluate Reading First applications submitted by States, to review the progress reports that States submit after the third year of the grant period, to advise on the awarding of Targeted Assistance Grants, and to advise the Secretary on other issues that the Secretary deems appropriate.

On May 1, 2008, the U.S. Department of Education's Institute of Education Sciences (IES) released the *Reading First Impact Study: Interim Report.* During the open meeting of the Committee on June 23, 2008, the Committee members will discuss their questions and concerns about the Interim Report. A more detailed agenda will be posted on the Committee Web site prior to the meeting.

The Final Report of the Impact Study, which will provide impact data from three years of program implementation and information on relationships between changes in instructional practice and student reading comprehension, is expected to be released in late 2008.

Individuals who will need accommodations for a disability in order to attend the meeting (e.g., interpreting services, assistance listening devices, or materials in alternative format) should notify Deborah Spitz at (202) 260–3793, no later than ten (10) days before the scheduled date of the meeting. We will attempt to meet requests for accommodations after this date but cannot guarantee their availability. The meeting site is accessible to individuals with disabilities.

Request for Written Comments: There will not be an opportunity for the public to speak during this meeting; however, the public is encouraged to submit

written comments. Written comments should be submitted via e-mail by June 19, 2008 to Deborah Spitz at *Deborah.Spitz@ed.gov.* These comments will be shared with the members of the Committee.

Records are kept of all Committee proceedings and are available for public inspection at 400 Maryland Avenue, SW., Washington, DC 20202, from the hours of 9 a.m. to 5 p.m., Eastern Standard Time Monday through Friday.

Electronic Access to This Document: You may 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/index.html.*

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.*

Amanda Farris,

Deputy Assistant Secretary, The Office of Elementary and Secondary Education.

[FR Doc. E8–12587 Filed 6–4–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; List of Correspondence

AGENCY: Department of Education.

ACTION: List of Correspondence from January 2, 2008 through March 31, 2008.

SUMMARY: The Secretary is publishing the following list pursuant to section 607(f) of the Individuals with Disabilities Education Act (IDEA). Under section 607(f) of IDEA, the Secretary is required, on a quarterly basis, to publish in the **Federal Register** a list of correspondence from the U.S. Department of Education (Department) received by individuals during the previous quarter that describes the interpretations of the Department of IDEA or the regulations that implement IDEA.

FOR FURTHER INFORMATION CONTACT: Melisande Lee or JoLeta Reynolds. Telephone: (202) 245–7468.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain a copy of this notice in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: The following list identifies correspondence from the Department issued from January 2, 2008 through March 31, 2008. Included on the list are those letters that contain interpretations of the requirements of IDEA and its implementing regulations, as well as letters and other documents that the Department believes will assist the public in understanding the requirements of the law and its regulations. The date of and topic addressed by each letter are identified, and summary information is also provided, as appropriate. To protect the privacy interests of the individual or individuals involved, personally identifiable information has been redacted, as appropriate.

Part A—General Provisions

Section 602—Definitions

Topic Addressed: Child With A Disability.

○ Letter dated January 15, 2008 to Coalition of Learning Disabled Chief Executive Officer Allen Brumbaugh, regarding criteria used under Part B of IDEA for determining whether a child is a ''child with a disability'' and requirements for individualized education programs (IEPs).

Part B—Assistance for Education of All Children With Disabilities

Section 612—State Eligibility

Topic Addressed: Free Appropriate Public Education.

○ Letter dated March 11, 2007 to Mountain Plains Regional Resource Center Director John Copenhaver, clarifying that the policy regarding making a free appropriate public education (FAPE) available to children with disabilities, contained in the Office of Special Education Programs' letter dated April 10, 1995 to Ms. Kathy Balkman, remains consistent with the requirements of the reauthorized IDEA.

○ Letter dated March 17, 2008 to individual (personally identifiable information redacted), regarding the policy on the use of mechanical restraints or other aversive behavioral techniques for children with disabilities.

Topic Addressed: Least Restrictive Environment.

○ Letter dated February 1, 2008 to New Jersey Office of Special Education Programs Director Roberta Wohle, clarifying reporting on indicators in the State Performance Plan and Annual Performance Reports relating to the least restrictive environment provisions in Part B of IDEA.

Topic Addressed: Confidentiality of Education Records.

○ Letter dated March 7, 2008 to Texas Education Agency General Counsel David Anderson, regarding complaints that allege violations of the confidentiality of information provisions in Part B of IDEA and the Family Educational Rights and Privacy Act.

Topic Addressed: Children in Private Schools.

○ Letter dated March 17, 2008 to individual (personally identifiable information redacted), regarding the interpretation of the requirements of Part B of IDEA that are applicable when a public agency places a preschool-age child with a disability in a private preschool that is not a school that is exclusively for children with disabilities as a means of providing FAPE to that child.

○ Letter dated January 25, 2008 to U.S. Senator Joseph I. Lieberman, regarding the obligations of States and local educational agencies (LEAs) to parentally-placed private school children with disabilities.

Topic Addressed: State Educational Agency General Supervisory Authority.

○ Letter dated February 4, 2008 to individual (personally identifiable information redacted), regarding a State complaint involving a public agency's obligation to provide private placements for children with disabilities at public expense.

Topic Addressed: Methods of Ensuring Services.

○ Letter dated January 24, 2008 to Mountain Plains Regional Resource Center Director John Copenhaver, clarifying that Impact Aid funds and Medicaid funds are considered Federal funds, and may not be treated as State and local funds for maintenance of effort calculations.

Topic Addressed: State Advisory Panel.

○ Letter dated March 11, 2008 to Mountain Plains Regional Resource Center Director John Copenhaver, regarding requirements for membership on the State Advisory Panel.

Topic Addressed: Access to Instructional Materials.

○ Letter dated January 30, 2008 to New Mexico State Director of Special

Education Denise Koscielniak, clarifying issues surrounding State and LEA implementation of the National Instructional Materials Accessibility Standard.

Section 614—Evaluations, Eligibility Determinations, Individualized Education Programs, and Educational Placements

Topic Addressed: Individualized Education Programs.

○ Letter dated March 31, 2008 to individual (personally identifiable information redacted), clarifying that Part B of IDEA does not require that public agencies obtain parental consent within a specific time period when a child is referred for an evaluation.

○ Letter dated March 31, 2008 to individuals (personally identifiable information redacted), regarding how public agencies meet the requirements for notifying parents of the individuals who will be attending meetings of their child's IEP Team.

○ Letter dated March 17, 2008 to Howard County, Maryland Public School System Facilitator Ronald Caplan, regarding when it is appropriate to invite a representative of any participating agency likely to be responsible for providing or paying for transition services to an IEP Team meeting involving the consideration of the child's postsecondary goals and the transition services needed to assist the child in reaching those goals.

○ Letter dated March 17, 2008 to Utah At Risk and Special Education Services Director Nan Gray, regarding the requirement to obtain the consent of the parents or a child who has reached the age of majority prior to inviting a representative of any participating agency that is likely to be responsible for providing or paying for transition services to an IEP Team meeting involving the consideration of the child's postsecondary goals and the transition services needed to assist the child in reaching those goals.

Section 615—Procedural Safeguards

Topic Addressed: Impartial Due Process Hearing.

○ Letter dated March 17, 2008 to Mountain Plains Regional Resource Center Director John Copenhaver, regarding electronic mail filings of State complaints and due process complaints.

○ Letter dated March 17, 2008 to New Jersey Office of the State Board of Appeals Acting Director John Worthington, clarifying when the due process hearing timeline would begin under specific circumstances after the 30-day resolution process has expired.

Section 618—Program Information

Topic Addressed: Disproportionality.

○ Letter dated February 1, 2008 to Nevada Office of Special Education and Diversity Programs Director Frankie McCabe, clarifying that OSEP continues to believe that the position set out in the April 24, 2007 memorandum, requiring States to reserve funds for comprehensive coordinated early intervening services when there is a finding of significant disproportionality based on race and ethnicity in disciplinary actions, is correct.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents 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/index.html.*

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.

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(Catalog of Federal Domestic Assistance Number 84.027, Assistance to States for Education of Children with Disabilities)

Dated: May 30, 2008.

Tracy R. Justesen,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E8–12639 Filed 6–4–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services: Overview Information; Rehabilitation Continuing Education Program (RCEP)—Regional Technical Assistance and Continuing Education (TACE) Centers; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2008

Catalog of Federal Domestic Assistance (CFDA) Number: 84.264A.

Dates: Applications Available: June 5, 2008.

Deadline for Transmittal of Applications: July 31, 2008.

Deadline for Intergovernmental Review: September 3, 2008.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Rehabilitation Continuing Education Program is to support training centers that serve either a Federal region or another geographical area and provide for a broad integrated sequence of training activities that focus on meeting recurrent and common training needs of employed rehabilitation personnel throughout a multi-State geographical area.

Priority: This priority is from the notice of final priority and definitions for this program, published elsewhere in this issue of the **Federal Register**.

Absolute Priority: For FY 2008, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: Regional Technical Assistance and Continuing Education *(TACE) Centers.*

Program Authority: 29 U.S.C. 772.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations for this program in 34 CFR parts 385 and 389. (c) The notice of final priority and definitions, published elsewhere in this issue of the **Federal Register**.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: $7,900,000.

Maximum Award: We will reject any application that proposes a budget exceeding the maximum amount for a single budget period of 12 months, as follows:

Region I: $727,185.
Region II: $802,710.
Region III: $796,122.
Region IV: $969,100.
Region V: $821,579.
Region VI: $832,684.
Region VII: $728,738.
Region VIII: $711,421.
Region IX: $792,405.
Region X: $718,056.

The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 10.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* States and public or nonprofit agencies and organizations, including Indian tribes and institutions of higher education.

2. *Cost Sharing or Matching:* The Secretary has determined that a grantee must provide a match of at least 10 percent of the total cost of the project (34 CFR 389.40).

Note: Under 34 CFR 75.562(c), an indirect cost reimbursement on a training grant is limited to the recipient's actual indirect costs, as determined by its negotiated indirect cost rate agreement, or 8 percent of a modified total direct cost base, whichever amount is less. Indirect costs in excess of the 8 percent limit may not be charged directly, used to satisfy matching or cost-sharing requirements, or charged to another Federal award.

IV. Application and Submission Information

1. *Address to Request Application Package:* Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone, toll free: 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.ed.gov/pubs/edpubs.html* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.264A.

Individuals with disabilities can obtain a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Alternative Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative [Part III] to the equivalent of no more than 45 pages, using the following standards:

- A page is 8.5'' by 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative [Part III].

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: June 5, 2008.

Deadline for Transmittal of Applications: July 31, 2008.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, 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* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in 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: September 3, 2008.

4. *Intergovernmental Review:* This competition 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 competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section in this notice.

6. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications. Applications for grants under the Rehabilitation Continuing Education Program—Regional Technical Assistance and Continuing Education (TACE) Centers, CFDA Number 84.264A, must be submitted electronically using the Governmentwide Grants.gov Apply site at *http://www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for Rehabilitation Continuing Education Program—Regional Technical Assistance and Continuing Education (TACE) Centers at *http://www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.*, search for 84.264, not 84.264A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date.

Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf.*

• To submit your application via Grants.gov, you must complete all steps in the Grants.gov registration process (see *http://www.grants.gov/applicants/get_registered.jsp*). These steps include (1) registering your organization, a multi-part process that includes registration with the Central Contractor Registry (CCR); (2) registering yourself as an Authorized Organization Representative (AOR); and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf).* You also must provide on your application the same D–U–N–S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to submit successfully an application via Grants.gov. In addition you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

• 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: 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. Please note that two of these forms—the SF 424 and the Department of Education Supplemental Information for SF 424—have replaced the ED 424 (Application for Federal Education Assistance).

• 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.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to register fully to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system; and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Christine Marschall, U.S. Department of Education, 400 Maryland Avenue, SW., room 5053, PCP, Washington, DC 20202–2800. FAX: (202) 245–6824.

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 applicable following address:

By mail through the U.S. Postal Service:
U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.264A) 400 Maryland Avenue, SW., Washington, DC 20202–4260
or
By mail through a commercial carrier:
U.S. Department of Education, Application Control Center, Stop 4260, *Attention:* (CFDA Number 84.264A) 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, 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 84.264A) 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from 34 CFR 75.210 and 34 CFR 389.30(a), and are listed in the application package.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notice (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 in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section in 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 Government Performance and Results Act of 1993 (GPRA) directs Federal departments and agencies to improve the effectiveness of their programs by engaging in strategic planning, setting outcome-related goals for programs, and measuring program results against those goals. Performance measures established for the RCEP are the percentage of participants who report an increase in their knowledge, skills, and abilities. RSA will use these data to assess the performance of the projects funded under this competition. RSA also will convene an independent review panel to evaluate the work of the grantees. The independent review panel will use the following performance measures: (a) The percentage of technical assistance and continuing education services provided by the grantee that are deemed to be of high quality; (b) the percentage of technical assistance and continuing education services provided by the grantee that are deemed to be of high relevance to State VR policies or practices; and (c) the percentage of technical assistance and continuing education services provided by the grantee that are deemed to be useful in improving State VR agency policies or practices.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Christine Marschall, U.S. Department of Education, 400 Maryland Avenue, SW., room 5053, PCP, Washington, DC 20202–2800. Telephone: (202) 245–7429 or by e-mail: *Christine.Marschall@ed.gov.*

If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Alternative Format: Individuals with disabilities can obtain this document and a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the

following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. 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: *www.gpoaccess.gov/nara/index.html.*

Dated: June 2, 2008.

Tracy R. Justesen,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E8–12633 Filed 6–4–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Rehabilitation Training—Rehabilitation Continuing Education Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of final priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services announces a priority under the Rehabilitation Continuing Education Program (RCEP) to fund regional Technical Assistance and Continuing Education (TACE) centers. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2008 and later years. We take this action to improve the quantity and quality of employment outcomes for individuals with disabilities through enhanced technical assistance (TA) and continuing education (CE) for State vocational rehabilitation (VR) agencies and agency partners that cooperate with State VR agencies in providing VR and other rehabilitation services (*e.g.*, Centers for Independent Living (CILs), Client Assistance Programs (CAPs), and Community Rehabilitation Programs (CRPs)).

DATES: *Effective Date:* This priority is effective July 7, 2008.

FOR FURTHER INFORMATION CONTACT: Christine Marschall, U.S. Department of Education, 400 Maryland Ave., SW., Room 5053, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–7429 or via Internet: *Christine.Marschall@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Through this priority, the Department revises the current structure of the RCEP, which includes 21 regional RCEP centers—11 centers that serve primarily State VR agencies and 10 centers that serve primarily CRPs. Instead of funding these two separate sets of centers, this priority supports 10 regional Technical Assistance and Continuing Education (TACE) centers to serve State VR agencies and agency partners that cooperate with State VR agencies in providing VR and other rehabilitation services. CRPs are among the agency partners that the TACE centers are expected to serve. While the current RCEP centers provide CE and limited TA to entities, TACE centers will provide both TA and CE as necessary to respond to the needs of the State VR agencies and agency partners served by the TACE centers.

We published a notice of proposed priority (NPP) for this program in the **Federal Register** on January 29, 2008 (73 FR 5179). The NPP included a discussion of the issues associated with modifying the RCEP structure. The background section of the NPP explained that the results of the Department's Rehabilitation Services Administration's (RSA) program monitoring required by section 107 of the Rehabilitation Act of 1973, as amended, and the needs assessments conducted by current RCEP grantees indicated the need to integrate and coordinate services provided to State VR agencies and agency partners that cooperate with State VR agencies in providing VR and other rehabilitation services, including CRPs. The NPP also explained that the modified RCEP structure would reduce administrative costs by combining the functions of the two sets of centers and that public comments on the Rehabilitation Training Program, solicited through a notice in the **Federal Register** (72 FR 9942), generally supported the role of the RCEP in providing TA and CE and the provision of these services through a regional model. The final priority announced in this notice contains differences from the priority proposed in the NPP.

Analysis of Comments and Changes

In response to our invitation in the NPP, 79 parties submitted comments on the proposed priority. An analysis of the comments and of any changes in the priority since publication of the NPP follows.

Multiple commenters raised a number of similar issues; therefore, we group major issues by subject area. Generally, we do not address technical and other minor changes and suggested changes the law does not authorize us to make under the applicable statutory authority.

Agency Partners

Comment: Fifty-four commenters requested that specific entities be added to the list of agency partners with whom State VR agencies cooperate to provide VR and other rehabilitative services. Various commenters recommended that the following entities be added: American Indian Vocational Rehabilitation Service programs (30 commenters); State Rehabilitation Councils (SRCs) (nine commenters); Migrant and Seasonal Farmworker programs (seven commenters); CILs (six commenters); Statewide Independent Living Councils (one commenter); and State agencies such as developmental disability, mental illness, and substance abuse agencies (one commenter).

Discussion: The agency partners included in the priority are examples of agencies with which State VR agencies cooperate to provide VR and other rehabilitative services; the list of agencies provided is not intended to be exhaustive. The entities suggested by the commenters could be agency partners—that is, if a State VR agency cooperates with any one of these entities to provide VR and other rehabilitative services, that entity would be considered an agency partner for purposes of this priority.

Changes: None.

Consolidation of the Regional Centers

Comment: Twenty-three commenters stated that CRPs will not be served adequately under the modified RCEP structure, and six commenters stated that the TA and CE needs of CRPs are significantly different from the needs of State VR agencies.

Discussion: This priority focuses on the needs of State VR agencies and their agency partners. RSA values the contribution of the CRPs in the VR service system and recognizes that CRPs may have TA and CE needs that are different from those of the State VR agency and its other agency partners. RSA expects that the needs of CRPs, along with the needs of other agency

partners, will be reflected in the annual needs assessment that will serve as the foundation for each TACE center's work plan.

Changes: None.

Comment: Two commenters asked whether the 10 TACE centers will provide the employment certificate series training that the RCEP centers serving CRPs currently provide.

Discussion: The TA and CE provided by each TACE center will be determined by each TACE center with input from RSA after the TACE center conducts an annual needs assessment of the State VR agency and agency partners in the TACE center's region. While the TACE centers are not required to provide the employment certificate series training referred to by the commenter, nothing in the priority prohibits a TACE center from doing so if it meets a need identified by the State VR agency or its agency partners.

Changes: None.

Comment: Twenty-three commenters stated that the TACE centers should balance the time and resources devoted to address TA needs, on the one hand, and CE needs, on the other. Twelve commenters stated that the proposed priority appears to emphasize TA more than CE.

Discussion: We do not agree that the priority places a greater emphasis on TA than CE. The priority clearly states that each TACE center must conduct an annual needs assessment to identify the TA and CE needs of State VR agencies and agency partners. Based on the annual needs assessment, each TACE center will determine and describe in its work plan the distribution of resources that will be devoted to TA and CE activities.

Changes: None.

Comment: One commenter expressed concern that the 10 TACE centers will not be able to handle the high volume of TA and CE requests as well as the 21 currently funded RCEP centers.

Discussion: We expect the 10 TACE centers to be able to handle the high volume of TA and CE requests as well as the 21 currently funded RCEP centers because we believe that these 10 centers will provide TA and CE more effectively and efficiently than the current 21 RCEP centers. Because each region will have one TACE center to serve all State VR agencies and agency partners in that region and because RSA will coordinate across the TACE centers on a national level, the modified structure will facilitate sharing materials and information, and coordinating TA and CE activities, as appropriate, within and across regions. The annual needs assessment and work plan requirements in the priority will also help focus resources more effectively. We believe that the modified structure of the program will decrease duplication of effort and enhance coordination between State VR agencies and their agency partners. In addition, fewer resources will be expended on administrative costs because there will be one center in each region rather than two.

Changes: None.

Comment: Six commenters expressed concern that the relationships that have been developed over time among the current RCEP centers, State VR agencies, and agency partners will be lost in the modified RCEP structure supported by the TACE center priority.

Discussion: The modified structure of the RCEP program is designed to ensure collaboration between the TACE center, the State VR agency and agency partners served, and RSA. We believe that this collaboration will result in increased coordination of TA and CE provided to State VR agencies and agency partners and enhance relationships among the TACE centers, State VR agencies, and agency partners. Further, we believe that each TACE center's advisory committee will provide an opportunity for the advisory committee members who represent State VR agencies, among others, to develop and sustain relationships.

Changes: None.

Funding

Comment: Eighteen commenters stated that requiring the TACE centers to take on more TA responsibilities than the current RCEP centers will require more funds than those allocated to the current RCEP centers. Fourteen commenters stated that the same amount of funds currently provided to the 21 RCEP grantees should be provided to the 10 TACE centers in order for the new RCEP structure to be effective.

Discussion: The estimated level of funding for the TACE centers will be included in the notice inviting applications for new awards. We do not anticipate maintaining the same level of funds for the TACE centers that has been available under the current structure of the RCEP program. One of the major reasons for the changes in the RCEP program is to facilitate close coordination within each TACE center and among the TACE centers in order to maximize the effective use of funds to meet the TA and CE needs of the State VR agencies and their agency partners. To help ensure collaboration among TACE centers, RSA will coordinate activities of the TACE centers at the national level. We believe that the increased coordination within each TACE center and across centers will result in significant administrative efficiencies that will offset some of the expected funding differential.

Changes: None.

Comment: Three commenters asked how available funds for the RCEP program will be allocated and whether the geographic size of regions will be considered when funds are allocated to the TACE centers.

Discussion: All TACE centers will receive the same base funding amount. Additional funding will be provided to individual TACE centers based on the number of State VR agency staff in the region each TACE center serves, as identified in the most recently published data from the RSA–2, the Annual VR Program/Cost Report. We will not base our funding allocations on the geographic size of regions because we do not believe that the size of a region alone should affect the level of services provided—since there are multiple ways to conduct TA and provide CE in addition to face-to-face meetings, such as video conferencing and Webcasts.

Changes: None.

Comment: One commenter stated that the majority of funds provided to the TACE centers should be used to address TA and CE needs of State VR agencies. Another commenter asked whether the TACE centers would share staff training costs with the State VR agencies they serve as they do under the current RCEP structure.

Discussion: The use of funds for TA and CE will be determined by each TACE center based on the TACE center's annual needs assessment (developed with input from its advisory committee) and the TACE center's annual work plan (developed with input from RSA). Nothing in the priority prohibits the majority of funds provided to the TACE centers from being used to address TA and CE needs of State VR agencies. However, we do not believe that it is appropriate to require all TACE centers to use the majority of their funding under this program to address these needs. With regard to sharing training costs, while nothing in this priority requires a TACE center to share staff training costs with the State VR agencies it serves, nothing in the priority prohibits the TACE center from doing so.

Changes: None.

RSA Involvement With the TACE Centers

Comment: Twenty-eight commenters expressed concern that the priority gives

RSA too much control over the decision-making of the TACE centers and that, as a result, each TACE center's needs assessment and annual work plan will be dictated by RSA and not adequately consider the needs of the State VR agency and its agency partners.

Discussion: Under the priority, the TACE centers must work in consultation with RSA to establish their annual work plans, which describe the activities the TACE centers will carry out during each year of their project. We believe that this level of RSA involvement in and approval of the work plan is critical to ensure that the TACE centers are familiar with relevant information from RSA's State monitoring activities and to facilitate alignment of the TA and CE provided by the TACE centers with the VR service system in each State and across States. Given the need to ensure coordination of the work of the TACE centers at the national level, we believe it is important for RSA to approve all TACE center annual work plans. While the TACE model provides RSA with the authority to approve each center's work plan, RSA recognizes that, in order for the TACE centers to be effective, the TACE centers must work with the State VR agencies and agency partners to ensure more integrated decision-making with regard to the needs of State VR agencies and agency partners within and across the regions.

Changes: Priority paragraph (1) has been amended to clarify that each TACE center must establish an annual work plan, in coordination with and subject to the approval of RSA.

Comment: Nine commenters stated that TA should be RSA's responsibility, not the TACE centers' responsibility. One commenter stated that there is a need to explain the difference between the TA provided by the TACE centers and that provided by RSA.

Discussion: RSA will utilize the TACE centers to supplement the TA it provides. In light of RSA's program monitoring and the needs assessments conducted by current RCEP grantees that indicate a significant need for TA, we believe that supplementing RSA's provision of TA is beneficial to State VR agencies and agency partners, and ultimately individuals with disabilities receiving services from State VR agencies and agency partners. RSA—not the TACE centers—will provide TA on the interpretation of the Rehabilitation Act of 1973, as amended, and its regulations. TACE centers will provide TA to State VR agencies and agency partners to assist them in improving their performance in areas such as program management and delivery of VR services to increase and improve employment outcomes for individuals with disabilities.

Changes: None.

Needs Assessment and Work Plan

Comment: The comments of 26 individuals indicated that there was confusion about the relationship between the annual needs assessment and the annual work plan, as well as the role of a TACE center's advisory committee.

Discussion: The proposed priority specified that each TACE center would conduct an annual needs assessment, with input from its advisory committee, and develop an annual work plan, with input from RSA. However, we agree that the proposed priority was not clear about how the results of the needs assessment would be used to develop the annual work plan. We intend that the annual work plan, developed in cooperation with RSA and approved by RSA, will take into consideration the TA and CE needs of State VR agencies and agency partners that are identified in the TACE center's annual needs assessment. We do not expect each annual work plan to address all of the needs identified in the needs assessment. We understand that, due to limited resources, each TACE center will prioritize needs to be addressed in the annual work plan.

Changes: We have modified paragraph (1) of the priority to make clear that annual work plans must consider, but not necessarily address, the TA and CE needs of State VR agencies and agency partners identified in the TACE center's annual needs assessment.

Comment: Four commenters stated that the needs assessment should consider what the State VR agencies and agency partners say they need and not be based solely on RSA-generated data. Eighteen commenters stated that the State VR agencies in a TACE center's region should be consulted in the development of the TACE center's needs assessment and that a representative from State VR agencies in the region should be a member of a center's advisory committee. Discussion: As specified in paragraph (2) of the priority, each TACE center's annual needs assessment must be based on the needs of State VR agencies and agency partners in its region. The priority lists several sources of information that will be important for each TACE center to consider in its annual needs assessment, including information from VR State plans, on-site monitoring reports, and annual review reports issued by RSA. A TACE center's needs assessment, therefore, could not be based solely on RSA-generated data. In addition, paragraph (3) of the priority requires each TACE center to solicit input from its advisory committee members in developing the needs assessment and to use this information in developing its annual work plan.

Members of the advisory committee include, at a minimum, the entities listed in 34 CFR 385.40 as well as those additional entities listed in paragraph (3) of the priority. We believe that adding a representative from each State VR agency in a TACE center's region will increase opportunities for State VR agencies to inform the TACE center about their needs and to provide input into a TACE center's annual work plan. For this reason, we are modifying the priority to require each TACE center to invite a representative from the State VR agencies in the TACE center's region to participate on its advisory committee.

Changes: Paragraph (3) of the priority has been modified to require a TACE center to invite a representative from each State VR agency in its region to participate on its advisory committee.

Comment: Fifteen commenters stated that basing the needs assessment on VR State plans will result in a reactive and deficiency-based needs assessment (*i.e.*, one that intends only to remediate skills identified as ineffective through RSA monitoring), rather than a proactive needs assessment (*i.e.*, one that considers the development of new professional skills of staff as a valuable activity). One commenter stated that TA should be focused on VR State plans.

Discussion: VR State plans document the agency's goals and priorities for the upcoming fiscal year, including the strategies that the agency will undertake to achieve them. Using the VR State plans as one source of information in the needs assessment process enhances the needs assessments' relevance to State VR agencies' goals and priorities.

It was not the intent of the priority that the needs assessment be based solely on VR State plans. These plans are listed as one of the data sources to be reviewed when conducting the needs assessment. Paragraph (2) of the priority lists several other sources of data that must be considered in the annual needs assessment, including on-site monitoring reports and annual review reports issued by RSA, other performance and compliance information from RSA and State VR agencies, and other data, as appropriate.

We also do not intend for the needs assessment in this priority to be a deficiency-based model. Instead, we expect that the needs assessment process will be guided by each TACE center's advisory committee to ensure

that TA and CE are provided both to remediate deficits and to support new professional development. Each TACE center will make collaborative decisions with RSA about the TA and CE to be provided through the annual work plan based on the needs identified using these multiple data sources.

Changes: None.

Comment: Eleven commenters disagreed with the requirement that TACE center representatives attend State VR agency monitoring exit conferences conducted by RSA. The commenters stated that the presence of TACE center staff would give the impression that the TACE centers have monitoring responsibilities. Three commenters stated that the exit conference is the wrong time to have the TACE centers involved in the monitoring process because the process is incomplete at that time; instead, the commenters recommended that the TACE centers be involved after the issuance of a State's final monitoring report.

Discussion: The priority does not assign monitoring responsibilities to the TACE centers. Rather, the priority requires that the TACE centers serve as observers in RSA's monitoring of State VR agencies in their region by participating, at a minimum, in each State VR agency's monitoring exit conference in order to gain a thorough understanding of each State VR agency's TA and CE needs. It is important to retain the requirement that TACE center representatives participate in State VR agency monitoring exit conferences because these exit conferences provide significant information about the TA and CE needs of the State VR agency and agency partners. Requiring that TACE center staff participate in the exit conferences is worthwhile because of the early, additional insight the TACE centers will gain. Once the final report is issued, the TACE centers will consider the report's recommendations in their needs assessment and in the development of their work plan.

Changes: None.

Comment: Five commenters stated that, given limited funding, a single center couldn't be expected to have expertise in the 12 areas identified in the third paragraph of the priority. Two commenters stated that the 12 areas in which a TACE center must demonstrate expertise focus on the needs of the State VR agency and do not include areas that apply to agency partners. One commenter stated that the State VR agency should have input on the subject matter experts selected by its regional TACE center to provide TA and CE.

Discussion: One of the purposes of the TACE centers is to ensure that State VR agencies and agency partners receive the TA and CE they need to improve program performance. The expertise areas identified are included to address the needs of agency partners in the activities the agency partners undertake in cooperation with the State VR agency in the provision of VR and other rehabilitation services authorized under the Rehabilitation Act of 1973, as amended (Act). The 12 expertise areas included in the third paragraph of the priority were identified based on the following: An assessment of the TA needs of State VR agencies and SRCs; RSA's monitoring reviews required by section 107 of the Act; and RSA's review of annual VR State plans. Based on this information, we have determined that it is important to require applicants to demonstrate that they have expertise or access to subject-matter experts in at least these areas in order to provide effective TA and CE under this priority. The priority requires an applicant to describe how it will access expertise in at least these 12 areas, but it does not require the applicant to have experts on staff in all 12 areas. Thus, we disagree that this requirement will be too costly for TACE center grantees.

We recognize that other areas of need may arise through the needs assessment and do not wish to limit the areas of expertise to those identified in the priority. Therefore, we have changed the priority to clarify that each TACE center must have expertise or access to subject matter experts in, at a minimum, the 12 areas of expertise identified in the third paragraph of the priority.

Finally, nothing in the priority prevents a TACE center from consulting with the State VR agency to select its experts.

Changes: We have revised the third paragraph of the priority to clarify that each TACE center must have expertise or access to subject-matter experts in at least the 12 areas identified.

Comment: One commenter stated that the TACE centers should focus on other areas of expertise, such as negotiation skills, the psychological adjustment of individuals to acquired disabilities, leadership development, and placement training. Another commenter stated that the TACE centers should increase their knowledge of unserved and underserved populations.

Discussion: The priority requires the applicant to describe how it will address the 12 specified areas of expertise. Nothing in the priority prohibits applicants from proposing to develop or provide expertise in additional areas, such as negotiation skills, psychological adjustment to disabilities, leadership development, placement training, and the needs of unserved or underserved populations. We agree that expertise in these and other areas may arise from the needs assessments and have revised the priority to make clear that applicants may propose to develop or provide expertise in other areas.

Changes: We have revised the third paragraph of the priority to clarify that each TACE center must have expertise or access to subject-matter experts in at least the 12 areas identified.

Comment: Three commenters stated that each TACE center's annual work plan should remain flexible and responsive to individual State's needs.

Discussion: We agree that each TACE center's annual work plan should remain flexible and responsive to individual State's needs. We anticipate that the annual needs assessment, with input from the TACE center's advisory committee, will ensure that each TACE center's annual work plan will be responsive to individual State's needs given that the annual work plan must consider the TA and CE needs identified in the annual needs assessment. Moreover, because the needs assessments are conducted and the work plans are established annually, they can easily be altered from year to year. Finally, the annual work plan can be revised in consultation with RSA if emerging needs are identified by the TACE center during that year of the project period.

Changes: None.

Comment: One commenter asked whether the TACE centers could coordinate multi-State teams and regional meetings as is done by the current RCEP grantees.

Discussion: There is nothing in the priority that would prohibit a TACE center from coordinating multi-State teams or regional meetings, if it determines that this activity is appropriate based on the results of the TACE center's annual needs assessment and work plan.

Changes: None.

Advisory Committee Members

Comment: Eight commenters objected to the Department's intent to publish a notice of proposed rulemaking (NPRM) to change the current requirement for an advisory committee to include members of minority groups. The commenters objected to the change that would require that an advisory committee include individuals who are knowledgeable about the special needs of individuals with disabilities from

diverse groups, including minority groups, because the new requirement would not ensure the participation of members of minority groups. One commenter suggested that members of the advisory committees include individuals with disabilities who are members of minority groups.

Discussion: Members of minority groups are listed in 34 CFR 385.40 as one of the categories of mandatory participants on rehabilitation training advisory committees. As the note to paragraph (3) of the priority indicates, the Department intends to publish an NPRM to amend 34 CFR 385.40, which would remove the requirement that an applicant include members of minority groups on all project advisory committees and add a requirement that an applicant include individuals who are knowledgeable about the special needs of individuals with disabilities from diverse groups, including minority groups. This proposed change is consistent with the Supreme Court ruling in *Adarand Constructors, Inc.* v. *Peña* (515 U.S. 200 (1995)) in which the Court held that all racial classifications are constitutional only if they are narrowly tailored measures that further compelling governmental interests. The proposed change is a race-neutral alternative that achieves the intent of the Department that project advisory committees include individuals who are familiar with the needs of individuals with disabilities from diverse groups, while ensuring compliance with the Supreme Court's decision in *Adarand.*

Changes: None.

Comment: Eleven commenters requested that various entities be required members of each TACE center's advisory committee. The entities that commenters recommended be added include: Representatives from State VR agencies (six commenters); representatives from agency partners (four commenters); and current or former recipients of VR services (one commenter). One commenter stated that State VR agency representatives should comprise 50 percent of the membership of each TACE center's advisory committee. Another commenter stated that individuals with disabilities should comprise the majority of the members of each TACE center's advisory committee.

Discussion: The required composition of an advisory committee for projects funded under the Rehabilitation Training Program, which includes the RCEP program, is defined in 34 CFR 385.40. The priority also requires that each TACE center advisory committee include members from Independent Living Training and Technical Assistance centers. We believe that adding a requirement to invite a representative from each State VR agency in a TACE center's region would increase the opportunities for State VR agencies to express their needs and provide input into the TACE center's annual work plans. Otherwise, we believe the composition of the advisory committee as specified in 34 CFR 385.40 and this priority is sufficiently broad to enable all appropriate constituents to be represented, including representatives from agency partners and former recipients of VR services. Nothing in the priority or applicable regulations prohibits an applicant from proposing additional members for its advisory committee.

Changes: We have modified paragraph (3) of the priority to require each TACE center to invite a representative from each State VR agency in its region to participate on its advisory committee.

Comment: One commenter asked if the role of the advisory committee is to provide advice to the TACE center or to set policy for the TACE center.

Discussion: The priority does not specify a policy-making role for the advisory committee. It simply requires that the advisory committee be established to provide input on the TACE center's annual needs assessment. We anticipate that the annual needs assessment will be an important source of input to each TACE center's annual work plan. Nothing in the priority requires center policies to be determined by the advisory committee, although this function could be proposed in the application.

Changes: None.

Comment: One commenter stated that the TACE centers' advisory committees, which, by definition, are regional in nature, would not take into account differences in States' needs and recommended that the TACE centers be required to have State advisory committees.

Discussion: The goal of TACE center advisory committees is to provide an opportunity for State VR agencies and agency partners to provide information about their TA and CE needs. For reasons of efficiency, the priority requires only one advisory committee for each TACE center. However, as noted elsewhere in this discussion, we have modified the priority to require each TACE center to invite a representative from each State VR agency served by the TACE center to participate on its advisory committee. We believe that this addresses the commenter's concern by allowing regional advisory committees to be informed about and take into account State differences.

Changes: None.

Performance Measures

Comment: Four commenters stated that the goal of improving the quality and quantity of VR outcomes is not adequately defined in the priority, and one commenter stated that the TACE centers should not be expected to contribute to increasing VR outcomes. Another four commenters stated that the performance measures identified for the program in paragraph (7) of the priority should be better defined and more objective.

Discussion: The goal of improving the quality and quantity of VR outcomes is an expected outcome of the provision of TA and CE to the State VR agency and agency partners. However, the Department does not intend to judge the performance of the TACE centers on the basis of changes in VR outcomes. The Department will establish an independent review panel to evaluate the performance of the TACE centers. The areas to be evaluated by the independent review panel—quality, relevance, and usefulness—are those areas typically examined by the Department in assessing the performance of TA activities supported by the Department. The Department will determine the methodology for this review, including the objective criteria to be used by the panel in rating the TA and CE services in these three areas.

Changes: None.

Other Comments

Comment: One commenter suggested that the priority allow consortia models—that is, models in which a TACE center would be operated by two or more entities, such as the National Rehabilitation Leadership Institute.

Discussion: Although the priority does not specifically address the establishment of consortia models for a TACE center, nothing in the priority would prohibit an applicant from proposing such a model.

Changes: None.

Comment: One commenter stated that the TACE centers should have explicit responsibility for disseminating evidence-based knowledge and best practices.

Discussion: The Department agrees that it would be advantageous to have the TACE centers disseminate evidence-based knowledge, including information on best practices to the extent that it is available. We have modified paragraph (5) of the priority to reflect this change.

Changes: We have modified paragraph (5) of the priority to indicate

that the TA provided by the TACE centers should be evidence-based to the extent possible.

Comment: Four commenters expressed concern about the timing of this priority and the fact that the TACE centers would be replacing current RCEP grantees that have not completed their five-year funding cycle. Two commenters stated that it creates a poor precedent not to continue grants that are in the middle of a five-year funding cycle, and one commenter stated that RSA is moving forward with this change too quickly.

Discussion: The Department has carefully considered the timing of this priority and believes it is the appropriate time to make this change. Seven of the current 11 RCEP centers that primarily serve State VR agencies will have completed their five-year project period, and three of the RCEP centers will have completed the fourth year of their grant prior to the establishment of the new TACE centers on October 1, 2008. In addition, the TA needs of the VR system have increased significantly, based on an assessment of the TA needs of State VR agencies and SRCs, RSA's monitoring reviews as required by section 107 of the Act, and RSA's review of annual State plans submitted by State VR agencies as a condition of Federal funding. The purpose of this priority is to ensure that State VR agencies and their agency partners receive the TA and CE they need to improve their performance. The Department believes that it is in the best interest of individuals with disabilities and their families that this change be made at this time.

Changes: None.

Comment: None.

Discussion: Based on internal departmental review, we determined that it was not appropriate to include the phrase ''as applicable'' in the first sentence of paragraph (2) of the priority. We expect the annual needs assessment to identify the TA and CE needs of all State VR agencies and agency partners in the region served by the TACE center.

Changes: We have deleted the phrase ''as applicable'' from the end of the first sentence in paragraph (2) of the priority.

Comment: None.

Discussion: Based on internal departmental review, we determined that ''agency partners'' was not adequately defined in the priority. Agency partners include all agencies with which the State VR agency cooperates in providing VR and other rehabilitation services.

Change: We have added language to the first paragraph of the priority to clarify that the term ''agency partners'' refers to all agencies with which the State VR agencies served by the TACE center cooperate in providing VR and other rehabilitation services.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**. When inviting applications we designate the priority as absolute, competitive preference, or invitational. The effect of each type of priority follows:

Absolute priority: Under an absolute priority we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority we give competitive preference to an application by either (1) awarding additional points, depending on how well or the extent to which the application meets the competitive priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the competitive priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the invitational priority. However, we do not give an application that meets the invitational priority a competitive or absolute preference over other applications (34 CFR 75.105(c)(1)).

Priority:

Regional Technical Assistance and Continuing Education Centers

The Assistant Secretary for Special Education and Rehabilitative Services establishes a priority to create 10 regional Technical Assistance and Continuing Education (TACE) centers to provide (1) technical assistance (TA) to State vocational rehabilitation (VR) agencies and agencies with which State VR agencies cooperate in providing VR and other rehabilitation services (agency partners) to improve services required under the Rehabilitation Act of 1973, as amended, and (2) continuing education (CE) to employees of State VR agencies and agency partners. For purposes of this priority, the term ''agency partners'' refers to all agencies with which the State VR agencies served by the TACE center cooperate in providing VR and other rehabilitation services.

Under this priority, the TACE centers must contribute to the following outcomes: improved quality of VR services, increased effectiveness and efficiency of State VR agencies in delivering VR services, and improved quantity and quality of VR employment outcomes for individuals with disabilities. The TACE centers must contribute to these outcomes by providing TA and CE, either directly or through contract, to employees of State VR agencies and agency partners on topics that are identified jointly by the Rehabilitation Services Administration (RSA) and each TACE center's advisory committee and included in the TACE center's annual work plan.

Under this priority, applicants must demonstrate their ability to respond rapidly to a broad range of TA and CE needs. Applicants must provide evidence in their applications that they have expertise, or access to subject-matter experts with experience, in conducting TA and CE in at least the following areas: Improvement of State VR agencies' service delivery; practices and interventions related to specific VR populations; quality assurance; case management at the administrative and counselor level; the use of assistive technology to achieve employment goals; personnel management (*e.g.*, staff retention strategies); fiscal management; data management; communication skills development; development of individualized plans for employment; development of VR State plans; and strategic planning.

Under this priority, each TACE center must—

1. Establish an annual work plan, in coordination with and subject to the approval of RSA, describing activities that it will conduct to assist State VR agencies to accomplish the goals identified in their VR State plans and to achieve other performance and compliance goals identified by RSA's monitoring reports. The annual work plan must identify the nature and scope, including delivery means and methods, of the TA and CE to be provided by the TACE center and consider, but not necessarily address, the TA and CE needs of State VR agencies and agency partners identified in the TACE center's annual needs assessment;

2. Conduct an annual needs assessment to identify the TA and CE needs of State VR agencies and agency partners in its region. Each TACE center must base its annual needs assessment on a thorough review of VR State plans, on-site monitoring reports and annual review reports issued by RSA, other performance and compliance information available from RSA and State VR agencies, and other data, as appropriate;

3. Establish a center advisory committee to provide input on the annual needs assessments conducted by the TACE center in accordance with paragraph (2) of this priority. In addition to the requirements in 34 CFR 385.40 for mandatory members of the center advisory committee, the committee must invite representatives from each of the State VR agencies in the region served by the TACE center and from RSA's Independent Living Training and Technical Assistance

grantees to serve on this committee. RSA representatives will serve as ex-officio members.

Note: Members of minority groups are listed in 34 CFR 385.40 as one of the categories of mandatory participants on rehabilitation training advisory committees. However, the Department intends to publish a notice of proposed rulemaking (NPRM) to amend 34 CFR 385.40, which would remove the requirement that an applicant include members of minority groups on all project advisory committees. The NPRM would add a requirement that an applicant include individuals who are knowledgeable about the special needs of individuals with disabilities from diverse groups, including minority groups. The purpose of this change would be to more clearly reflect the Department's intent that project advisory committees include individuals who are familiar with the needs of individuals with disabilities from diverse groups, rather than individuals who are just members of such groups;

4. Serve as an observer in RSA's monitoring of State VR agencies in its region by participating, at a minimum, in each State VR agency's monitoring exit conference in order to gain a thorough understanding of each State VR agency's TA and CE needs;

5. Collaborate and coordinate with other TACE centers to provide TA and CE as efficiently as possible to employees of State VR agencies and agency partners that have similar needs. TA should be evidence-based, to the extent possible, and include information on best practices to the extent evidence or research is available.

6. Coordinate services with other entities that provide TA and CE to State VR agencies and agency partners, including, but not limited to, Independent Living Training and Technical Assistance grantees and Assistive Technology projects funded by RSA; and

7. Evaluate how well each TA and CE activity provided by the TACE center meets a targeted area of need (*e.g.*, the improvement of State VR agencies' service delivery; practices and interventions related to specific VR populations; quality assurance), based on goals and objectives established for the activity in the TACE center's annual work plan. Each TACE center must provide data on each TA and CE activity it conducts, including information on the topic of the activity, the number and types of personnel and agencies participating in the activity, participant evaluations of the effectiveness of the activity, and any other data required by the Department. Each TACE center must include the results of its evaluation in its annual performance report. RSA will convene an independent review panel to evaluate the work of the TACE centers. The independent review panel will use the following performance measures: (a) The percentage of TA and CE services provided by the TACE center that are deemed to be of high quality; (b) the percentage of TA and CE services provided by the TACE center that are deemed to be of high relevance to State VR policies or practices; and (c) the percentage of TA and CE services provided by the TACE center that are deemed to be useful in improving State VR agency policies or practices.

Executive Order 12866

This notice of final priority (NFP) has been reviewed in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with the NFP are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of this NFP, we have determined that the benefits of the final priority justify the costs.

We have also determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

We summarized the costs and benefits in the NPP.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Applicable Program Regulations: 34 CFR parts 385 and 389.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents 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.*

(Catalog of Federal Domestic Assistance Number 84.264A Rehabilitation Continuing Education Program)

Program Authority: 29 U.S.C. 772.

Dated: June 2, 2008.

Tracy R. Justesen,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E8–12636 Filed 6–4–08; 8:45 am]

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DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; Overview Information; Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—Technical Assistance Coordination Center; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2008

Catalog of Federal Domestic Assistance (CFDA) Number: 84.326Z.

DATES:

Applications Available: June 5, 2008.

Deadline for Transmittal of Applications: July 7, 2008.

Deadline for Intergovernmental Review: September 3, 2008.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing technical assistance (TA), supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute or otherwise authorized in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA), 20 U.S.C. 1400 *et seq.*).

Absolute Priority: For FY 2008, this priority is an absolute priority. Under 34

CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities—Technical Assistance Coordination Center.

Background: Under Part D of IDEA, the Office of Special Education Programs (OSEP) developed a comprehensive Technical Assistance & Dissemination (TA&D) Network, which is comprised of approximately 40 TA&D OSEP-funded centers that work at the national and regional levels to improve the education of and services to eligible children with disabilities. These centers provide TA covering a variety of areas to State educational agencies (SEAs), local educational agencies (LEAs), Part C lead agencies, families of children with disabilities, and others to improve services and outcomes for children served under Part B and Part C of IDEA. (For more information regarding Parts B and C of IDEA see sections 611 and 631 of IDEA (20 U.S.C. 1400 *et seq.*))

Ongoing communication, collaboration, and coordination among the centers in the OSEP TA&D Network are essential to (a) increase the impact of the TA&D centers' efforts, (b) maximize efficiency, and (c) ensure that products and services are non-duplicative. Furthermore, communication, collaboration, and coordination between OSEP's TA&D Network and other relevant federally-funded TA&D centers are necessary to improve early intervention and education outcomes for children with disabilities. For example, the Department's Office of Elementary and Secondary Education (OESE) funds a Comprehensive Center on Assessments, which provides TA to States on assessment issues related to all children, including children with disabilities; and the U.S. Department of Health and Human Services supports the Center for Social and Emotional Foundations for Early Learning.

Communication, collaboration, and coordination, however, are difficult to initiate and sustain without logistical (e.g., arranging meetings, coordinating schedules) and structural supports (e.g., documenting decisions, developing agendas).

OSEP funded a Federal Resource Center for Special Education (FRC) in 2003 as a way to facilitate communication, collaboration, and coordination among OSEP-funded Regional Resource Centers (RRCs). The FRC worked closely with the six RRCs to help them coordinate their TA to States. In addition to the coordination among RRCs, the FRC coordinated, to a limited extent, the exchange of information between the RRCs and other OSEP and Department-funded TA&D centers. (For further information on the work of the FRC, go to *http://www.rrfcnetwork.org*). In addition to more efficient use of RRC staff time, expertise, and funds, the FRC found that RRC products and service delivery improved when the work of the RRCs was coordinated. OSEP believes that similar positive results can be achieved if support for communication, collaboration, and coordination is extended beyond the six RRCs to include all of the OSEP and other relevant Department and federally-funded technical assistance projects, national professional organizations, and stakeholders such as associations that are members of the IDEA Partnership, which OSEP intends to fund in FY 2008.

Priority: The purpose of this priority is to fund a cooperative agreement to support the establishment and operation of a Technical Assistance Coordination Center (TACC) that will assist OSEP in supporting ongoing communication, collaboration, and coordination among the centers in the OSEP-funded TA&D Network, and between these centers and other relevant federally-funded TA&D centers, national professional organizations, and a broad spectrum of stakeholders.

To be considered for funding under this absolute priority, applicants must meet the application requirements contained in this priority. A project funded under the absolute priority also must meet the programmatic and administrative requirements specified in the priority.

Application Requirements. An applicant must include in its application—

(a) A logic model that depicts, at a minimum, the goals, activities, outputs, and outcomes of the proposed project. A logic model communicates how a project will achieve its outcomes and provides a framework for both the formative and summative evaluations of the project;

Note: The following Web site provides more information on logic models and lists multiple online resources: *http://www.cdc.gov/eval/resources.htm.*

(b) A plan to implement the activities described in the *Project Activities* section of this priority;

(c) A plan, linked to the proposed project's logic model, for a formative evaluation of the proposed project's activities. The plan must describe how the formative evaluation will use clear performance objectives to ensure continuous improvement in the operation of the proposed project, including objective measures of progress in implementing the project and ensuring the quality of products and services;

(d) A budget for attendance at the following:

(1) A one and one half day kick-off meeting to be held in Washington, DC within four weeks after receipt of the award, and an annual planning meeting held in Washington, DC with the OSEP Project Officer during each subsequent year of the project period.

(2) A three-day Project Directors' Conference in Washington, DC during each year of the project period.

(3) Five two-day trips annually to attend Department briefings, Department-sponsored conferences, and other meetings requested by OSEP; and

(e) A line item in the proposed budget for an annual set-aside of five percent of the grant amount to support emerging needs that are consistent with the proposed project's activities, as those needs are identified in consultation with OSEP.

Note: With approval from the OSEP Project Officer, the TACC must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period.

Project Activities. To meet the requirements of this priority, the TACC, at a minimum, must conduct the following activities.

Logistical Support and Coordination Activities.

(a) Facilitate ongoing communication, collaboration, and coordination among the centers in the OSEP TA&D Network, and between those centers and other Department-funded TA&D centers, including the Comprehensive Centers, Equity Assistance Centers, and Regional Educational Laboratories; relevant TA centers funded by the U.S. Department of Health and Human Services; national professional organizations, and other stakeholders, as appropriate. The TACC, at a minimum, must—

(1) Provide logistical support to establish and maintain topical workgroups comprised of OSEP TA&D Network center staff, including information specialists and other TA&D staff, as appropriate, to share information and develop coordinated TA strategies and products on issues, priorities, and strategic initiatives identified by OSEP.

(2) Establish and maintain listservs and other electronic mechanisms for communication, collaboration, and coordination.

(3) Maintain OSEP's Proposed Product Advisory Board (PPAB), which reviews information on products proposed by the OSEP TA&D Network centers to ensure non-duplication of products across TA&D centers. Information about PPAB is available at: *http://www.nichcy.org/ppab/index.htm.* The TACC, at a minimum, must ensure that this independent review panel conducts a systematic review, at least twice annually and more frequently if needed, of products proposed by the TA&D Network centers and offer recommendations to OSEP regarding whether the proposed products are duplicative.

(4) Maintain and expand, as appropriate, the communities of practice Web site (*http://www.tacommunities.org*) to support discussions among centers in the OSEP TA&D Network and between these centers and other federally-funded TA&D centers on specific topical areas such as those currently found at *http://www.rrfcnetwork.org/content/view/21/49/.* The TACC must, at a minimum, maintain the facilitator section of the Web site, organize and host facilitator community meetings, provide training and support to current and new facilitators, and develop communications and outreach materials about the communities of practice that are listed at *http://www.tacommunities.org/.*

(5) Develop, maintain, update, and integrate, when appropriate, searchable databases of OSEP's (i) discretionary grants, (ii) TA&D Network centers' proposed and current products and services, and (iii) events. This work must include, at a minimum, the following:

(i) Expanding, modifying, maintaining, and integrating, as appropriate, the existing databases of OSEP-funded discretionary grants and their products to assist in coordinating TA&D activities within and across all Part D programs. These databases include the OSEP Discretionary Projects Databases, which must be in compliance with the 2002 E-Government Act and the 2002 Federal Information Security Management Act requirements. Information about these databases is available at: *http://www.nichcy.org/directories/sepm/default.asp* and *http://www.nichcy.org/search.htm#tad.*

(ii) Expanding the TA&D Matrix, which is a searchable database that provides current information on Department-funded TA services to a range of stakeholders, to include current information on federally-funded early intervention and early childhood education TA services. This matrix must be integrated with the databases mentioned in paragraph (i). Information about the TA&D Matrix is available at: *http://matrix.rrfcnetwork.org.*

(6) Maintain and update, at least twice annually, the TA&D Placemat, which is a tool that includes the contact information for all Department-funded TA&D centers. The current TA&D Placemat is available at: *http://www.rrfcnetwork.org/content/view/137/192/.*

(7) Maintain a Web portal that includes—(i) a work area for the OSEP TA&D Network centers to develop and share resources and products and that links to the Web sites operated by centers in the OSEP TA&D Network; and (ii) an events calendar that includes information on national and regional events hosted by the OSEP TA&D Network centers and OSEP.

(8) Provide an orientation for new OSEP TA&D Network centers and ongoing support for existing OSEP TA&D Network centers on topics such as: (i) PPAB product submission guidelines; (ii) TA&D Matrix data input and maintenance; (iii) Events calendar input and maintenance; (iv) Communities of practice participation; (v) Web site protocols; (vi) Annual performance report (APR) schedules and updates; and (vii) Government Performance and Results Act performance measures.

(b) Facilitate ongoing communication, collaboration, and coordination among the OSEP TA&D Network regional centers, such as the RRCs and the Postsecondary Education Programs Network Regional Centers. The TACC, at a minimum, must (i) develop and maintain an area of the Web portal for use by these regional TA&D centers, (ii) coordinate monthly phone calls among the regional TA&D centers, and (iii) establish and maintain topical workgroups comprised of staff across the regional TA&D centers to identify and develop TA tools and resources.

(c) Support OSEP in sharing information with the OSEP TA&D Network, States, national professional organizations, and other relevant stakeholders on national priorities, issues, and initiatives. The TACC, at a minimum, must—

(i) Provide logistical support for annual conferences hosted by OSEP (e.g., Leadership Conference, TA&D Conference, Joint Leveraging Resources Conference, and Summer Monitoring Institutes) as well as any national meetings, public meetings, and hearings associated with the reauthorization of IDEA.

(ii) Maintain and update, as appropriate, OSEP's existing IDEA Web site (located at *http://idea.ed.gov*), which contains searchable versions of the IDEA statute and regulations and resources to support the implementation of the statute and regulations. The Web portal referenced in paragraph (a)(7) of the *Logistical Support and Coordination Activities* section must link to the IDEA Web site.

(iii) Maintain and update, as appropriate, the State Performance Plans (SPPs) and APRs Planning Calendar, which contains information to assist States with the preparation and timely completion of their SPPs and APRs. The Web portal referenced in paragraph (a)(7) of the *Logistical Support and Coordination Activities* section must include the SPP and APR Planning Calendar. Information about the SPP and APR Planning Calendar is available at: *http://www.rrfcnetwork.org/content/view/458/414/.*

(iv) Develop a summary report for all SPP and APR performance and compliance indicators using data compiled by centers within the OSEP TA&D Network that includes information about States' progress in meeting targets for IDEA Part B and Part C indicators, as well as any revisions made to States' monitoring and data systems, measurement systems, or improvement strategies. OSEP staff and the OSEP TA&D Network centers will use this information to plan and coordinate their TA efforts. The TACC must participate in OSEP-requested teleconferences to discuss the findings of the summary report.

(d) Prepare and disseminate reports, documents, and other materials on OSEP-sponsored conference proceedings, Federal initiatives and policies, evidence-based TA practices, and related topics, as requested by OSEP, for specific audiences, including the OSEP TA&D Network centers, other federally-funded TA&D centers, SEAs, LEAs, and Part C lead agencies. In consultation with the OSEP Project Officer, make selected reports, documents, and other materials available in both English and Spanish, when appropriate.

(e) Ensure that any Web site established or maintained by the TACC under this priority meets a government or an industry-recognized standard for accessibility.

Leadership and Collaboration Activities.

(a) Establish and maintain an advisory committee to review the activities and outcomes of the TACC and provide programmatic support and advice throughout the project period. At a minimum, the advisory committee must

meet on an annual basis in Washington, DC, and consist of OSEP and OESE TA providers, SEA personnel, and families of children with disabilities. The TACC must submit the names of proposed members of the advisory committee to OSEP for approval within eight weeks after receipt of the award.

(b) Communicate and collaborate, on an ongoing basis, with OSEP-funded projects outside of the TA&D Network, including Parent Training and Information Centers, personnel preparation projects, State Personnel Development Grant projects, and State TA Deaf-Blind projects to support the ongoing exchange of information and resources.

(c) Prior to developing any new product, whether paper or electronic, submit to the OSEP Project Officer, for approval, a proposal describing the content and purpose of the product.

(d) Collaborate with the National Dissemination Center for Individuals with Disabilities, which OSEP intends to fund in FY 2008, to develop an efficient and high-quality dissemination strategy that reaches the broad audiences to be targeted by the project. The TACC must report to the OSEP Project Officer the outcomes of these coordination efforts.

(e) Conduct a summative evaluation of the TACC in collaboration with the OSEP-funded Center to Improve Project Performance (CIPP) as described in the following paragraphs. This summative evaluation must examine the outcomes or impact of the TACC's activities in order to assess the effectiveness of those activities.

Note: The major tasks of CIPP would be to guide, coordinate, and oversee the summative evaluations conducted by selected Technical Assistance, Personnel Development, Parent Training and Information Center, and Technology projects that individually receive $500,000 or more funding from OSEP annually. The efforts of CIPP are expected to enhance individual project evaluations by providing expert and unbiased assistance in designing evaluations, conducting analyses, and interpreting data.

To fulfill the requirements of the summative evaluation to be conducted under the guidance of CIPP and with the approval of the OSEP Project Officer, the TACC must—

(1) Hire or designate, with the approval of the OSEP Project Officer, a project liaison staff person with sufficient dedicated time, experience in evaluation, and knowledge of the TACC to work with CIPP on the following tasks: (i) Planning for the TACC's summative evaluation (e.g., selecting evaluation questions, developing a timeline for the evaluation, locating sources of relevant data, and refining the logic model used for the evaluation), (ii) developing the summative evaluation design and instrumentation (e.g., determining quantitative or qualitative data collection strategies, selecting respondent samples, and pilot testing instruments), (iii) coordinating the evaluation timeline with the implementation of TACC activities, (iv) collecting summative data, and (v) writing reports of summative evaluation findings;

(2) Cooperate with CIPP staff in order to accomplish the tasks described in paragraph (1) of this section; and

(3) Dedicate $60,000 of the annual budget request for this project to cover the costs of carrying out the tasks described in paragraphs (1) and (2) of this section, implementing the TACC's formative evaluation, and traveling to Washington, DC in the second year of the project period for the TACC's review for continued funding.

(f) Maintain ongoing communication with the OSEP Project Officer through monthly phone conversations and e-mail communication.

Fourth and Fifth Years of the Project: In deciding whether to continue funding the TACC for the fourth and fifth years, the Secretary will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of experts selected by the Secretary. This review will be conducted during a one-day intensive meeting in Washington, DC that will be held during the last half of the second year of the project period;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the TACC; and

(c) The quality, relevance, and usefulness of the TACC's activities and products and the degree to which the TACC's activities and products have contributed to changed practice and improved communication, collaboration, and coordination among OSEP TA&D Network centers.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1463 and 1481.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

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 (IHEs) only.

II. Award Information

Type of Award: Cooperative Agreement.

Estimated Available Funds: $1,800,000.

Estimated Average Size of Awards: $1,800,000.

Maximum Awards: We will reject any application that proposes a budget exceeding $1,800,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* SEAs; LEAs, including public charter schools that are considered LEAs under State law; IHEs; other public agencies; private nonprofit organizations; outlying areas; freely associated States; Indian tribes or tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants and grant recipients funded under this competition must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the projects (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address To Request Application Package:* Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone, toll free: 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also, *http://www.ed.gov/pubs/*

edpubs.html or at its e-mail address, *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA Number 84.326Z.

Individuals with disabilities can obtain a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Alternative Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative to the equivalent of no more than 70 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, or no smaller than 10 pitch (characters per inch).

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the references, or the letters of support. The page limit, however, does apply to the application narrative in Part III.

We will reject your application if you exceed the page limit or if you use other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: June 5, 2008.

Deadline for Transmittal of Applications: July 7, 2008.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV.6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in 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: September 3, 2008.

4. *Intergovernmental Review:* This competition 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 competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section in this notice.

6. *Other Submission Requirements:* Applications for grants under this program may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications.* To comply with the President's Management Agenda, we are participating as a partner in the Governmentwide Grants.gov Apply site. The Technical Assistance Coordination Center competition, CFDA Number 84.326Z, is included in this project. We request your participation in Grants.gov.

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *http://www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

You may access the electronic grant application for the Technical Assistance Coordination Center competition at *http://www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.326, not 84.326Z).

Please note the following:

- Your participation in Grants.gov is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date and time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf.*
- To submit your application via Grants.gov, you must complete all steps in the Grants.gov registration process (see *http://www.grants.gov/applicants/get_registered.jsp*). These steps include (1) registering your organization, a multi-part process that includes registration with the Central Contractor Registry (CCR); (2) registering yourself as an Authorized Organization Representative (AOR); and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf*). You also must provide on your application the same D–U–N–S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all

registration steps to allow you to submit successfully an application via Grants.gov. In addition you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.

• If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: 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. Please note that two of these forms—the SF 424 and the Department of Education Supplemental Information for SF 424—have replaced the ED 424 (Application for Federal Education Assistance).

• If you submit your application electronically, 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.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.326Z),
400 Maryland Avenue, SW.,
Washington, DC 20202–4260.

or

By mail through a commercial carrier:

U.S. Department of Education,
Application Control Center, Stop 4260, Attention: (CFDA Number 84.326Z), 7100 Old Landover Road,
Landover, MD 20785–1506.

Regardless of which address you use, 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 submit your application in paper format by hand delivery, you (or a courier service) 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 84.326Z), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed in the application package.

2. *Peer Review:* In the past, the Department has had difficulty finding peer reviewers for certain competitions

because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within the specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

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 Notice (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 in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section in 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:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities program. These measures focus on the extent to which projects provide high quality products and services, the relevance of project products and services to educational and early intervention policy and practice, and the use of products and services to improve educational and early intervention policy and practice.

Grantees will be required to provide information related to these measures in annual reports to the Department.

Grantees also will be required to report information on their project's performance in annual reports to the Department (34 CFR 75.590).

VII. Agency Contact

For Further Information Contact: Rex Shipp or Debra Price-Ellingstad, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4178 and 4097, respectively, Potomac Center Plaza (PCP), Washington, DC 20202–2550. Telephone: (202) 245–7523 and 245–7481, respectively.

If you use a TDD, call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

VIII. Other Information

Alternative Format: Individuals with disabilities can obtain this document and a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. 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.*

Dated: May 30, 2008.

Tracy R. Justesen,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E8–12634 Filed 6–4–08; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Notice

AGENCY: United States Election Assistance Commission.

ACTION: Notice of public meeting.

DATE & TIME: Thursday, June 19, 2008, 10 a.m.–3 p.m.

PLACE: U.S. Election Assistance Commission, 1225 New York Ave, NW., Suite 150, Washington, DC 20005 (Metro Stop: Metro Center).

AGENDA: The Commissioners will consider the following items:

Commissioners will consider and vote on whether to modify Advisory Opinion 07–003–A regarding Maintenance of Effort (MOE) funding, pursuant to HAVA Section 254 (a)(7). Commissioners will consider and vote on a Proposed Replacement Advisory Opinion 07–003–B Regarding Maintenance of Effort. Commissioners will consider the Adoption of EAC Draft Chapters of the Election Management Guidelines Project; Commissioners will consider the Adoption of EAC Laboratory Accreditation Program Manual; Commissioners will consider a Draft Policy for Joint Partnership Task Force of EAC and State Election Officials Regarding Spending of HAVA Funds; Commissioners will consider a Draft Policy for Notice and Public Comment; Commissioners will consider a Draft Policy regarding Allocable Cost Principles for HAVA Funding. Commissioners will consider whether to update the Maryland state instructions, the Michigan state instructions and the Louisiana state instructions on the national voter registration form. Commissioners will consider Administrative Regulations. Commissioners will receive a briefing regarding a HAVA State Spending Report to Congress; Commissioners will receive a Presentation on a Draft of EAC Guidance to States Regarding Updates to the State Plans; Commissioners will receive a Presentation on EAC Draft

Chapters of the Election Management Guidelines Project; Commissioners will receive a Presentation on the EAC Laboratory Accreditation Program Manual. The Commission will consider other administrative matters.

This meeting will be open to the public.

PERSON TO CONTACT FOR INFORMATION: Bryan Whitener, Telephone: (202) 566–3100.

Donetta L. Davidson,

Commissioner, U.S. Election Assistance Commission.

[FR Doc. E8–12507 Filed 6–4–08; 8:45 am]

BILLING CODE 6820–KF–M

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2004–0013; FRL–8575–8]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; EPA Strategic Plan Information on Source Water Protection (Renewal); EPA ICR No. 1816.04; OMB Control No. 2040–0197

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before July 7, 2008.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2004–0013 to (1) EPA online using *http://www.regulations.gov* (our preferred method), by e-mail to *OW-Docket@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Water Docket, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jill Dean, Drinking Water Protection Division—Prevention Branch, Office of Ground Water and Drinking Water (MC 4606M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–564–8241; fax number: 202–564–3756; e-mail address: *dean.jill@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On February 29, 2008 (73 FR 11108), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OW–2004–0013, which is available for online viewing at *www.regulations.gov,* or in person viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Water Docket is 202–566–2426.

Use EPA's electronic docket and comment system at *www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: EPA Strategic Plan Information on Source Water Protection (Renewal).

ICR numbers: EPA ICR No. 1816.04, OMB Control No. 2040–0197.

ICR Status: This ICR is scheduled to expire on June 30, 2008. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 1453(a)(3) of the Safe Drinking Water Act (SDWA) required States to submit a Source Water Assessment Program within 18 months after the U.S. Environmental Protection Agency (EPA) published its State Source Water Assessment and Protection Programs Guidance: Final Guidance. Upon EPA approval of their programs, States conducted source water assessments of their public water systems. State assessments were required to be completed three and a half years after approval of a state's program; the assessment program is therefore complete relative to the SDWA requirements. The burden and cost associated with all of the assessment was accounted for in three previous information collection requests (EPA ICR Nos. 1816.01, 1816.02, and 1816.03).

The 2006–2011 EPA Strategic Plan incorporates a source water contamination prevention measure to describe the voluntary source water protection (SWP) actions taken at the local or regional level based on the results of completed source water assessments. EPA's strategic target for SWP sets a goal of minimized risk to public health in 50 percent of community water systems (CWSs) and the 62 percent of the U.S. population served by those CWSs by 2011. Achieving minimized risk to public health focuses on developing and substantially implementing SWP strategies to address potential contamination risks within each CWS source water area.

EPA is collecting, on a voluntary basis, data from the States on their progress toward substantial implementation of prevention strategies for all CWS SWAs. While Section 1453(a)(3) of the SDWA does not authorize source water protection, States are encouraged to use the data collected in the source water assessments to develop protection plans for source water areas. Drinking Water State Revolving Fund monies authorized in Section 1452(g)(2)(B) may be used for activities to support efforts in source water protection. The

information is being collected under EPA's Office of Water National Program Guidance and the State Grant Performance Measures Template.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 33 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: State environmental and health agencies.

Estimated Number of Respondents: 52.

Frequency of Response: Annual.

Estimated Total Annual Hour Burden: 1,716.

Estimated Total Annual Cost: $820,287, includes $748,257 annualized capital or O&M costs, and $72,030 labor costs.

Changes in the Estimates: There is a decrease of 149,215 hours per year in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease in burden is due to a decrease in the number of items being reported. The burden estimates were considerably greater in the current ICR because it included an additional 146,719 hours annually and $0.24 million annually to allow nine states to complete the source water assessments.

Dated: May 28, 2008.

Sara Hisel-McCoy,

Director, Collection Strategies Division.

[FR Doc. E8–12586 Filed 6–4–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval, Comments Requested

June 2, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 7, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC or via Internet at *Cathy.Williams@fcc.gov* or *PRA@fcc.gov.*

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB control number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.''

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0419.

Title: Sections 76.94, Notification; 76.95, Exceptions; 76.105, Notification; 76.106, Exceptions; 76.107, Exclusivity Contracts; and 76.1609, Non-Duplication and Syndicated Exclusivity.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 5,555 respondents; 199,304 responses.

Estimated Time per Response: 0.5—2.0 hours.

Frequency of Response: Third party disclosure requirement; One time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in 4(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 183,856 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR Sections 76.94(a) and 76.105(a) require television stations and program distributors to notify cable television system operators of non-duplication protection and exclusivity rights being sought. The notification shall include (1) the name and address of the party requesting non-duplication protection/exclusivity rights and the television broadcast station holding the non-duplication right; (2) the name of the program or series for which protection is sought; and (3) the dates on which protection is to begin and end.

47 CFR Section 76.94(b) requires broadcasters entering into contracts providing for network non-duplication protection to notify cable systems within 60 days of the signing of such a contract. If they are unable to provide notices as provided for in Section

74.94(a), they must provide modified notices that contain the name of the network which has extended non-duplication protection, the time periods by time of day and by network for each day of the week that the broadcaster will be broadcasting programs from that network, and the duration and extent of the protection.

47 CFR Section 76.94(d) requires broadcasters to provide the following information to cable television systems under the following circumstances: (1) In the event the protection specified in the notices described in 47 CFR Section 76.94(a) or (b) has been limited or ended prior to the time specified in the notice, or in the event a time period, as identified to the cable system in a notice pursuant to Section 76.94(b) for which a broadcaster has obtained protection is shifted to another time of day or another day (but not expanded), the broadcaster shall, as soon as possible, inform each cable television system operator that has previously received the notice of all changes from the original notice. Notice to be furnished ''as soon as possible'' under this subsection shall be furnished by telephone, telegraph, facsimile, overnight mail or other similar expedient means. (2) In the event the protection specified in the modified notices described in Section 76.94(b) has been expanded, the broadcaster shall, at least 60 calendar days prior to broadcast of a protected program entitled to such expanded protection, notify each cable system operator that has previously received notice of all changes from the original notice.

47 CFR Sections 76.94(e)(2) and 76.105(c)(2) state that if a cable television system asks a television station for information about its program schedule, the television station shall answer the request.

47 CFR Sections 76.94(f) and 76.107 require a distributor or broadcaster exercising exclusivity to provide to the cable system, upon request, an exact copy of those portions of the contracts, such portions to be signed by both the network and the broadcaster, setting forth in full the provisions pertinent to the duration, nature, and extent of the non-duplication terms concerning broadcast signal exhibition to which the parties have agreed. Providing copies of relevant portions of the contracts is assumed to be accomplished in the notification process set forth in Sections 76.94 and 76.105.

47 CFR Section 76.95 states that the provisions of Sections 76.92 through 76.94 (including the notification provisions of Section 76.94) shall not apply to a cable system serving fewer than 1,000 subscribers. Within 60 days following the provision of service to 1,000 subscribers, the operator of each such system shall file a notice to that effect with the Commission, and serve a copy of that notice on every television station that would be entitled to exercise network non-duplication protection against it.

47 CFR Section 76.105(d) requires that in the event the exclusivity specified in Section 76.94(a) has been limited or has ended prior to the time specified in the notice, the distributor or broadcaster who has supplied the original notice shall, as soon as possible, inform each cable television system operator that has previously received the notice of all changes from the original notice. In the event the original notice specified contingent dates on which exclusivity is to begin and/or end, the distributor or broadcaster shall, as soon as possible, notify the cable television system operator of the occurrence of the relevant contingency. Notice to be furnished ''as soon as possible'' under this subsection shall be furnished by telephone, telegraph, facsimile, overnight mail or other similar expedient means.

47 CFR Section 76.106(b) states that the provisions of Sections 76.101 through 76.105 (including the notification provisions of Section 76.105) shall not apply to a cable system serving fewer than 1,000 subscribers. Within 60 days following the provision of service to 1,000 subscribers, the operator of each such system shall file a notice to effect with the Commission, and serve a copy of that notice on every television station that would be entitled to exercise syndicated exclusivity protection against it.

47 CFR Section 76.1609 states that network non-duplication provisions of Sections 76.92 through 76.94 shall not apply to cable systems serving fewer than 1,000 subscribers. Within 60 days following the provision of service to 1,000 subscribers, the operator of each system shall file a notice to that effect with the Commission, and serve a copy of that notice on every television station that would be entitled to exercise network non-duplication or syndicated exclusivity protection against it.

OMB Control Number: 3060–0548.

Title: Section 76.1708, Principal Headend; Sections 76.1709 and 76.1620, Availability of Signals; Section 76.56, Signal Carriage Obligations; Section 76.1614, Identification of Must-Carry Signals.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 11,000 respondents; 132,000 responses.

Estimated Time per Response: 0.5–1.0 hour.

Frequency of Response: Recordkeeping requirement; Third party disclosure requirement; On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Section 4(i), 614 and 615 of the Communications Act of 1934, as amended.

Total Annual Burden: 66,000 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR Section 76.56 requires cable television systems to carry signals of all qualified local Noncommercial Educational (NCE) sting carriage. As a result of this requirement, the following information collection requirements are needed for this collection:

47 CFR Section 76.1708 requires that the operator of every cable television system shall maintain for public inspection the designation and location of its principal headend. If an operator changes the designation of its principal headend, that new designation must be included in its public file.

47 CFR Section 76.1709(a) states effective June 17, 1993, the operator of every cable television system shall maintain for public inspection a file containing a list of all broadcast television stations carried by its system in fulfillment of the must-carry requirements pursuant to 47 CFR Section 76.56. Such list shall include the call sign; community of license, broadcast channel number, cable channel number, and in the case of a noncommercial educational broadcast station, whether that station was carried by the cable system on March 29, 1990.

47 CFR Sections 76.1614 and 1709(c) states that a cable operator shall respond in writing within 30 days to any written request by any person for the identification of the signals carried on its system in fulfillment of the requirements of 47 CFR Section 76.56.

47 CFR Section 76.1620 states that if a cable operator authorizes subscribers to install additional receiver connections, but does not provide the subscriber with such connections, or with the equipment and materials for such connections, the operator shall notify such subscribers of all broadcast stations carried on the cable system which cannot be viewed via cable

without a converter box and shall offer to sell or lease such a converter box to such subscribers. Such notification must be provided by June 2, 1993, and annually thereafter and to each new subscriber upon initial installation. The notice, which may be included in routine billing statements, shall identify the signals that are unavailable without an additional connection, the manner for obtaining such additional connection and instructions for installation.

OMB Control Number: 3060–0750.

Title: 47 CFR Section 73.671 Educational and Informational Programming for Children; 47 CFR Section 73.673, Public Information Initiatives Regarding Educational and informational Programming for Children.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2,323 respondents; 4,266 responses.

Estimated Time per Response: 1 to 5 minutes.

Frequency of Response: Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Total Annual Burden: 31,319 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR 73.671(c)(5) states that a core educational television program must be identified as specifically designed to educate and inform children by the display on the television screen throughout the program of the Educational/Informational ''E/I.''

47 CFR 73.673 states each commercial television broadcast station licensee must provide information identifying programming specifically designed to educate and inform children to publishers of program guides. Such information must include an indication of the age group for which the program is intended.

These requirements are intended to provide greater clarity about broadcasters' obligations under the Children's Television Act (CTA) of 1990 to air programming ''specifically designed'' to serve the educational and informational needs of children and to improve public access to information about the availability of these programs. These requirements provide better information to the public about the shows broadcasters air to satisfy their obligation to provide educational and informational programming under the Children's Television Act.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–12626 Filed 6–4–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Meeting

Agency Holding the Meeting: Federal Maritime Commission.

Time and Date: June 4, 2008—10 a.m.

Place: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

Status: A portion of the meeting will be in Open Session and the remainder of the meeting will be in Closed Session.

Matters To Be Considered

Open Session

(1) Agency FAIR Act Report/Recommendation.

(2) Docket No. 07–05 KEI Enterprises dba KEI Logix v. Greenwest Activewear, Inc.

Closed Session

(1) Direction to Staff Regarding Budget Hearing Committee Requests.

(2) Show Cause Order re OTI Licensing Matter.

(3) Agreement No. 201178—Los Angeles/Long Beach Port/Terminal Operator Administration and Implantation Agreement and Agreement No. 201170—Los Angeles and Long Beach Port Infrastructure and Environmental Programs.

(4) Export Cargo Issues.

(5) Internal Administrative Practices and Personnel Matters.

Contact Person for More Information: Karen V. Gregory, Assistant Secretary, (202) 523–5725.

Karen V. Gregory,

Assistant Secretary.

[FR Doc. E8–12269 Filed 6–4–08; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Notice.

SUMMARY: The Federal Trade Commission is seeking public comments on its proposal to conduct consumer research on parental use of the Motion Picture Association of America (''MPAA'') movie rating information as it appears on DVD packaging for home video releases of rated motion pictures. The FTC is also seeking comment on a related proposal to conduct consumer research on parental attitudes toward the marketing of unrated DVD versions of rated motion pictures. To examine both issues, the Commission intends to conduct surveys of parents who have one or more children ages 7 to 16, and who have bought or rented a movie on DVD within the past year. The information collection requirements described below will be submitted to the Office of Management and Budget (''OMB'') for review, as required by the Paperwork Reduction Act (''PRA'').

DATES: Comments must be filed by August 4, 2008.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''DVD Rating Symbol Study: FTC Matter No. P994511,'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Ave., NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Moreover, because paper mail in the Washington area and at the Agency is subject to delay, please consider submitting your comments in electronic form, as prescribed below. If, however, the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled ''Confidential.''[1]

[1] FTC Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for

Comments filed in electronic form should be submitted by following the instructions on the web-based form at *https://secure.commentworks.com/ftc-DVDRatingStudy*. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the *https://secure.commentworks.com/ftc-DVDRatingStudy* weblink. If this notice appears at *www.regulations.gov*, you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it.

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

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Michelle K. Rusk (202) 326-3148, or Keith R. Fentonmiller (202) 326-2775, Attorneys, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: In September 2000, the Commission issued a report requested by the President and the Congress entitled, ''Marketing Violent Entertainment to Children: A Review of Self-Regulation and Industry Practices in the Motion Picture, Music Recording & Electronic Game Industries'' (hereafter ''2000 Report'').[2] That report found that the entertainment industry had engaged in widespread marketing of violent movies, video games, and music to children in a manner that was inconsistent with the industry's own rating systems and that undermined parents' attempts to make informed decisions about their children's exposure to violent content. Beginning with its 2000 Report, the Commission has made a series of specific recommendations to the industry regarding the disclosure of rating information, placement of advertising in media popular with children, and other aspects of marketing violent entertainment to children. The Commission has now issued five follow-up reports on the industry's progress toward implementing those recommendations.[3]

As one aspect of its ongoing monitoring, the Commission has examined the disclosure of MPAA ratings and rating reasons on DVD packaging for home video releases of MPAA-rated motion pictures. The MPAA Advertising Handbook requires that ''all packaging of rated home video releases must carry the rating of the motion picture and the rating reasons,'' and that ''the rating symbol and specific rating reasons must be clearly and legibly displayed.''[4] The MPAA Advertising Handbook does not specify the location, size, or other aspects of how the rating information must be displayed. To assess compliance with MPAA requirements, the Commission looked at a sample of packaging for 12 movies on DVD as part of its June 2002 Report. The Commission found that all of the DVDs displayed the ratings and rating reasons, but that the small size, inconsistent positioning on the back of the package, and poor contrast made the rating information less noticeable.[5] The Commission recommended that the industry improve the disclosure of rating information to ensure that it was effectively and clearly communicated on product packaging.[6] Subsequently, in its July 2004 Report, the Commission again noted that the movie industry typically places the movie's rating and rating reasons on the back of the DVD packaging and recommended that all of the rating information be placed prominently on the front of the packaging to make it more visible for parents and children and to assist retail store clerks in enforcing policies against selling R-rated DVDs to children.[7] The Commission renewed this recommendation in its April 2007 Report.[8]

In the April 2007 Report, the Commission also reviewed, for the first time, the movie industry's practice of releasing unrated DVD versions of movies that were rated R when they were first released in theaters.[9] The Commission expressed concern that these unrated, or so-called ''Director's Cut,'' home video releases sometimes contain additional footage that would result in a more restrictive rating if resubmitted for review by the MPAA. The agency cited examples of DVD movie packaging where studios exploited the lack of an MPAA rating to promote the movie. The Commission questioned whether the marketing of these unrated DVDs undermines the self-regulatory system. The agency suggested that the MPAA and DVD retailers establish policies on the advertising and sale of these DVDs to children.[10]

The FTC is seeking public comments on its proposal to examine, through consumer research, two issues relating to MPAA ratings and DVD home video releases: (1) how the placement and size of MPAA rating information on DVD packaging for rated movies affects parental use of the rating; and (2) parental awareness and attitudes about the marketing of unrated DVDs. The Commission will seek OMB clearance under the PRA, 44 U.S.C. 3501-3521, before engaging in the proposed consumer research.

Under the PRA, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB grant the clearance for this consumer survey.

The FTC invites comments on: (1) whether the required collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

[2] Available at (*http://www.ftc.gov/bcp/conline/edcams/ratings/reports.htm*).

[3] The follow-up reports were issued in April 2001, December 2001, June 2002, July 2004, and April 2007. They are available at (*http://www.ftc.gov/bcp/conline/edcams/ratings/reports.htm*).

[4] 2006 MPAA Advertising Handbook at 38 (on file with Federal Trade Commission staff).

[5] June 2002 Report at 10-11, available at (*http://www.ftc.gov/bcp/conline/edcams/ratings/reports.htm*).

[6] *Id.*

[7] July 2004 Report at 29, available at (*http://www.ftc.gov/bcp/conline/edcams/ratings/reports.htm*).

[8] April 2007 Report at 32, available at (*http://www.ftc.gov/bcp/conline/edcams/ratings/reports.htm*).

[9] *Id.* at 8-11.

[10] *Id.* at 33.

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including 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.

All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before August 4, 2008.

1. Description of the Collection of Information and Proposed Use

The FTC proposes to conduct a mall intercept study, using an experimental design with two treatment conditions, to assess how the placement and size of MPAA rating information on DVD packaging affects parental use of the rating. The FTC proposes to conduct a telephone survey to assess parental awareness and attitudes about the marketing of unrated DVDs. The methodologies for both consumer research proposals are detailed below.

a. The Mall Intercept Study on DVD Rating Prominence

A mall intercept study is the most appropriate methodology for assessing differences in the effect of placement and size of the MPAA rating because it allows respondents to physically examine samples of DVD packaging. The study will have an experimental design with respondents randomly assigned to one of two treatment conditions. The study will analyze differences in response between the two groups.

The FTC proposes to conduct the study in multiple locations across the country using a random sample of 400 adult respondents who are parents of one or more children ages 7 to 16, and who have bought or rented a DVD movie for their children within the past year. The study will be divided into two groups of 200. Each group will be given the opportunity to examine a DVD package for a movie that has been rated either PG-13 or R due in part to violent content.[11] One group will be exposed to DVD packaging that displays the rating information as it actually appears on the back cover. The other group will be exposed to the same DVD packaging, with the exception that the rating information will be graphically altered to appear on the front panel and in a larger size. After exposure to the package, respondents will be asked a series of questions related to what respondents noticed about the package, whether they noticed the rating information, and whether or not they would allow their child to watch the movie.

The information from the questionnaires will be collected on a voluntary basis, and the identities of the respondents will remain confidential. Subject to OMB approval for the collection of information, the FTC plans to contract with a consumer research firm that will identify respondents, conduct a pretest, refine the questionnaire, and conduct the study. The results will assist the FTC in determining how easy or difficult it is for parents to find and use MPAA rating information on DVD packaging and whether changes in presentation of the rating information will significantly improve the ease of use.

b. The Telephone Survey

To assess parental awareness and attitudes about the marketing of unrated DVDs, the FTC plans to conduct a national telephone survey of 1,000 adult respondents who are parents of one or more children ages 7 to 16, and who have bought or rented a DVD movie for their children within the past year. This approach will allow the agency to have a sufficiently large and representative sample of the population to accurately assess parents' awareness and attitudes. Respondents will be asked a combination of open-ended and closed-ended questions. The questions will measure the level of parents' awareness of the marketing of unrated DVDs and assess whether parents understand that unrated DVD movies may contain content that could result in a more restrictive rating than the rating assigned to the theater version of the same movie. Additional questions will be designed to assess parents' attitudes about the marketing of unrated DVDs, including how the absence of a rating affects their decision whether to allow their children to watch the movie. Finally, respondents will be asked questions about what policy they expect DVD retailers to apply to the sale of unrated DVDs directly to children.

As with the mall intercept study, the information from the telephone survey questionnaires will be collected on a voluntary basis, and the identities of the respondents will remain confidential. Subject to OMB approval for the collection of information, the FTC plans to contract with a consumer research firm that will identify respondents, conduct a pretest of the survey, refine the questionnaire, and conduct the survey. The results of the telephone survey will assist the FTC in assessing how the marketing of unrated DVDs impacts parents' decisions about what movies they will allow their children to watch. It will also help the FTC in forming recommendations about retail policies for the sale of unrated DVDs directly to children.

2. Estimated Hours Burden

For the mall intercept study and a pretest of the study, the contractor will screen respondents to identify parents with children ages 7 to 16 who have bought or rented a DVD movie for their child within the past year. Allowing for non-response, the FTC staff estimates that the screening questions will be asked of approximately 2,000 respondents in order to obtain a large enough sample for the study and the pretest. The FTC staff estimates that screening will require no more than two minutes per person for a maximum hour burden of 67 hours (2,000 respondents 2 minutes for each).

The FTC intends to pretest the questionnaire on 15 parents to ensure that all questions are easily understood. The FTC expects that the pretest will require no more than 10 minutes per person. The hours burden imposed by the pretest will be approximately 2.5 hours (15 respondents 10 minutes for each).

The FTC staff estimates that the study of 400 respondents also will require no more than 10 minutes per person or, cumulatively, 67 hours (400 respondents 10 minutes for each).

Thus, the estimated total hours burden attributable to the mall intercept study is 136.5 hours (67 + 2.5 + 67).

For the telephone survey and a pretest of the survey, the contractor will apply the same screening threshold, identifying respondents who are parents with children ages 7 to 16 who have bought or rented a DVD movie for their child within the past year. Allowing for non-response, the FTC staff estimates that the screening questions will be asked of approximately 9,000 respondents in order to obtain a large enough sample for the survey and the pretest. The FTC staff estimates that screening will require no more than one minute per person for a maximum hour burden of 150 hours (9,000 respondents 1 minute for each).

The FTC intends to pretest the questionnaire on 100 parents to ensure that all questions are easily understood. The FTC expects that the pretest will require no more than 5 minutes per

[11] Parents of children ages 7 to 11 will be shown DVD packaging for a PG-13-rated movie and parents of children ages 12 to 16 will be shown packaging for an R-rated movie. Parents with children in both age groups will be randomly assigned to either the PG-13 or R group.

person. The hours burden imposed by the pretest will be approximately 8.5 hours (100 respondents 5 minutes for each).

The FTC staff estimates that the survey of 1,000 respondents also will require no more than 5 minutes per person or 83.5 hours (1,000 respondents 5 minutes for each).

Thus, the estimated total hours burden attributable to the telephone survey research is 242 hours (150 + 8.5 + 83.5).

The combined total hours burden attributable to both research projects is 378.5 hours (242 + 136.5).

3. Estimated Cost Burden

The cost per respondent should be negligible. Participation is voluntary and will not require any labor expenditures by respondents nor capital, start-up, operation, maintenance, or other similar costs.

William Blumenthal

General Counsel

[FR Doc. E8–12590 Filed 6–4–08: 8:45 am]

[Billing code: 6750–01–S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a meeting. The meeting is open to the public.

DATES: The meeting will be held on June 18, 2008, from 8:30 a.m. to 5 p.m.

ADDRESSES: The Sheraton National Hotel, 900 S. Orme Street, Arlington, VA 22204. Phone: 703–521–1900.

FOR FURTHER INFORMATION, CONTACT: CAPT Leigh A. Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 200 Independence Ave SW., Room 638G, Washington, DC 20201; 202–205–3815; fax: 202–205–0613; e-mail address: *leigh.sawyer@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d–7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board.

The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

Topics to be discussed include updates from the Pandemic Influenza Working Group, the Disaster Medicine Working Group, the Markets and Sustainability Working Group, and the U.S. Medical Countermeasure Research and Development Processes for Chemical, Biological, Radiological and Nuclear Agents Working Group. Additionally, the NBSB will discuss preparedness and planning issues related to at-risk populations and pandemic influenza , consider issues related to medical response and preparedness for radiological and nuclear events, and receive an update on the activities of the Homeland Security Presidential Directive #21, Federal Biosurveillance Working Group. The NBSB will also receive a briefing on issues related to the Department of Health and Human Services development of MedKits. This agenda is subject to change as priorities dictate. A tentative schedule will be made available on June 6, 2008 at the NBSB Web site, *http://www.hhs.gov/aspr/omsph/nbsb.*

Any member of the public interested in presenting oral comments at the meeting may notify the Contact person listed on this notice by June 11, 2008. Interested individuals and representatives of an organization may submit a letter of intent and a brief description of the organization represented. In addition, any interested person may file written comments with the committee. All written comments must be received prior to June 11, 2008 and should be sent by e-mail with ''NBSB Public Comment'' as the subject line or by regular mail to the Contact person listed above. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person.

Dated: May 30, 2008.

RADM William C. Vanderwagen,

Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.

[FR Doc. 08–1321 Filed 6–2–08; 2:27pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0474] (formerly Docket No. 2005N–0210)

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of Veterinary Feed Directive drugs and animal feeds containing Veterinary Feed Directive drugs.

DATES: Submit written or electronic comments on the collection of information by August 4, 2008.

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 the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910–0363)—Extension

With passage of the Animal Drug Availability Act, Congress enacted legislation establishing a new class of restricted feed use drugs called Veterinary Feed Directive (VFD drugs). The VFD class of drugs may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to controls for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 503(f), the implementing VFD regulation under section 558.6 (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and the distribution records of all medicated feeds containing VFD must be maintained. The VFD regulation ensures the protection of the public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5
558.6(d)(2)	1,000	5	5,000	.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total	16,321				95,083

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total	117,500				25,051

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry and agency records and experience.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12648 Filed 6–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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 July 22 and 23, 2008, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Diem.Ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. 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 July 22, 2008, the committee will do the following: (1) Receive presentations from the Office of Pharmaceutical Science (OPS) and discuss current thinking on issues pertaining to the use of nanotechnology in drug manufacturing, drug delivery, or drug products, and (2) receive an update from OPS, discuss, and make comments on current strategies and directions for the testing of lead in pharmaceutical products.

On July 23, 2008, the committee will do the following: (1) Receive and discuss presentations from the Office of Generic Drugs (OGD) on the bioequivalence methods for locally acting drugs that treat gastrointestinal (GI) conditions, (2) receive and discuss presentations from OGD on the use of inhaled corticosteroid dose-response as a means to establish bioequivalence of inhalation drug products, and (3) receive and discuss presentations from OPS on the drug classification of orally disintegrating tablets (ODT) as a separate dosage form, and the need for subsequent guidance on expectations and recommendations that would be required for applications proposing the dosage form.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 July 8, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. 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 June 30, 2008. 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 July 1, 2008.

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 Diem-Kieu Ngo 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/oc/advisory/default.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: May 27, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–12647 Filed 6–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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: Arthritis 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 July 29, 2008, from 8:30 a.m. to 3:30 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512532. 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: The committee will discuss biologics license application (BLA) 125276, ACTEMRA (tocilizumab),

Hoffman-La Roche, Inc., for the proposed treatment of adult patients with moderately to severely active rheumatoid arthritis.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 July 15, 2008. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:45 p.m. 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 July 7, 2008. 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 July 8, 2008.

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 Nicole Vesely 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/oc/advisory/default.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: May 27, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–12646 Filed 6–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Behavioral Health Preventive Care Assessment Focus Group Guide; Correction

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** (FR) on April 29, 2008. The document contained one error.

FOR FURTHER INFORMATION CONTACT: Christina Rouleau, Office of Management Services, Indian Health Service, 801 Thompson Avenue, Suite 450, Rockville, MD 20852, Telephone (301) 443–5938. (This is not a toll-free number.)

Correction

In the **Federal Register** of April 29, 2008, in FR Doc. E8–9258, on page 23254, in the second column, second paragraph, under **SUMMARY**, correct Domestic/Intimate Partner Violence screening in women ages 14–15 to read: Domestic/Intimate Partner Violence screening in women ages 15–40.

Dated: May 29, 2008.

Robert G. McSwain,

Director, Indian Health Service.

[FR Doc. E8–12509 Filed 6–4–08; 8:45 am]

BILLING CODE 4165–16–M

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. Appendix 2), 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: Allergy, Immunology, and Transplantation Research Committee; Allergy, Immunology and Transportation Research Committee (AITRC).

Date: June 24, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree Hotel, 1515 Rhode Island Ave., NW., Director's Room 2nd Floor, Washington, DC 20005.

Contact Person: Katrin Eichelberg, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda MD 20892, (301) 496–0818, *keichelberg@niaid.nih.gov.*

(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: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12282 Filed 6–4–08; 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, June 30, 2008, 8 a.m. to July 1, 2008, 5 p.m., Doubletree Hotel, 1515 Rhode Island Avenue, NW., Washington, DC 20005, which was published in the **Federal Register** on May 15, 2008, 73 FR 28122–28123.

The meeting will be held one day only, June 30, 2008. The meeting time and location remain the same. The meeting is closed to the public.

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12275 Filed 6–4–08; 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 Biobehavioral Mechanisms of Emotion, Stress and Health Study Section, June 5, 2008, 8 a.m. to June 6, 2008, 5 p.m., The Hotel Lombardy, 2019 Pennsylvania Avenue, NW., Washington, DC 20006, which was published in the **Federal Register** on April 11, 2008, 73 FR 19855–19857.

The meeting will be held one day only, June 5, 2008, from 8 a.m. to 6 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12278 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

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. Appendix 2), 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, Fellowship.
Date: June 23–24, 2008.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
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.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Psychopharmacology and Ethology.
Date: June 27, 2008.
Time: 12 p.m. to 4 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: Cheri Wiggs, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3180, MSC 7848, Bethesda, MD 20892, (301) 435–1261, *wiggsc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cancer Biology and Related Topics.
Date: June 30, 2008.
Time: 2 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Angela Y. Ng, PhD, MBA., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, (For courier delivery, use MD 20817), Bethesda, MD 20892, 301–435–1715, *nga@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group AIDS-associated Opportunistic Infections and Cancer Study Section.
Date: July 9, 2008.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Deca, 4507 Brooklyn Avenue, NE., Seattle, WA 98105.
Contact Person: Eduardo A Montalvo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5212, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Oral and Dental Small Business Panel.
Date: July 9–10, 2008.
Time: 8 a.m. to 11 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016K, MSC 7814, Bethesda, MD 20892, 301–451–1327, *tthyagar@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neural Control of Cardiovascular Function.
Date: July 10, 2008.
Time: 2:30 p.m. to 4 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: Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, *chaudhaa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Computational Tools for Human Microbiome Data.
Date: July 11, 2008.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.
Contact Person: Ping, Fan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–435–1740, *fanp@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group AIDS, Discovery and Development of Therapeutics Study Section.
Date: July 14, 2008.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: The Fairmont Hotel, 2401 M 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 AIDS, Molecular and Cellular Biology Study Section.
Date: July 14, 2008.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: The Fairmont Hotel, 2401 M Street, NW., Washington, DC 20037.
Contact Person: Kenneth A. Roebuck, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel (VED), Chronic Conditions and Psychopathology: Interventions and Outcomes.
Date: July 15, 2008.
Time: 11 a.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Gabriel B. Fosu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3215, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cardiovascular Development and Stem Cells.

Date: July 15, 2008.
Time: 1 p.m. to 3 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: Larry Pinkus, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Collaborations with NCBCs.
Date: July 16, 2008.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Lombardy, 2019 Pennsylvania Avenue, NW., Washington, DC 20006.
Contact Person: Malgorzata Klosek, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435–2211, *klosekm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Cell, Biology SBIR/STTR.
Date: July 16–17, 2008.
Time: 9 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: David Balasundaram, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Technology Development in Epigenetics.
Date: July 17, 2008.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Alexandra M. Ainsztein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892, 301–451–3848, *ainsztea@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Shared X-Ray Crystallography Equipment.
Date: July 17–18, 2008.
Time: 8 a.m. to 11:59 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: David R. Jollie, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435–1722, *jollieda@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Biophysical and Physiological Science.
Date: July 17, 2008.
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: Michael A. Lang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7850, Bethesda, MD 20892, (301) 435–1265, *langm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Assays and Detectors.
Date: July 17, 2008.
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: Ping, Fan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–435–1740, *fanp@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group NeuroAIDS and other End-Organ Diseases Study Section.
Date: July 18, 2008.
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: Ranga V. Srinivas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, (301) 435–1167, *srinivar@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Physical Activities in Older Populations.
Date: July 18, 2008.
Time: 12 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: Gabriel B. Fosu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rocklege Drive, Room 3215, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@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: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12279 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; Member Conflict: Ultrasound and Imaging.
Date: June 5, 2008.
Time: 10 a.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Khalid Masood, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12280 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, June 3, 2008, 3 p.m. to June 3, 2008, 4 p.m.,

National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 15, 2008, 73 FR 28122–28123.

The meeting was cancelled due to administration problems.

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12281 Filed 6–4–08; 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, May 28, 2008, 1 p.m. to May 28, 2008, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 16, 2008, 73 FR 28489–28490.

The meeting will be held June 12, 2008. The meeting time and location remains the same. The meeting is closed to the public.

Dated: May 29, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12534 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

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. Appendix 2), 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, Research on Ethical Issues, Special Emphasis Panel.

Date: June 19, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street, NW., Washington, DC 20007.

Contact Person: Susan F. Marden, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7770, Bethesda, MD 20892, 301–435–0692, *mardens@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Health of the Population, Member Conflict Special Emphasis Panel.

Date: June 19, 2008.

Time: 10:30 a.m. to 1:30 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: Fungai F. Chanetsa, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–435–1262, *chanetsaf@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, EPIC II Member Conflict Special Emphasis Panel.

Date: June 19–20, 2008.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Fungai F. Chanetsa, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–435–1262, *chanetsaf@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Pathogenic Viruses.

Date: June 24, 2008.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Soheyla Saadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business Grant Applications: Immunology.

Date: June 26–27, 2008.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact 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, Member Conflict Application Review.

Date: June 26, 2008.

Time: 1 p.m. to 4 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: Jin Huang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Nephrology Overflow Applications.

Date: June 26, 2008.

Time: 3 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: Krystyna E. Rys-Sikora, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016J, MSC 7814, Bethesda, MD 20892, 301–451–1325, *ryssokok@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Health and Health Related Behavior of Individuals and Populations Fellowship Meeting.

Date: July 9, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Frances Drake Hotel, 452 Powell Street, San Francisco, CA 94102.

Contact Person: Susan F. Marden, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7770, Bethesda, MD 20892, 301–435–0692, *mardens@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Viruses.

Date: July 9, 2008.

Time: 1 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: Soheyla Saadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Environmental Monitoring.

Date: July 15–16, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: George W. Chacko, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7849, Bethesda, MD 20892, 301–435–1245, *chackoge@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: May 29, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12535 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, Thrombotic Venous Disease Research Projects.

Date: June 20, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Robert T. Su, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892–7924, 301–435–0297, *sur@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12272 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, Institutional Training Programs (T32s).

Date: June 19, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge Two, 6701 Rockledge Drive, 7192, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mark Roltsch, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892–7924, 301–435–0287, *roltschm@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12273 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the 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 Child Health and Human Development Special Emphasis Panel; Health, Behavior and Context.

Date: June 30, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ramada Inn Rockville, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver National Institute for Child Health & Development, 1600 Executive Boulevard, R. 5b01, Bethesda, MD 20812–7510, (301) 435–8382, *hindialm@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Associations of Household Risk Phenotype to Repeat Child Abuse.

Date: June 30, 2008.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Ramada Inn Rockville, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver National Institute for Child Health & Development, 1600 Executive Boulevard, R. 5b01, Bethesda, MD 20812–7510, (301) 435–8382, *hindialm@mail.nih.gov.*

(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: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12274 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the 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: NIDCR Special Grants Review Committee; Review R03s, Fs, Ks.

Date: June 12–13, 2008.

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: Raj K. Krishnaraju, PhD, MS, Scientific Review Officer, Scientific Review Branch, National Inst. of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr. Rm 4AN 32J, Bethesda, MD 20892, 301–594–4864, *kkrishna@nidcr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 27, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12276 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the 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 General Medical Sciences Special Emphasis Panel; Clinical and Pediatric Research—Loan Repayment.

Date: June 16, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN–18, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Margaret Weidman, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18B, Bethesda, MD 20892, 301–594–3663, *weidmanma@nigms.nih.gov*.

This meeting is being published less than 15 days prior to the meeting due to timing limitations imposed by administrative matters.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 29, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12537 Filed 6–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

National Protection and Programs Directorate; Submission for Review: Constellation/Automated Critical Asset Management System (C/ACAMS) Functional Survey, 1670—NEW

AGENCY: National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Information Collection Division, DHS.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Department of Homeland Security (DHS) invites the general public and other federal agencies the opportunity to comment on new information collection request 1670—NEW, Constellation/Automated Critical Asset Management System (C/ACAMS) Functional Survey. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), DHS is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until August 4, 2008. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Comments and questions about this Information Collection Request should be forwarded to the Department of Homeland Security, National Protection and Programs Directorate, Infrastructure Protection, Infrastructure Information Collection Division, Attn: Veronica Heller, Team Lead, Ballston One, 5th Floor, 4601 N. Fairfax Dr., Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Department of Homeland Security, National Protection and Programs Directorate, Infrastructure Protection, Attn: Veronica Heller, *veronica.heller@hq.dhs.gov* or 703–235–3035. This is not a toll free number.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs, Directorate, Infrastructure Protection, Infrastructure Information Collection Division.

Title: Constellation/Automated Critical Asset Management System (C/ACAMS) Functional Survey.

OMB Number: 1670—NEW.

Frequency: Once a year.

Affected Public: State employees.

Number of Respondents: 650 per year.

Estimated Time per Respondent: 15 minutes.

Total Burden Hours: 163 hours.

Total Burden Cost (capital/startup): $1,800.00.

Total Burden Cost (operating/maintaining): $1,250.00 (This is a shared cost which will diminish as more surveys use the system.)

Description: The Constellation/Automated Critical Asset Management System (C/ACAMS) Program Management Office (PMO) uses the Constellation/Automated Critical Asset Management System (C/ACAMS) Functional Survey customer survey to determine levels of customers' satisfaction with experience using the C/ACAMS tool. The survey supports data-based decision-making because it evaluates quantitative and qualitative data to identify improvements and identify significant issues based on customers' experience. Obtaining current fact-based actionable data about user experience and tool features allows the program to recalibrate its resources to address new or emerging issues.

Dated: May 29, 2008.

Matt Coose,

Acting Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. E8–12551 Filed 6–4–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Science and Technology Directorate; Notice of Public Meeting of the Project 25 Compliance Assessment Program Governing Board

AGENCY: Science and Technology Directorate, DHS.

ACTION: Notice of public meeting.

SUMMARY: The Department of Homeland Security's (DHS) Office for Interoperability and Compatibility (OIC) will hold a public meeting of its Project 25 (P25) Compliance Assessment Program (CAP) Governing Board (GB). The P25 CAP GB is composed of public sector officials who represent the collective interest of organizations that procure P25 equipment. The purpose of the meeting is to review and approve the proposed Compliance Assessment Bulletin(s).

The P25 CAP GB will not receive public comments during the session. DHS OIC will post details of the meeting, including the agenda and instructions on how to provide comments to the GB, ten business days in advance of the meeting at *www.safecomprogram.gov*.

DATES: The meeting will take place on Wednesday, June 25, 2008, from 2 p.m. to 3 p.m. (EST).

ADDRESSES: The session will take place via conference call. To listen, please send an e-mail to *david.keller@touchstone.com* or call 202–449–7142 by June 23 for access information.

FOR FURTHER INFORMATION CONTACT: Luke Klein-Berndt, Department of Homeland Security, Science and Technology Directorate, Office for Interoperability and Compatibility, Washington Navy Yard, 245 Murray Lane, SW., Building #410, Washington, DC 20528. Telephone: (202) 254–5332. E-mail: *Luke.Klein-Berndt@dhs.gov*.

SUPPLEMENTARY INFORMATION: Emergency responders—emergency medical services, fire personnel, and law enforcement officers—need to seamlessly exchange communications across disciplines and jurisdictions to successfully respond to day-to-day incidents and large-scale emergencies. P25 focuses on developing standards that allow radios and other components to interoperate, regardless of the manufacturer. In turn, these standards enable emergency responders to exchange critical communications with other disciplines and jurisdictions.

An initial goal of P25 is to specify formal standards for interfaces between the components of a land mobile radio (LMR) system; LMR systems are commonly used by emergency responders in portable handheld and mobile vehicle-mounted devices. Although formal standards are being developed, no process is currently in place to confirm that equipment advertised as P25-compliant meets all aspects of P25 standards.

To address discrepancies between P25 standards and industry equipment, Congress passed legislation calling for the creation of the P25 CAP. The P25 CAP is a partnership of the DHS Command, Control and Interoperability Division; the Department of Commerce's National Institute of Standards and Technology; industry; and the emergency response community.

The P25 CAP works to establish a process for ensuring that equipment complies with P25 standards and can interoperate across manufacturers. By providing manufacturers with a method to test their equipment for compliance with P25 standards, the P25 CAP helps emergency response officials make informed purchasing decisions. The program's initial focus is on the Common Air Interface, which allows for over-the-air compatibility between mobile and portable radios and tower equipment.

For more information on the program, please review OIC's *Charter for the Project 25 Compliance Assessment Program*, which is available at *http://www.safecomprogram.gov*.

Dated: May 30, 2008.

Luke Klein-Berndt,

P25 CAP Program Manager.

[FR Doc. E8–12554 Filed 6–4–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1758–DR]

Arkansas; Amendment No. 1 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 Arkansas (FEMA–1758–DR), dated May 20, 2008, and related determinations.

DATES: *Effective Date:* May 23, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Arkansas is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a

major disaster by the President in his declaration of May 20, 2008.

Phillips County for Individual Assistance.

Arkansas County for Individual Assistance and Public Assistance.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12521 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1755–DR]

Maine; Amendment No. 4 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 Maine (FEMA–1755–DR), dated May 9, 2008, and related determinations.

DATES: *Effective Date:* May 23, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Maine is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 9, 2008.

Penobscot County for Public Assistance (already designated for Individual Assistance.)

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12522 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1756–DR]

Oklahoma; Amendment No. 2 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 Oklahoma (FEMA–1756–DR), dated May 14, 2008, and related determinations.

DATES: *Effective Date:* May 23, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include the following areas among the areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 14, 2008.

Craig, Latimer, and Pittsburg Counties for Individual Assistance.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12518 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1756–DR]

Oklahoma; Amendment No. 3 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 Oklahoma (FEMA–1756–DR), dated May 14, 2008, and related determinations.

DATES: *Effective Date:* May 29, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 14, 2008.

Craig, Latimer, and Ottawa Counties for Public Assistance, including direct Federal assistance, (already designated for Individual Assistance.)

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially

Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12528 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1762–DR]

Colorado; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Colorado (FEMA–1762–DR), dated May 26, 2008, and related determinations.

DATES: *Effective Date:* May 26, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 26, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Colorado resulting from severe storms and tornadoes on May 22, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Colorado.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. If Public Assistance is later requested and warranted, Federal funds provided under that program also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth R. Tingman of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

The following areas of the State of Colorado have been designated as adversely affected by this declared major disaster:

Larimer and Weld Counties for Individual Assistance.

All counties within the State of Colorado are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12526 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1761–DR]

Georgia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Georgia (FEMA–1761–DR), dated May 23, 2008, and related determinations.

DATES: *Effective Date:* May 23, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 23, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Georgia resulting from severe storms and tornadoes during the period of May 11–12, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Georgia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jeffery L. Bryant, of FEMA, is appointed to act as the Federal Coordinating Officer for this declared disaster.

The following areas of the State of Georgia have been designated as adversely affected by this declared major disaster:

Bibb, Carroll, Douglas, Emanuel, Jefferson, Jenkins, Johnson, Laurens, McIntosh, and Twiggs Counties for Individual Assistance.

Bibb, Carroll, Crawford, Emanuel, Glynn, Jefferson, Jenkins, Johnson, Laurens, McIntosh, Treutlen, Twiggs, and Wilkinson Counties for Public Assistance.

All counties within the State of Georgia are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12524 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1763–DR]

Iowa; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Iowa (FEMA–1763–DR), dated May 27, 2008, and related determinations.

DATES: *Effective Date:* May 27, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 27, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Iowa resulting from severe storms, tornadoes, and flooding beginning on May 25, 2008, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Iowa.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program in the designated areas; Hazard Mitigation throughout the State; and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments (PDAs), unless you determine that the incident is of such unusual severity and magnitude that PDAs are not required to determine the need for supplemental Federal assistance pursuant to 44 CFR 206.33(d).

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation, and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, William L. Vogel, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following area of the State of Iowa to have been affected adversely by this declared major disaster:

Butler County for Individual Assistance.

Butler County for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

All counties within the State of Iowa are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individual and Household Housing; 97.049, Individual and Household Disaster Housing Operations; 97.050, Individual and Household Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12527 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1764–DR]

Mississippi; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Mississippi (FEMA–1764–DR), dated May 28, 2008, and related determinations.

DATES: *Effective Date:* May 28, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 28, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Mississippi resulting from severe storms and tornadoes on April 4, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Mississippi.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the

requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael L. Parker, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

The following areas of the State of Mississippi have been designated as adversely affected by this declared major disaster:

Hinds County for Individual Assistance and Public Assistance.

All counties within the State of Mississippi are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12530 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1760–DR]

Missouri; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Missouri (FEMA–1760–DR), dated May 23, 2008, and related determinations.

DATES: *Effective Date: May 23, 2008.*

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 23, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Missouri resulting from severe storms and tornadoes during the period of May 10–11, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Missouri.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. If Public Assistance is later warranted, Federal funds provided under that program also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael L. Karl, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

The following areas of the State of Missouri have been designated as adversely affected by this declared major disaster:

Barry, Jasper, and Newton Counties for Individual Assistance.

All counties within the State of Missouri are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12525 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1759–DR]

South Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of South Dakota (FEMA–1759–DR), dated May 22, 2008, and related determinations.

DATES: *Effective Date:* May 22, 2008.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency

Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 22, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of South Dakota resulting from a severe winter storm and record and near record snow during the period of May 1–2, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of South Dakota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas; assistance for emergency protective measures (Public Assistance Category B), including snow removal for any continuous 48-hour period during or proximate to the incident period in the designated areas; Hazard Mitigation throughout the State; and any other forms of assistance under the Stafford Act that you deem appropriate.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777. If Other Needs Assistance under Section 408 of the Stafford Act is later requested and warranted, Federal funding under that program also will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Tony Russell, of FEMA, is appointed to act as the Federal Coordinating Officer for this declared disaster.

The following areas of the State of South Dakota have been designated as adversely affected by this declared major disaster:

Bennett, Butte, Harding, Jackson, and Perkins Counties for Public Assistance.

Butte, Harding, and Lawrence Counties for emergency protective measures (Category B), including snow removal assistance, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

All counties within the State of South Dakota are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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 Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households, 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–12523 Filed 6–4–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF THE INTERIOR

Outer Continental Shelf (OCS) Policy Committee—Notice of Renewal

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of Renewal of the Outer Continental Shelf Policy Committee.

SUMMARY: Following consultation with the General Services Administration, notice is hereby given that the Secretary of the Interior (Secretary) is renewing the OCS Policy Committee.

The OCS Policy Committee will provide advice to the Secretary through the Director of the Minerals Management Service related to the discretionary functions of the Bureau under the OCS Lands Act and related statutes. The Committee will review and comment on all aspects of leasing, exploration, development and protection of OCS resources and provide a forum to convey views representative of coastal states, local government, offshore industries, environmental community, other users of the offshore, and the interested public.

FOR FURTHER INFORMATION CONTACT: Ms. Jeryne Bryant, Minerals Management Service, Offshore Minerals Management, Herndon, Virginia 20170–4817, telephone (703) 787–1213.

Certification

I hereby certify that the renewal of the OCS Policy Committee is in the public interest in connection with the performance of duties imposed on the Department of the Interior by 43 U.S.C. 1331 *et seq.*

Dated: May 30, 2008.

Dirk Kempthorne,

Secretary of the Interior.

[FR Doc. E8–12617 Filed 6–4–08; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Rate Adjustments for Indian Irrigation Projects

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of rate adjustments.

SUMMARY: The Bureau of Indian Affairs (BIA) owns or has an interest in irrigation projects and facilities located on various Indian reservations throughout the United States. We are authorized to establish rates to recover the costs to administer, operate, maintain, and rehabilitate those facilities. We are notifying you that we have adjusted the irrigation assessment rates at several of our irrigation projects and facilities for operation and maintenance.

DATES: *Effective Date:* The irrigation assessment rates shown in the tables are effective on January 1, 2008.

FOR FURTHER INFORMATION CONTACT: For details about a particular BIA irrigation project or facility, please use the tables in **SUPPLEMENTARY INFORMATION** section to contact the regional or local office where the project or facility is located.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Rate Adjustment was published in the **Federal Register** on February 8, 2008 (73 FR 7583) to adjust the irrigation rates at several BIA irrigation projects and facilities. The public and interested parties were provided an opportunity to submit written comments during the 60-day period that ended April 8, 2008.

Did the BIA Defer Any Proposed Rate Increases?

For the Fort Belknap Indian Irrigation Project, the BIA, in consultation with the Gros Ventre and Assiniboine Tribes and Project water users, has deferred the rate increase for 2008.

Did the BIA Receive Any Comments on the Proposed Irrigation Assessment Rate Adjustments?

Written comments were received for the proposed rate adjustments for the Blackfeet Irrigation Project, Fort Belknap Irrigation Project, and the Wind River Irrigation Project.

What Issues Were of Concern by the Commenters?

Individuals and entities commenting on the proposed rates for 2008 were concerned with one or more of the following issues: (1) How funds are expended for operation and maintenance (O&M) costs; (2) how rate increases are justified and communicated to water users; (3) how rate increases impact the local agricultural economy and individual land owners; (4) the role of the BIA's Central Office in managing projects and the burden of federal regulations; (4) land owners without access to project water being assessed irrigation charges; (5) the BIA's non-delivery of water to water users with outstanding O&M charges; and (6) the BIA's trust responsibility for projects. The following comment is specific to the Wind River Irrigation Project: users assert that O&M rates should not be adjusted until a study of the project's irrigable and assessable acreage is completed.

How Does the Bia Respond to Concerns Regarding How Funds Are Expended for O&M Costs?

The BIA considers the following expenses when determining an irrigation project's budget: project personnel costs; materials and supplies; vehicle and equipment repairs; equipment; capitalization expenses; acquisition expenses; rehabilitation costs; maintenance of a reserve fund for contingencies or emergencies; and other expenses that we determine are necessary to properly operate and maintain an irrigation project.

One common misconception water users have is that all salary costs are administrative. Only a portion of each project's budget is for administrative costs. The administrative costs for a project includes office costs, office staff (accounting and clerical), and a portion of the project manager's salary. Non-administrative costs are the cost to operate and maintain the project or facility. Operation and maintenance workers perform operation and maintenance work, thus their salaries are considered operation and maintenance costs, not administrative costs. All projects need essential personnel to operate and maintain the project, including a project manager, accounting staff, and irrigation system operators (ditchriders).

How Does the Bia Respond to Concerns Regarding the Justification for and Communication of Rate Increases to Land Owners?

BIA policy states that irrigation project managers are required to meet, at a minimum, twice annually with their water users—once at the end of the irrigation season and once before the next season. For projects that operate year-round, project managers will determine the best schedule for holding these meetings. At these meetings, irrigation staff will provide water users with information regarding project operations—including budget plans and actual annual expenditures—and obtain feedback and input from water users.

Individuals concerned with the BIA's management of its projects and its O&M rates may review the BIA's records at their convenience. The BIA's project budget estimates and expense records are available for review by stakeholders or interested parties. Stakeholders (water users, land owners, or tribes) can review these records during normal business hours at the individual agency office. Alternatively, stakeholders or interested parties may request project records under the Freedom of Information Act (FOIA). The BIA will provide copies of such records to the requesting party in accordance with FOIA.

To review or obtain copies of project records, stakeholders and interested parties should contact the BIA representative at the specific project or facility serving them, using the tables in the **SUPPLEMENTARY INFORMATION** section below.

How does the BIA respond to concerns regarding the impact of irrigation assessment rate increases on local agricultural economies and individual land owners?

The BIA's projects are important economic contributors to the local communities they serve. These projects contribute millions of dollars in crop value annually. Historically, the BIA tempered irrigation rate increases to demonstrate sensitivity to the economic impact on water users. This past practice resulted in a rate deficiency at some irrigation projects. The BIA does not have discretionary funds to subsidize irrigation projects. Funding to operate and maintain these projects needs to come from revenues from the water users served by those projects.

Over the past several years, the BIA's irrigation program has been the subject of several Office of Inspector General (OIG) and GAO audits. In the most recent OIG audit, No. 96–I–641, March 1996, the OIG concluded: ''Operation and maintenance revenues were insufficient to maintain the projects, and some projects had deteriorated to the extent that their continued capability to deliver water was in doubt. This occurred because operation and maintenance rates were not based on the full cost of delivering irrigation water, including the costs of systematically rehabilitating and replacing project facilities and equipment, and because project personnel did not seek regular rate increases to cover the full cost of project operation.'' A previous OIG audit performed on one of the BIA's largest irrigation projects, the Wapato Indian Irrigation Project, No. 95–I–1402, September 1995, reached the same conclusion.

To address the issues noted in these audits, the BIA must systematically review and evaluate irrigation assessment rates and adjust them, when necessary, to reflect the full costs to properly operate and perform all appropriate maintenance on the irrigation project or facility infrastructure to ensure safe and reliable operation. If this review and adjustment is not accomplished, a rate deficiency can accumulate. Rate deficiencies force the BIA to raise irrigation assessment rates in larger increments over shorter periods of time than would have been otherwise necessary.

How does the BIA respond to concerns regarding the role of the BIA's Central Office in managing projects and the costs associated with complying with federal regulations?

The BIA must follow Federal regulations as it operates and maintains the projects under its ownership or control. Specifically, the BIA must follow Federal guidelines in hiring and compensating personnel to operate and manage irrigation projects. The BIA sets rates in accordance with the criteria identified above. The BIA Central Office does not unilaterally impose rate increases on projects. The BIA is reviewing various options for cost savings, including turning over projects or sections of projects to water users and sharing personnel between or among projects.

How does the BIA respond to concerns regarding land owners without access to project water being assessed irrigation charges?

As mentioned above, OIG and GAO performed audits on the BIA irrigation program and noted that the BIA has not set irrigation assessment rates at levels high enough to operate and maintain its irrigation projects. The BIA has been increasing rates to address this concern. Because rates were low for many years, numerous maintenance items were deferred. At some projects, this deferral resulted in the BIA's inability to deliver water to all users. To assist water users in this regard, the BIA updated its Irrigation Operations and Maintenance regulations, 25 CFR part 171, to allow a water user to apply for a waiver of irrigation assessment charges if the BIA is incapable of delivering water to that water user. To apply for this waiver, a water user must meet with local project staff.

How does the BIA respond to concerns regarding the BIA's refusal to deliver water to water users with outstanding O&M charges?

The BIA's irrigation regulations, 25 CFR part 171, require the BIA to withhold irrigation services from users who have delinquent debt with the BIA, including balances that have been referred to the United States Treasury.

How does the BIA respond to comments regarding the BIA's trust responsibility in relation to projects?

The BIA disagrees that increasing O&M rates for projects violates any trust duty. The BIA has no trust obligation to operate and maintain irrigation projects. *See, e.g., Grey* v. *United States*, 21 Cl. Ct. 285 (1990), *aff'd*, 935 F.2d 281 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 1057 (1992). The BIA, pursuant to 25 U.S.C. section 381 *et seq.* and 25 CFR Part 171, has the responsibility to administer constructed projects, set rates, collect assessments, and make decisions regarding water delivery. The BIA must collect O&M assessments to operate and maintain the irrigation infrastructure on its projects. Over time, the costs of operating and maintaining these projects increases, and rates must be adjusted accordingly to enable the BIA to continue to provide irrigation services. Raising rates to reflect the full costs associated with operating and maintaining projects is essential because O&M rates are the only regular source of funding for the BIA's irrigation projects.

How does the BIA response to the issue raised by users of the Wind River Irrigation Project, that O&M rates should not be adjusted until the re-designation study of the project's irrigable and assessable acreage is completed?

The BIA levies assessments on lands to which its project is authorized and capable of delivering water. Thus, a parcel's irrigation history is immaterial to whether it is subject to an irrigation assessment. The Secretary may deem lands within a project non-assessable, in which case those lands may be removed from the project—permanently or temporarily—with the landowner's consent. 25 U.S.C. sections 389a, 389b. The redesignation study will not determine what O&M assessment the lands could support. The study only determines if the lands are irrigable and if they should remain assessable. The overall O&M assessment for a project is based on its total assessable acres. If the redeisgnation study recommends removing assessable acres from the project, the O&M assessment rate would increase significantly for those acres remaining in the project. Until such time as the land re-designation study referenced by this commenter is finished, individual users may apply for an annual assessment waiver under 25 CFR part 171.

Did the BIA receive comments on any proposed changes other than rate adjustments?

No.

Does this notice affect me?

This notice affects you if you own or lease land within the assessable acreage of one of our irrigation projects, or you have a carriage agreement with one of our irrigation projects.

Where can I get information on the regulatory and legal citations in this notice?

You can contact the appropriate office(s) stated in the tables for the irrigation project that serves you, or you can use the Internet site for the Government Printing Office at *http://www.gpo.gov.*

What authorizes you to issue this notice?

Our authority to issue this notice is vested in the Secretary of the Interior by 5 U.S.C. section 301 and the Act of August 14, 1914 (38 Stat. 583; 25 U.S.C. 385). The Secretary has in turn delegated this authority to the Assistant Secretary—Indian Affairs under Part 209, Chapter 8.1A, of the Department of the Interior's Departmental Manual.

Whom can I contact for further information?

The following tables are the regional and project/agency contacts for our irrigation projects and facilities.

Project name	Project/agency contacts
Northwest Region Contacts	
Stanley Speaks, Regional Director, Bureau of Indian Affairs, Northwest Regional Office, 911 N.E. 11th Avenue, Portland, OR 97232–4169, Telephone: (503) 231–6702.	
Flathead Irrigation Project	Chuck Courville, Acting Superintendent, Flathead Agency Irrigation Division, P.O. Box 40, Pablo, MT 59855–0040, Telephone: (406) 675–2700.
Fort Hall Irrigation Project	Eric J. LaPointe, Superintendent, Alan Oliver, Supervisory General Engineer, Fort Hall Agency, P.O. Box 220, Fort Hall, ID 83203–0220, Telephone: (208) 238–2301.
Wapato Irrigation Project	Pierce Harrison, Project Administrator, Wapato Irrigation Project, P.O. Box 220, Wapato, WA 98951–0220, Telephone: (509) 877–3155.
Rocky Mountain Region Contacts	
Ed Parisian, Regional Director, Bureau of Indian Affairs, Rocky Mountain Regional Office, 316 North 26th Street, Billings, MT 59101, Telephone: (406) 247–7943.	
Blackfeet Irrigation Project	Stephen Pollock, Superintendent, Ted Hall, Irrigation Project Manager, Box 880, Browning, MT 59417, Telephones: (406) 338–7544, Superintendent, (406) 338–7519, Irrigation Project Manager.
Crow Irrigation Project	George Gover, Superintendent, Karl Helvik, Irrigation Project Manager, P.O. Box 69, Crow Agency, MT 59022, Telephones: (406) 638–2672, Superintendent, (406) 638–2863, Irrigation Project Manager.

Project name	Project/agency contacts
Fort Belknap Irrigation Project	Judy Gray, Superintendent, Ralph Leo, Irrigation Project Manager, R.R. 1, Box 980, Harlem, MT 59526, Telephones: (406) 353–2901, Superintendent, (406) 353–2905, Irrigation Project Manager.
Fort Peck Irrigation Project	Florence White Eagle, Superintendent, P.O. Box 637, Poplar, MT 59255, Richard Kurtz, Irrigation Manager, 602 6th Avenue North, Wolf Point, MT 59201, Telephones: (406) 768–5312, Superintendent, (406) 653–1752, Irrigation Manager.
Wind River Irrigation Project	Ed Lone Fight, Superintendent, Ray Nation, Acting Irrigation Project Manager, P.O. Box 158, Fort Washakie, WY 82514, Telephones: (307) 332–7810, Superintendent, (307) 332–2596, Irrigation Project Manager.
Southwest Region Contacts	
Larry Morrin, Regional Director, Bureau of Indian Affairs, Southwest Regional Office, 1001 Indian School Road, Albuquerque, NM 87104, Telephone: (505) 563–3100.	
Pine River Irrigation Project	Ross P. Denny, Superintendent, John Formea, Irrigation Engineer, P.O. Box 315, Ignacio, CO 81137–0315, Telephones: (970) 563–4511, Superintendent, (970) 563–9484, Irrigation Engineer.
Western Region Contacts	
Allen Anspach, Regional Director, Bureau of Indian Affairs, Western Regional Office, Two Arizona Center, 400 N. 5th Street, 12th floor, Phoenix, AZ 85004, Telephone: (602) 379–6600.	
Colorado River Irrigation Project	Perry Baker, Superintendent, Ted Henry, Irrigation Project Manager, R.R. 1, Box 9–C, Parker, AZ 85344, Telephone: (928) 669–7111.
Duck Valley Irrigation Project	Joseph McDade, Superintendent, 1555 Shoshone Circle, Elko, NV 89801, Telephone: (775) 738–0569.
Fort Yuma Irrigation Project	Raymond Fry, Superintendent, P.O. Box 11000, Yuma, AZ 85366, Telephone: (520) 782–1202.
San Carlos Irrigation Project Joint Works.	Carl Christensen, Supervisory General Engineer, P.O. Box 250, Coolidge, AZ 85228, Telephone: (520) 723–6216.
San Carlos Irrigation Project Indian Works.	Joe Revak, Supervisory General Engineer, Pima Agency, Land Operations, Box 8, Sacaton, AZ 85247, Telephone: (520) 562–3372.
Uintah Irrigation Project	Lynn Hansen, Irrigation Manager, P.O. Box 130, Fort Duchesne, UT 84026, Telephone: (435) 722–4341.
Walker River Irrigation Project	Athena Brown, Superintendent, 311 E. Washington Street, Carson City, NV 89701, Telephone: (775) 887–3500.

What irrigation assessments or charges are adjusted by this notice?

The rate table below contains the current rates for all of our irrigation projects where we recover our costs for operation and maintenance. The table also contains the final rates for the 2008 season and subsequent years where applicable. An asterisk immediately following the name of the project notes that the BIA adjusted that project's rates for 2009.

NORTHWEST REGION RATE TABLE

Project name	Rate category	Final 2007 rate	Final 2008 rate	Final 2009 rate
Flathead Irrigation Project	Basic per acre—A	$23.45	$23.45	$23.45
	Basic per acre—B	10.75	10.75	10.75
	Minimum Charge per tract	65.00	65.00	65.00
Fort Hall Irrigation Project*	Basic per acre	27.00	31.00	[1]
	Minimum Charge per tract	25.00	27.00	
Fort Hall Irrigation Project—Minor Units*	Basic per acre	17.00	21.00	
	Minimum Charge per tract	25.00	27.00	
Fort Hall Irrigation Project—Michaud*	Basic per acre	35.75	39.75	
	Pressure per acre	50.00	55.50	
	Minimum Charge per tract	25.00	27.00	
Wapato Irrigation Project—Toppenish/Simcoe Units*.	Billing Charge per Tract	5.00	5.00	5.00
	Minimum Charge for farm unit/land tracts up to one acre.	14.00	14.00	15.00
	Farm unit/land tracts over one acre—per acre	14.00	14.00	15.00
Wapato Irrigation Project—Ahtanum Units*	Billing Charge per Tract	5.00	5.00	5.00
	Minimum Charge for farm unit/land tracts up to one acre.	14.00	14.00	15.00
	Farm unit/land tracts over one acre—per acre	14.00	14.00	15.00
Wapato Irrigation Project—Satus Unit*	Billing Charge per Tract	5.00	5.00	5.00
	Minimum Charge for farm unit/land tracts up to one acre.	55.00	55.00	58.00
	"A" farm unit/land tracts over one acre—per acre	55.00	55.00	58.00
	Additional Works farm unit/land tracts over one acre—per acre.	60.00	60.00	63.00
	"B" farm unit/land tracts over one acre—per acre	65.00	65.00	68.00

NORTHWEST REGION RATE TABLE—Continued

Project name	Rate category	Final 2007 rate	Final 2008 rate	Final 2009 rate
	Water Rental Agreement Lands—per acre	67.00	67.00	70.00

[1]To be determined.

Project name	Rate category	Final 2007 rate	Final 2008 rate
Rocky Mountain Region Rate Table			
Blackfeet Irrigation Project*	Basic-per acre	$15.50	$17.00
Crow Irrigation Project—Willow* Creek O&M (includes Agency, Lodge Grass #1, Lodge Grass #2, Reno, Upper Little Horn, and Forty Mile Units).	Basic-per acre	19.30	20.80
Crow Irrigation Project—All* Others (includes Bighorn, Soap Creek, and Pryor Units).	Basic-per acre	19.00	20.50
Crow Irrigation Two Leggins Drainage District	Basic-per acre	2.00	2.00
Fort Belknap Irrigation Project	Basic-per acre	13.88	13.88
Fort Peck Irrigation Project*	Basic-per acre	20.00	22.00
Wind River Irrigation Project*	Basic-per acre	15.00	16.00
Wind River Irrigation Project—LeClair District	Basic-per acre	17.00	17.00
Southwest Region Rate Table			
Pine River Irrigation Project	Minimum Charge per tract	50.00	50.00
	Basic-per acre	15.00	15.00

Project name	Rate category	Final 2007 rate	Final 2008 rate	Final 2009 rate
Colorado River Irrigation Project	Basic per acre up to 5.75 acre-feet	$47.00	$47.00	To be determined.
	Excess Water per acre-foot over 5.75 acre-feet.	17.00	17.00	
Duck Valley Irrigation Project	Basic-per acre	5.30	5.30	
Fort Yuma Irrigation Project*	Basic-per acre up to 5.0 acre-feet	72.00	77.00	
(See Note #1)	Excess Water per acre-foot over 5.0 acre-feet.	10.50	14.00	
	Basic-per acre up to 2.0 acre-feet (Ranch 5)	.....	28.00	
San Carlos Irrigation Project (Joint Works) (See Note #2).	Basic-per acre	30.00	21.00	21.00
San Carlos Irrigation Project* (Indian Works)	Basic-per acre	77.00	57.00	To be determined.
Uintah Irrigation Project*	Basic-per acre	12.00	12.50	
	Minimum Bill	25.00	25.00	
Walker River Irrigation Project* (See Note #3).	Indian per acre	10.00	13.00	16.00
	non-Indian per acre	16.00	16.00	16.00

* Irrigation projects where rates were adjusted.

Note #1—The O&M rate for Fort Yuma Irrigation Project has two components. The first component is the O&M rate established by the Bureau of Reclamation (BOR), the owner and operator of the Project. The BOR rate for 2008 is $70.00/acre. The second component is for the O&M rate established by the Bureau of Indian Affairs (BIA) to cover administrative costs including billing and collections for the Project. The 2008 BIA rate remains unchanged at $7.00/acre. The 2008 BOR rate for "Ranch 5" is $28.00/acre. In 2008, the BIA is not charging administrative costs on "Ranch 5" acreage. For 2009, the BIA will be proposing the addition of the $7.00 BIA administrative fee to the "Ranch 5" acreage.

Note #2—The 2008 and 2009 rate was established by final notice published in the FEDERAL REGISTER on April 20, 2007 (Vol. 72, No. 76, page 19954). The 2010 rate is to be determined. The Arizona Water Settlement Act is expected to be effective December 31, 2007, and this circumstance may affect what the O&M rate should be for the SCIPJW in 2010.

Note #3—The 2008 and 2009 irrigation rates are established through this notice.

Consultation and Coordination With Tribal Governments (Executive Order 13175)

To fulfill its consultation responsibility to tribes and tribal organizations the BIA communicates, coordinates, and consults on a continuing basis with these entities on issues of water delivery, water availability, and costs of administration, operation, maintenance, and rehabilitation of projects that concern them. This is accomplished at the individual projects by Project, Agency, and Regional representatives, as appropriate, in accordance with local protocol and procedures. This notice is one component of the BIA's overall coordination and consultation process to provide notice to, and request comments from, these entities when the BIA adjusts irrigation rates.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (Executive Order 13211)

The rate adjustments will have no adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increase use of foreign supplies) should the proposed rate adjustments be implemented. This is a notice for rate adjustments at BIA-owned and operated projects, except for the Fort Yuma

Irrigation Project. The Fort Yuma Irrigation Project is owned and operated by the Bureau of Reclamation with a portion serving the Fort Yuma Reservation.

Regulatory Planning and Review (Executive Order 12866)

These rate adjustments are not a significant regulatory action and do not need to be reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

This rate making is not a rule for the purposes of the Regulatory Flexibility Act because it is ''a rule of particular applicability relating to rates.'' 5 U.S.C. 601(2).

Unfunded Mandates Reform Act of 1995

These rate adjustments impose no unfunded mandates on any governmental or private entity and are in compliance with the provisions of the Unfunded Mandates Reform Act of 1995.

Takings (Executive Order 12630)

The Department has determined that these rate adjustments do not have significant ''takings'' implications. The rate adjustments do not deprive the public, state, or local governments of rights or property.

Federalism (Executive Order 13132)

The Department has determined that these rate adjustments do not have significant Federalism effects because they pertain solely to Federal-tribal relations and will not interfere with the roles, rights, and responsibilities of states.

Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act of 1995

These rate adjustments do not affect the collections of information which have been approved by the Office of Information and Regulatory Affairs, Office of Management and Budget, under the Paperwork Reduction Act of 1995. The OMB Control Number is 1076–0141 and expires August 31, 2009.

National Environmental Policy Act

The Department has determined that these rate adjustments do not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370(d)).

Dated: May 16, 2008.

Carl J. Artman,

Assistant Secretary—Indian Affairs.

[FR Doc. E8–12610 Filed 6–4–08; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–050–1310–DB]

Notice of Intent To Prepare an Environmental Impact Statement (EIS) for the GMI Natural Gas Development Project, Fremont and Natrona Counties, WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent (NOI).

SUMMARY: The Bureau of Land Management (BLM) Lander Field Office announces its intent to prepare an EIS for a proposed conventional natural gas field development near Lysite, Wyoming. The proposed development project is known as the Gun Barrel/Madden and Iron Horse (GMI) Natural Gas Development Project and is located in Fremont and Natrona Counties, Wyoming.

DATES: This NOI initiates the public scoping process for the EIS. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis and EIS alternatives. To provide the public with an opportunity to review the proposed project and project information, the BLM will host a meeting in Lander and a meeting in Casper, Wyoming, within 30 days of the publication of this notice. The BLM will notify the public of these meetings and any other opportunities for the public to be involved in the environmental process for this proposal at least 15 days prior to the event. Meeting dates, locations, and times will be announced by news release to the media, individual mailings, and postings on the following BLM Web site: *http://www.blm.gov/wy/st/en/info/NEPA/lfodocs/gmi.html.* To be most helpful, you should submit formal scoping comments within 30 days after this NOI is published.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publically available at any time. While you can ask us in your comment to withhold your personal indentifying information from public review, we cannot guarantee that we will be able to do so. The minutes and list of attendees for each scoping meeting will be made available to the public and open for 30 days after the meeting to any participant who wished to clarify the views he or she expressed.

ADDRESSES: You may submit written comments by any of the following methods:

- Web site: *http://www.blm.gov/wy/st/en/info/NEPA/lfodocs/gmi.html*
- E-mail: 3Pam_Olson@blm.gov
- Fax: 307–332–8444
- Mail: Lander Field Office, 1335 Main Street, Lander, WY 82520.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pam Olson, GMI Project Leader, Lander Field Office, 1335 Main Street, Lander, Wyoming 82520 or call (307) 332–8400, or send an electronic message to: *Pam_Olson@blm.gov*.

SUPPLEMENTARY INFORMATION: Under Section 102(2)(C) of the National Environmental Policy Act (NEPA), the BLM Lander Field Office announces its intent to prepare an EIS on the potential impacts of a proposed natural gas field development, ancillary facilities, pipelines and roads. The project area is located in Fremont and Natrona Counties, Wyoming, and encompasses approximately 146,000 acres of land, the majority of which is public land administered by the BLM Lander Field Office. A small portion of the project area is administered by the BLM Casper Field Office.

In January 2008, oil and gas operators and proponents of the project, EnCana Oil & Gas (USA), Inc. (EnCana), Burlington Resources Oil and Gas Company LP (Burlington), and Noble Energy, Inc. (Noble) submitted a proposal to the BLM to develop approximately 1,470 wells near Lysite, Wyoming. The proposed project area consists of three units operated by three different companies: the Gun Barrel Federal Exploratory Unit (Encana), the Madden Deep Federal Exploratory Unit (Burlington), and the Iron Horse Federal Exploratory Unit (Noble).

The purpose of the proposal is to continue extracting and developing natural gas within these three units during a ten to fifteen year period. The proponents estimate that within the Gun Barrel Unit, an additional 750 natural gas wells may be drilled; within the

Madden Deep Unit, approximately 300 wells may be drilled; and within the Iron Horse Unit, approximately 420 wells may be drilled.

Infrastructure required to support gas production would include: Well pads; water wells; gathering, treating, processing and compression facilities; water injection and evaporation facilities; electric powerlines; roads; gas flow lines; and pipelines. Gas would be transported through pipelines to centralized compression and treatment facilities.

Produced water would be reinjected in some instances, and disposed of through the use of surface facilities in other instances. Major issues identified at this time include: potential impacts to air quality; disposal of produced waste water; and potential effects of development and production on surface resources including vegetation and wildlife habitat.

Martin G. Griffith,

Acting State Director.

[FR Doc. E8–12620 Filed 6–4–08; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–558]

In the Matter of Certain Personal Computer/Consumer Electronic Convergent Devices, Components Thereof, and Products Containing Same; Notice of Determination Not To Review an Initial Determination Granting Complainant's Motion To Terminate the Investigation Based on Withdrawal of the Complaint

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 30) in the above-referenced investigation granting complainant's motion to terminate the investigation based on withdrawal of the complaint.

FOR FURTHER INFORMATION CONTACT: Michelle Walters, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On January 4, 2006, the Commission instituted this investigation, based on a complaint filed by InterVideo Technology Corporation of Taiwan (''InterVideo''), alleging violations of section 337 of the Tariff Act of 1930 (19 U.S.C. **1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain personal computer consumer electronic convergent devices, components thereof, and products containing the same by reason of infringement of claims 1–10 of United States Patent No. 6,765,788 (''the '788 patent''). Complainant Intervideo, through subsequent corporate mergers, now operates and is known as Corel (Taiwan) Corporation (''Corel''). The complaint named four respondents: Dell, Inc. of Texas, WinBook Computer Corporation of Ohio (''WinBook''), Cyberlink Corporation of Taiwan, and Cyberlink.com Corporation of California. WinBook has been terminated from the investigation on the basis of a settlement agreement.

On April 29, 2008, complainant Corel filed a motion to terminate the investigation based on withdrawal of the complaint in its entirety.

On May 12, 2008, the ALJ issued the subject ID, granting complainant's motion to terminate the investigation. No petitions for review were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.21(a)(1) and 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.21(a)(1) and 210.42).

By order of the Commission.

Issued: May 30, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–12600 Filed 6–4–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–651]

In the Matter of Certain Automotive Parts; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on May 2, 2008, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Ford Global Technologies, LLC of Dearborn, Michigan. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain automotive parts that infringe on U.S. Design Patent Nos. D498,444; D501,162; D510,551; D508,223; D500,717; D539,448; D500,969; and D500,970. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue exclusion orders and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Stephen R. Smith, Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2746.

Authority: The authority for institution of this investigation is contained in section 337

of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2008).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on May 28, 2008, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain automotive parts that infringe on U.S. Design Patent Nos. D498,444; D501,162; D510,551; D508,223; D500,717; D539,448; D500,969; or D500,970; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—

Ford Global Technologies, LLC, 330 Townsend Drive, Suite 800 South, Dearborn, Michigan 48126

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Keystone Automotive Industries, Inc., 700 East Bonita, Pomona, California 91767

LKQ Corporation, 120 North LaSalle Street, Suite 3300, Chicago, Illinois 60602

U.S. Autoparts Networks, Inc., 17150 S. Margay Avenue, Carson, California 90746

Jui Li Enterprise Co., No. 22 Kaonan Road, Jenwu Hsiang, Kaohsiung Hsien, Taiwan

Y.C.C. Parts Manufacturing Co., Ltd., No. 21, Si Chou Road, Si Hai Village, Ta Yuan Hsiang, Tao-yuan Hsien, Taiwan

TYC Brother Industrial Co., Ltd., 72–2 Shin-leh Road, Tainan, Taiwan

Taiwan Kai Yih Industrial Co., Ltd., 202, Lane 250, Jheng An Road, Tainan City, Taiwan

T.Y.G. Products, L.P., 1800 N. McDonald Street, McKinney, Texas 75069

(c) The Commission investigative attorney, party to this investigation, is Stephen R. Smith, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Honorable Theodore Essex is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: May 29, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–12598 Filed 6–4–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with 28 CFR 50.7 and Section 122 of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9622, the Department of Justice gives notice that a proposed Consent Decree, in *United States* v. *Waste Management of Illinois, Inc. et al.*, Civil No. 08–50094 (N.D. Ill.), was lodged with the United States District Court for the Northern District of Illinois on May 29, 2008, pertaining to the Evergreen Manor Groundwater Contamination Superfund Site (''Site'' or ''Evergreen Manor Site''), located in Roscoe Township, Winnebago County, Illinois. In this action, the United States brought civil claims under Sections 106, 107 and 113(g)(2) of CERCLA, 42 U.S.C. 9606, 9607 and 9613(g)(2), against Waste Management of Illinois, Inc., Waste Management of Wisconsin, Inc., and Ecolab, Inc. (''Settling Defendants'') for implementation of remedial action and recovery of response costs incurred and to be incurred by the United States at the Site.

Under the proposed Consent Decree, the Settling Defendants are obligated to implement the remedy selected by the U.S. Environmental Protection Agency (''EPA'') in the Record of Decision (''ROD'') for the Site, and to pay $550,000 in partial recovery of the United States' past response costs incurred at the Site as well as EPA's future costs of overseeing the implementation of the remedial action.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to United States Department of Justice, P.O. Box 7611, Washington, DC 20044–7611, and should refer to *United States* v. *Waste Management of Illinois, Inc. et al.*, Civil No. 08–50094 (N.D. Ill.), and DOJ Reference No. 90–11–3–08952/1.

The proposed Consent Decree may be examined at: (1) The Office of the United States Attorney for the Northern District of Illinois, Rockford Division, 308 West State Street, Suite 300, Rockford, Illinois 61101 (815) 987–4444); and (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Blvd., Chicago, IL 60604–3507 (contact: John C. Matson ((312) 886–2243).

During the public comment period, the proposed Consent Decree may also be examined on the following U.S. Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the proposed Consent Decree may also be obtained by mail from the Consent Decree Library, U.S. Department of Justice, P.O. Box 7611, 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 no. (202) 514–1547. In requesting a copy from the Consent Decree Library, please refer to the referenced case and DOJ Reference Number and enclose a check in the amount of $21.50 for the Consent Decree only (86 pages, at 25 cents per

page reproduction costs), or in the amount of $799.25 for the Consent Decree and Appendices (3197 pages), made 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.

William D. Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–12514 Filed 6–4–08; 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—Cooperative Research Group on Clean Diesel V

Notice is hereby given that, on April 23, 2008, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Clean Diesel V (''Clean Diesel V'') 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, Chevron, Richmond, CA; Modine Mfg. Co., Racine, WI; Dayco Ensa, S.I., Vigo, Spain; Nissan Technical Center N.A., Inc., Farmington Hills, MI; EP America, Inc., Global Fuels Technology, Naperville, IL; International Truck & Engine Corp., Melrose Park, IL; Sasol Technology (PTY) Ltd., Johannesburg, Republic Of South Africa; Robert Bosch LLC, Farmington Hills, MI; and NGK Spark Plug Co., Ltd., Nagoya, Japan 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 Clean Diesel V intends to file additional written notifications disclosing all changes in membership.

On January 10, 2008, Clean Diesel V 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 February 25, 2008 (73 FR 10064).

The last notification was filed with the Department on February 27, 2008. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on April 7, 2008 (73 FR 18812).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E8–12529 Filed 6–4–08; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Correction Notice.

SUMMARY: This is a correction to a notice of petitions for modification of existing safety standards that was published in the **Federal Register** on May 30, 2008 (73 FR 31149). In the notice we inadvertently listed the company name as TJS Mining Company, Inc., for petition for modification, docket number M–2008–024–C. The correct company name is the Penn View Mining Company, Inc., TJS #6 Mine, MSHA Mine I.D. 36–09464.

Dated: May 30, 2008.

Jack Powasnik,

Deputy Director, Office of Standards, Regulations, and Variances.

[FR Doc. E8–12597 Filed 6–4–08; 8:45 am]

BILLING CODE 4510–43–P

MARINE MAMMAL COMMISSION

Availability of Grant Funds for Fiscal Year 2008

AGENCY: Marine Mammal Commission.

ACTION: Notice.

Authority: Marine Mammal Protection Act of 1972 (1361 *et seq.*)

SUMMARY: The U.S. Marine Mammal Commission is seeking proposals for research and related activities that will further the conservation and management goals of the Marine Mammal Protection Act. Proposals should be tailored to address either of two focused research topics: (1) Conservation of Critically Endangered Marine Mammal Species or Populations and (2) Indirect Effects of Fisheries on Marine Mammals.

DATES: Proposals must be received by 15 July 2008, 5 p.m., EDT.

ADDRESSES: Proposals should be submitted electronically in MSWord, WordPerfect, or Adobe PDF format to Ms. Mina Innes, Research Program Officer, at the Marine Mammal Commission, e-mail address: *minnes@mmc.gov.*

FOR FURTHER INFORMATION CONTACT: Inquiries should be directed to Dr. Robert Gisiner, Scientific Program Director, by mail (4340 East-West Highway, Room 700, Bethesda, MD 20814), phone (301–504–0087), or e-mail *(bgisiner@mmc.gov).* Please also copy e-mail inquiries to Ms. Mina Innes *(minnes@mmc.gov).*

SUPPLEMENTARY INFORMATION:

Title: Marine Mammal Commission FY2008 Focused Research Topics.

Purpose: The U.S. Marine Mammal Commission is seeking proposals for research and related activities that will further the conservation and management goals of the Marine Mammal Protection Act. Proposals should be tailored to address either of two focused research topics: (1) Conservation of Critically Endangered Marine Mammal Species or Populations and (2) Indirect Effects of Fisheries on Marine Mammals.

Grantees or contractors whose projects involve the taking of marine mammals will be expected to obtain all necessary permits and authorizations for their projects before engaging in such activities.

Information on the focused research topics, selection criteria, required formats for full proposals, the submission process, and the submission schedule is provided below.

Financial Information: A total of $450,000 has been allocated for this RFP. Allocation of the total amount between the two focused research topics will be determined by the nature and quality of proposals within each topic and the degree to which the selected proposals contribute to an integrated program of effort within each research topic as determined during the final review phase.

Duration of Effort: The Commission strongly encourages that proposals be limited to a single period of effort, usually one year. Multi-year proposals, not to exceed three years, may be considered, but only if a strong case can be made for the necessity of a prolonged effort.

Individual Award Amount: No upper or lower limit has been set for an individual proposal due to the wide range of potential levels of effort within each focused research topic. However, it is anticipated that few if any awards will exceed $50,000 to $100,000, and that most will range between $30,000 and $50,000, based on the Commission's

desire to focus on initial phase scoping efforts and to be able to address a sufficient range of actions and approaches within each area. Proposers are encouraged to present a budget consistent with the type and level of effort proposed, rather than on a specific dollar target, since budget realism, aligned with anticipated scientific and conservation impact, constitutes the largest share of the review weighting process.

Indirect Costs: Proposers are encouraged to keep their overhead costs at or below 10 percent in keeping with the Marine Mammal Commission's stated policy on indirect costs. This policy is intended to maximize the impact on science and conservation from the limited resources available to the Commission for discretionary spending (also see *http://www.mmc.gov/research/*).

Focused Research Topics

1. Conservation of Critically Endangered Marine Mammal Species or Populations

The Commission is requesting proposals for research or other activities that will promote the conservation of critically endangered marine mammal species or populations, with a particular focus on those for which current research efforts are non-existent or underfunded. Such proposals could include the following:

- Collection and analysis of data on critically endangered marine mammals and/or the threats facing them, with the goal of informing conservation decisions;
- Development and implementation of strategies for prioritizing and commumcating critical conservation needs to the public and decision-makers;
- Initiation of conservation activities to address the principal threats facing critically endangered marine mammals.

The at-risk species or populations may occur in domestic, foreign, or international waters. The Commission is not likely to fund proposals to continue ongoing conservation programs but will consider proposals to provide seed money or start-up funds to initiate new efforts, with the goal of creating self-sustaining conservation efforts that do not duplicate pre-existing efforts. Priority will be given to proposals based on the degree of endangerment to the species or population, the usefulness and relevance of the research in addressing a threat and promoting conservation, and the extent to which other funding sources are or are not available. Proposals should reflect a thorough knowledge of ongoing research and conservation efforts and should clearly indicate both the importance of the proposed work and the limitations imposed by current funding levels or opportunities.

2. InDirect Effects of Fisheries on Marine Mammals

Commercial, recreational, and subsistence fisheries have the potential to affect marine mammals and other predators directly through bycatch and indirectly by altering the availability of prey resources (*e.g.*, exploitative or interference competition). The Marine Mammal Protection Act establishes a comprehensive framework for managing bycatch of marine mammals, but the indirect effects of fishing are poorly understood and largely unmanaged. Despite growing emphasis on ecosystem-based fisheries management, much of the research effort to date has been limited to the indirect effects of fishing on non-target fish stocks with little attention paid to the effects on higher-trophic-level predators. Indirect effects of fisheries can be complex, and research programs to investigate those effects have been slow to develop.

The Commission is requesting proposals for studies that seek to describe quantitatively the indirect effects of fishing on marine mammals or to develop approaches for mitigating those effects. Proposals may include, but are not limited to, the following approaches:

- Comparative experiments between fished and unfished areas to assess the potential impact of fisheries on marine mammals;
- Development and performance testing of conceptual fishery management approaches that explicitly consider indirect effects of fishing on marine mammals;
- Ecosystem dynamics modeling studies that investigate the functional relationships between marine mammal predators, their prey, and fisheries in appropriate spatial/temporal context (*i.e.*, including consideration of spatial and temporal overlap between predators, prey, and fisheries);
- Field validation of such modeling studies.

Methodological approaches and data requirements for such projects are described on pages 41–44 of Chapter 3, ''Indirect Fisheries Interactions,'' in J.E. Reynolds III *et al.* ''Marine Mammal Research: Conservation Beyond Crisis'' (The Johns Hopkins University Press, Baltimore, MD). Proposers may find this reference helpful in organizing their proposed efforts, although adherence to the referenced guidance is not required. Proposals will be considered both for small stocks and fisheries as well as for larger marine mammal populations or large-scale fisheries.

Proposals on other aspects of indirect fishery effects on marine mammals will be considered, but priority will be given to proposals that address critical gaps in current understanding of indirect fishery effects. In all cases, proposals should indicate a thorough knowledge of relevant topics and should describe explicitly how the proposed work will build upon, but not duplicate, previous efforts. The Commission will consider proposals for workshops or reviews of historical data as well as original research projects.

Selection criteria: Proposals will be evaluated using the normal consultative process of the Marine Mammal Commission with its Committee of Scientific Advisors on Marine Mammals and the Commission staff. The following factors will be considered.

- Relevance to the focused research topic as described in this statement and to the overall mission of the Marine Mammal Commission as described on the Commission's Web site *(http://www.mmc.gov/aboutmmc/)* (40 points).
- Scientific and conservation merit of the proposed approach and anticipated end products (30 points).
- Qualifications of the proposal team (15 points).
- Realism of the proposed budget (15 points).

Commission staff will compile reviewer recommendations and forward the ranked recommendations to the Commissioners for final review. The Commissioners will make the final funding determination based on their assessment of the combination of projects that will most effectively promote the conservation and management goals of the Marine Mammal Protection Act within the funds allocated for this funding opportunity.

Proposal Format

The proposal body must not exceed eight pages (single-sided, or four pages double-sided) using 12 point font, exclusive of cover page, budget page(s), curriculum vitae, and supporting materials.

- *Cover Page:* The cover page shall include the following information, in any format:
  - *Title:* The full title of the proposal. A shorter, running title is optional.
  - *Research Topic:* List the RFP topic to which the proposal is addressed (1) Critically Endangered Species or (2) Indirect Effects of Fisheries. Listing of topic subheadings (items indicated by bullets under each topic) is optional.

○ *Keywords (optional):* a list of three to six keywords, indicating species, regions, research methods, or disciplinary areas of effort.

○ *Principal Investigator:* Please list only one (corresponding) principal investigator even if your proposal team consists of two or more co-equal investigators and institutions (also see instructions for Curricula Vitae, below).

○ *PI Contact Information:* Address, phone, and e-mail for the principal investigator.

○ *Financial Point of Contact:* The individual (with or without institutional affiliation, as appropriate) who will be responsible for contractual and fiscal matters. This may or may not be the same individual and institution listed as principal investigator.

○ *Financial Point of Contact Information:* address, phone, and e-mail for the financial point of contact.

• *Body of Proposal*

○ *Abstract (optional):* Provide an abstract of the proposal summarizing the problem or question to be addressed, the methods to be used to address the problem or question, possible outcomes of the work, and the utility of the research for advancing science and management related to marine mammals. Please limit the abstract to approximately 200 words.

○ *Introduction, Background, or Problem Statement:* Provide a review of past related effort by the research team or others. Indicate knowledge gaps, shortfalls of prior efforts, or challenges to further progress and describe how the proposed effort will address these issues.

○ *Goals and Objectives:* Provide statements of both the general or broad goal of the proposed research and the specific objectives that will be addressed within the scope of this proposal to make progress toward the broader, general goal.

○ *Methods:* Provide a detailed description of the methods of the investigation so that the reviewer can understand how you will address each of the specific objectives. If you are not conducting original research but are developing a workshop, review panel or other activity, describe the nature of the activity, the planned agenda or working format, likely attendees/participants, and

○ Tentative dates and location of the planned activity.

○ *Anticipated Outcomes:* Describe the short-term outcomes and those anticipated to occur within the scope of effort and time span of the proposed project (e.g., completion of a workshop report, one or more peer-reviewed journal articles, an equipment prototype, and report).

○ *Research and Management Utility (Long-Term Outcome):* Describe the anticipated long-term utility of the project and its implications for future research, management, or conservation activities.

• *Budget and Time Line:* Although there is no specified format for the budget, this section should provide sufficient detail to inform the reviewer of expenses or costs by general category (salary, equipment, supplies, travel, publication, overhead, miscellaneous) and by sub-tasks within the proposed effort, as appropriate. Include information on other sources of funding for the project, if applicable. For multi-year or multi-stage projects, include a time table for completion of each phase as a means of gauging progress toward completion of the full proposed effort.

• *Curricula Vitae, Research Team Qualifications:* Provide a curriculum vitae or short biography of no more than two pages for all key members of the proposal team (those individuals whose unique background and experience are essential to completion of the project), including their experience or expertise related to the subject proposal. Although there can only be one principal investigator (see Title Page guidance), multiple co-investigators can be designated in this portion of the proposal, if desired.

• *Supporting Materials:* Supporting materials such as recent publications, short descriptions of relevant work in progress or recently completed, organization charts or time lines will be accepted, but should be limited to information absolutely essential to understanding the significance, approach and context of the proposed work. The presence or absence of supporting materials will not be a consideration in proposal evaluations. It is highly recommended that supporting materials be limited to fewer than 20 to 30 pages or 5 Mb; the more material provided, the less likely it is to be used by the reviewers in developing their evaluations.

Submission process: Proposals should be submitted electronically in MSWord, WordPerfect, or Adobe PDF format to Ms. Mina Innes, Research Program Officer, at the Marine Mammal Commission, e-mail address minnes@mmc.gov.

Timing of Submission and Review Process

15 July 2008; 5 p.m. EDT Full proposals due to the Marine Mammal Commission.

11 August 2008; 5 p.m. EDT Successful applicants informed of final Decisions.

Proposals received after the due date and time listed above will not, under any circumstances, be forwarded for review.

Inquiries: Inquiries should be directed to Dr. Robert Gisiner, Scientific Program Director, by mail (4340 East-West Highway, Room 700, Bethesda, MD 20814), phone (301–504–0087) or e-mail (*bgisiner@minc.gov*). Please also copy e-mail inquiries to Ms. Mina Innes (*minnes@mmc.gov*).

Dated: May 29, 2008.

Timothy J. Ragen,

Executive Director.

[FR Doc. E8–12459 Filed 6–4–08; 8:45 am]

BILLING CODE 6820–31–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

May 30, 2008.

TIME AND DATE: 10 a.m., Wednesday, June 11, 2008

PLACE: The Richard V. Backley Hearing Room, 9th Floor, 601 New Jersey Avenue, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Twentymile Coal Company,* Docket No. WEST 2007–892–E. (Issues include whether the Secretary properly interpreted the breathable air provisions of section 316 of the Mine Act and whether the MSHA District Manager erred in refusing to approve the operator's emergency response plan unless it provided for a refuge chamber in the main entry.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Jean Ellen, (202) 434–9950 / (202) 708–9300 for TDD Relay / 1–800–877–8339 for toll free.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 08–1327 Filed 6–3–08; 3:55 pm]

BILLING CODE 6735–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30 a.m., Tuesday, June 10, 2008.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594.

STATUS: The three items are open to the public.

MATTERS TO BE CONSIDERED:

8015 Aircraft Accident Report—Runway Overrun During Landing, Pinnacle Airlines Flight 4712, Bombardier/Canadair Regional Jet CL600–2B19, N8905F, Traverse City, Michigan, April 12, 2007.

8013 Safety Recommendation Letter to the Federal Aviation Administration regarding Aviation Fatigue Management Systems.

8014 Highway Accident Brief—Commuter Train Highway— Railroad Grade Crossing Accident in Elmwood Park, Illinois, November 23, 2005 (HWY–06–MH–007).

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

Individuals requesting specific accommodations should contact Carol Bowling at (202) 314–6238 by Friday, June 6, 2008.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *http://www.ntsb.gov*.

FOR MORE INFORMATION CONTACT: Vicky D'Onofrio, (202) 314–6410.

Dated: May 30, 2008.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. E8–12508 Filed 6–4–08; 8:45 am]

BILLING CODE 7533–01–M

NUCLEAR REGULATORY COMMISSION

Notice of Availability of Regulatory Issue Summary 2008–12 Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: The NRC staff has issued Regulatory Issue Summary (RIS) 2008–12; Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees. The RIS is intended to update and replace information provided in Information Notice 90–09, ''Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,'' February 5, 1990. The RIS is dated May 9, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. James Shaffner, Project Manager, Low-Level Waste Branch, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection (DWMEP), U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 415–5496; fax number (301) 415–5397; e-mail *james.shaffner@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

In its annual report (SECY 06–193, ''Annual Review of the Need for Rulemaking and/or Regulatory Guidance on Low-Level Radioactive Waste Storage,'' September 6, 2006) to the Commission on the need for rulemaking or guidance related to extended interim storage of Low-Level Radioactive Waste (LLRW), the NRC staff reported its intention to review and revise, as necessary, guidance to NRC licensees faced with the prospect of mandatory extended interim storage of low-level radioactive waste. Staff stated that the emphasis of the effort would be directed toward the needs of fuel cycle and radioactive materials licenses that may be required to store waste classified as Class B or C waste, in accordance with 10 CFR part 61, ''Licensing Land Disposal of Radioactive Waste,'' after June 30, 2008, because of the limitation of access to the Barnwell Low-Level Radioactive Waste Disposal Facility. In its follow-up report on the topic, SECY 07–083, dated October 22, 2007, staff outlined the process and timeline for accomplishment of the guidance update. The emphasis on fuel cycle and radioactive materials licensees was based on the understanding that 10 CFR part 50 licensees (production and utilization facilities) were more likely to have pre-existing technical, physical, and financial infrastructure to adequately manage any required extended interim storage of LLRW.

II. Background

The limitation of disposal access at the Barnwell disposal facility to States that comprise the Atlantic LLRW Compact (South Carolina, Connecticut, and New Jersey) as of July 1, 2008 is likely to require many radioactive materials licensees outside of that compact that generate Class B and C LLRW to store such waste. In anticipation of this circumstance, NRC staff reviewed and updated information related to extended interim storage of LLRW by fuel cycle and radioactive materials licensees. In SECY–07–083, staff determined that the most efficient and transparent means to accomplish this was to revise IN 90–09. However, in consultation with other NRC offices it was later determined that the most appropriate form of generic communication for imparting the information was a RIS. Although the RIS does not impose any additional regulatory requirements on NRC licensees, staff considered that it also may be of some interest to Agreement State radiation control programs and their licensees.

III. Need for the Revision

NRC staff considered the need for the revision of IN 90–09 based on changes in regulatory circumstances that have occurred since 1990. These include, but are not limited to, the changing nature of and access to permanent disposal capacity, emerging technologies related to the processing, treatment and handling of radioactive waste, and changed security considerations based on the circumstances of September 11, 2001.

The updated information in the form of RIS 2008–12 is responsive to both licensees who will be able to store LLRW in accordance with terms and conditions of existing licenses as well as those whose circumstances may have changed such that a license amendment is required. The RIS includes a number of major considerations related to extended interim storage. These include reaffirmations of two considerations, related to storage time limit and suitable waste forms for storage, formerly addressed but never finalized by NRC staff in SECY 94–198, ''Review of Existing Guidance Concerning Extended Storage of Low-Level Radioactive Waste'' (August 1, 1994).

The RIS includes four enclosures to inform its contents and facilitate its use. The enclosures include licensing considerations, updated State and compact contacts, additional references, and recently issued generic communications.

IV. Intended Use

RIS 2008–12 provides updated information related to extended interim storage of LLRW by fuel cycle and materials licensees. It imposes no additional regulatory requirements. The RIS is intended to replace the IN 90–09 dated February 5, 1990. Further, any references to IN 90–09 contained in other NRC guidance or technical

references should now be interpreted to refer to RIS 2008–12.

V. Agencies and Persons Consulted

The RIS was developed in accordance with the requirements of NRC Inspection Manual Chapter 0730, ''Generic Communications Regarding Materials and Fuel Cycle Issues.'' In the process of preparing RIS 2008–12, FSME staff consulted with other NRC Headquarters offices, NRC regional offices, State officials in both Agreement States and non-Agreement States and territories, the Organization of Agreement States, the Conference of Radiation Control Program Directors and several licensees licensed by either NRC or Agreement State Radiation Control Programs.

VI. Further Information

Documents related to this action are available electronically in the NRC's Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The package which contains RIS 2008–12 and four enclosures can be found in ADAMS at accession number ML073330609. If you do not have access to ADAMS, or if there are problems accessing documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference Staff at 1–800–397–4209, 301–415–4737, or e-mail *pdr@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland, this 29th day of May 2008.

For the Nuclear Regulatory Commission.

Scott C. Flanders,

Deputy Director, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. E8–12575 Filed 6–4–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–282, 50–306 and 72–10]

Nuclear Management Company, LLC; Prairie Island Nuclear Generating Plant (PINGP), Units 1 And 2, and PINGP Independent Spent Fuel Storage Installation (ISFSI); Notice of Consideration of Approval of Transfer of Facility Operating Licenses and Materials License and Conforming Amendments, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering the issuance of an order under 10 CFR 50.80 and 10 CFR 72.50 approving the direct transfer of Facility Operating Licenses, which are numbered DPR–42 and DPR–60 for the Prairie Island Nuclear Generating Plant (PINGP), Units 1 and 2 and Material License No. SNM–2506 (the licenses) for the PINGP Independent Spent Fuel Storage Installation (ISFSI), to the extent currently held by Nuclear Management Company, LLC (NMC) as operator of PINGP Units 1 and 2, and PINGP ISFSI. The transfer would be to Northern States Power Company (NSPM), an Xcel Energy company, and current licensed owner of PINGP, Units 1 and 2 and PINGP ISFSI. The Commission is also considering amending the license for administrative purposes to reflect the proposed transfer.

According to an application for approval dated April 16, 2008, filed by NMC, NSPM would acquire operating authority of the facilities following approval of the proposed license transfer, and would be responsible for the operation and maintenance of PINGP Units 1 and 2, and PINGP ISFSI. NMC would be integrated into the current NSPM organization which would combine the ownership and operating authority into a single organization.

No physical changes to the PINGP Units 1 and 2, or PINGP ISFSI facility or operational changes are being proposed in the application.

The proposed amendment would delete references to NMC, and authorize NSPM to operate PINGP and the PINGP ISFSI, and to receive, possess, or use related licensed materials under the applicable conditions and authorizations included in the licenses. This request to transfer operating authority and the conforming license amendments involve no change in plant ownership.

Pursuant to 10 CFR 50.80 and 10 CFR 72.50, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the direct transfer of a license, if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility, or to the license of an ISFSI, which does no more than conform the license to reflect the transfer action involves no significant hazards consideration, and no genuine issue as to whether the health and safety of the public will be significantly affected. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C ''Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings,'' of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely

request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)–(viii).

A request for hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated on August 28, 2007 (72 FR 49139). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the petitioner/requestor must contact the Office of the Secretary by e-mail at *hearingdocket@nrc.gov,* or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html.* Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.*

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date. Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this license transfer application, see the application dated April 16, 2008, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency wide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr.resource@nrc.gov.*

Dated at Rockville, Maryland, this 28th day of May 2008.

For the Nuclear Regulatory Commission.

Mahesh Chawla,

Project Manager, Plant Licensing Branch III–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E8–12576 Filed 6–4–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–263]

Nuclear Management Company, LLC; Monticello Nuclear Generating Plant (MNGP); Notice of Consideration of Approval of Transfer of Renewed Facility Operating License and Conforming Amendment, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering the issuance of an order under 10 CFR 50.80 approving the direct transfer of the Renewed Facility Operating License No. DPR–22 (the license) for the Monticello Nuclear Generating Plant (MNGP) to the extent currently held by Nuclear Management Company, LLC (NMC), as operator of MNGP. The transfer would be to Northern States Power Company (NSPM), an Xcel Energy company, and current licensed owner of MNGP. The Commission is also considering amending the license for administrative purposes to reflect the proposed transfer.

According to an application for approval dated April 16, 2008, filed by NMC, NSPM would acquire operating authority of the facility following approval of the proposed license transfer, and would be responsible for the operation and maintenance of MNGP. NMC will be integrated into the current NSPM organization which would combine the ownership and operating authority into a single organization.

No physical changes to the MNGP facility or operational changes are being proposed in the application.

The proposed amendment would delete references to NMC, and to authorize NSPM to operate MNGP, and to receive, possess, or use related licensed materials under the applicable conditions and authorizations included in the license. This request to transfer operating authority and the conforming license amendment involve no change in plant ownership.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the direct transfer of a license, if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility, which does no more than conform the license to reflect the transfer action involves no significant hazards consideration. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C ''Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings,'' of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)–(viii).

A request for hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated on August 28, 2007 (72 FR 49139). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the petitioner/ requestor must contact the Office of the Secretary by e-mail at *hearingdocket@nrc.gov,* or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/ requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html.* Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.*

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public website at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary

that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

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Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this license transfer application, see the application dated April 16, 2008, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency wide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr.resource@nrc.gov.*

Dated at Rockville, Maryland, this 28th day of May 2008.

For the Nuclear Regulatory Commission.

Peter S. Tam,

Senior Project Manager, Plant Licensing Branch III–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E8–12578 Filed 6–4–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the Economic Simplified Boiling Water Reactor (ESBWR) Subcommittee; Notice of Meeting

The ACRS Subcommittee on ESBWR will hold a meeting on June 18–19, 2008, Room T2 B3, 11545 Rockville Pike, Rockville, Maryland.

The entire 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 (GEH) Nuclear Energy and its contractors pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

Wednesday June 18, 2008—8:30 a.m., until 5 p.m.

Thursday June 19, 2008—8:30 a.m., until 5 p.m.

The Subcommittee will review several chapters of the Safety Evaluation Report with Open Items associated with the Economic Simplified Boiling Water Reactor (ESBWR) Design Certification Application. 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, Dr. Harold VanderMolen (telephone 301–415–6236) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007 (72 FR 54695).

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between

7:45 a.m. and 4:30 p.m. (ET). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes to the agenda.

Dated: May 28, 2008.

Cayetano Santos,

Branch Chief, ACRS.

[FR Doc. E8–12570 Filed 6–4–08; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Audits of States, Local Governments, and Non-Profit Organizations; Circular A–133 Compliance Supplement

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice of availability of the 2008 Circular A–133 Compliance Supplement.

SUMMARY: This notice announces the availability of the 2008 Circular A–133 Compliance Supplement. The notice also offered interested parties an opportunity to comment on the 2008 Circular A–133 Compliance Supplement. The 2008 Supplement adds seven programs, including three programs added to an existing cluster. It has also been updated for program changes and technical corrections. In total, the 2008 Compliance Supplement includes 178 individual programs. A list of changes to the 2008 Supplement can be found at Appendix V. Due to its length, the 2008 Supplement is not included in this Notice. See **ADDRESSES** for information about how to obtain a copy.

DATES: The 2008 Supplement will apply to audits of fiscal years beginning after June 30, 2007 and supersedes the 2007 Supplement. All comments on the 2008 Supplement must be in writing and received by October 31, 2008. Late comments will be considered to the extent practicable.

Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date.

Electronic mail comments may be submitted to: *Hai_M._Tran@omb.eop.gov*. Please include ''A–133 Compliance Supplement—2008'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message. Comments may also be submitted via facsimile at 202–395–3952.

Comments may be mailed to Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, 725 17th Street, NW., Room 6025, New Executive Office Building, Washington, DC 20503.

Comments may also be sent via *http://www.regulations.gov*—a Federal E-Government Web site that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type ''A-133 Compliance Supplement-2008'' (in quotes) in the Comment or Submission search box, click Go, and follow the instructions for submitting comments. Comments received by the date specified above will be included as part of the official record.

ADDRESSES: Copies of the 2008 Supplement may be purchased at any Government Printing Office (GPO) bookstore (stock number: 041–001–00658–3). The main GPO bookstore is located at 710 North Capitol Street, NW., Washington, DC 20401, (202) 512–0132. A copy may also be obtained under the Grants Management heading from the OMB home page on the Internet at *http://www.whitehouse.gov/omb/grants/grants_circulars.html*.

FOR FURTHER INFORMATION CONTACT: Recipients should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate under the circumstances. Subrecipients should contact their pass-through entity. Federal agencies should contact Gilbert Tran, Office of Management and Budget, Office of Federal Financial Management, at (202) 395–3052.

Danny Werfel,

Deputy Controller.

[FR Doc. E8–12561 Filed 6–4–08; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–28291]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

May 30, 2008.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of May 2008. A copy of each application may be obtained for a fee at the SEC's Public Reference Branch (tel. 202–551–5850). An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 24, 2008, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Office of Investment Company Regulation, 100 F Street, NE., Washington, DC 20549–4041.

The Provident Riverfront Funds

[File No. 811–6082]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 12, 2004, applicant transferred its assets to Allegiant Funds (formerly known as Armada Funds), based on net asset value. Expenses of approximately $526,430 incurred in connection with the reorganization were paid by the acquiring fund and Allegiant Asset Management Company (formerly known as National City Investment Management Company) the acquiring fund's investment adviser.

Filing Date: The application was filed on May 9, 2008.

Applicant's Address: 5800 Corporate Dr., Pittsburgh, PA 15237–7010.

Oppenheimer Growth Fund

[File No. 811–2306]

Oppenheimer Enterprise Fund

[File No. 811–7265]

Summary: Each applicant seeks an order declaring that it has ceased to be an investment company. On November 8, 2007 and December 7, 2007, respectively, applicants transferred their assets to Oppenheimer Capital Appreciation Fund, based on net asset value. Expenses of $116,749 and

$68,933, respectively, incurred in connection with the reorganizations were paid by each applicant.

Filing Dates: The applications were filed on May 6, 2008 and May 7, 2008, respectively.

Applicants' Address: 6803 S. Tucson Way, Centennial, CO 80112.

X Exchange-Traded Funds, Inc.

[File No. 811–22053]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on April 1, 2008, and amended on May 12, 2008.

Applicant's Address: 420 Lexington Ave., Suite 2550, New York, NY 10170.

Prudential Tax-Free Money Fund, Inc. (DBA Dryden Tax-Free Money Fund)

[File No. 811–2927]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On April 7, 2008, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $14,340 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on April 21, 2008.

Applicant's Address: Gateway Center Three, 100 Mulberry St., Newark, NJ 07102–4077.

RMR Real Estate Securities Fund

[File No. 811–21490]

RMR Healthcare and Real Estate Fund

[File No. 811–21510]

RMR Securities REIT

[File No. 811–21790]

RMR Healthcare Growth and Income Fund

[File No. 811–21585]

RMR Opportunity Fund

[File No. 811–21841]

RMR Preferred Dividend Fund II

[File No. 811–21807]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicants have never made a public offering of their securities and do not propose to make a public offering or engage in business of any kind.

Filing Date: The applications were filed on April 22, 2008.

Applicants' Address: 400 Centre St., Newton, MA 02458.

J.P. Morgan Series Trust

[File No. 811–7795]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On February 18, 2005, applicant transferred its assets to JPMorgan Trust I, based on net asset value. Expenses of $850,000 incurred in connection with the reorganization were paid by applicant's investment adviser, J.P. Morgan Investment Management Inc., or its affiliates.

Filing Date: The application was filed on April 28, 2008.

Applicant's Address: 245 Park Ave., New York, NY 10167.

Federated Covered Call Treasury Fund

[File No. 811–21838]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on April 30, 2008.

Applicant's Address: 5800 Corporate Dr., Pittsburgh, PA 15237–7000.

Van Eck Funds II, Inc.

[File No. 811–21046]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On December 13, 2007, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $20,000 incurred in connection with the liquidation were paid by applicant.

Filing Dates: The application was filed on April 3, 2008, and amended on April 24, 2008.

Applicant's Address: 99 Park Ave., 8th Floor, New York, NY 10016.

Morgan Stanley Government Income Trust

[File No. 811–5400]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On March 23, 2007, applicant transferred its assets to Morgan Stanley U.S. Government Securities Trust, based on net asset value. Expenses of $217,000 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on April 15, 2008, and amended on May 23, 2008.

Applicant's Address: Morgan Stanley Investment Advisors Inc., 522 Fifth Ave., New York, NY 10036.

IndexIQ™ Exchange-Traded Funds, Inc.

[File No. 811–22008]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on February 27, 2008, and amendments were filed on May 20, 2008, and May 21, 2008.

Applicant's Address: 420 Lexington Ave., Suite 2550, New York, NY 10170.

Guerite Funds

[File No. 811–21951]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On November 27, 2007, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $4,199 incurred in connection with the liquidation were paid by Guerite Advisors LLC, applicant's investment adviser.

Filing Date: The application was filed on May 20, 2008.

Applicant's Address: Guerite Advisors LLC, 347 Prado Way, Greenville, SC 29607–6512.

Credit Suisse Emerging Markets, Inc.

[File No. 811–8252]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On December 29, 2007, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $32,616 incurred in connection with the liquidation were paid by Credit Suisse Asset Management, LLC, applicant's investment adviser. Applicant has retained $4,992 in cash to pay for certain outstanding liquidation expenses.

Filing Date: The application was filed on May 15, 2008.

Applicant's Address: Credit Suisse Asset Management, LLC, Eleven Madison Ave., New York, NY 10010.

Energy Strategies Fund, Inc.

[File No. 811–21783]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make

a public offering or engage in business of any kind.

Filing Date: The application was filed on May 16, 2008.

Applicant's Address: BlackRock, Inc., 800 Scudders Mill Rd., Plainsboro, NJ 08536.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–12595 Filed 6–4–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57894; File Nos. SR–Amex–2008–15; SR–CBOE–2005–11; SR–ISE–2008–12; SR–NYSEArca–2008–52; and SR–Phlx–2008–17]

Self-Regulatory Organizations; American Stock Exchange LLC, Chicago Board Options Exchange, Incorporated, International Securities Exchange, LLC, Philadelphia Stock Exchange, Inc., and NYSE Arca, Inc.; Order Granting Approval of a Proposed Rule Change, as Modified, and Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes, as Modified, Relating to Listing and Trading Options on the SPDR Gold Trust

May 30, 2008.

On January 25, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4[2] thereunder to list and trade options on shares of the SPDR Gold Trust (formerly, the streetTRACKS Gold Trust) (''Gold Trust Options''). On April 12, 2005, CBOE submitted Amendment No. 1 to the proposed rule change. On March 7, 2008, CBOE submitted Amendment No. 2 to the proposed rule change. The proposed rule change, as amended, was published for comment in the **Federal Register** on March 17, 2008 for a 21-day comment period.[3] On May 21, 2008, CBOE submitted Amendment No. 3 to the proposed rule change.[4] This order approves the proposed rule change, as modified by Amendment Nos. 1, 2, and 3.

In addition, four other exchanges submitted proposals to list and trade Gold Trust Options. Specifically, the International Securities Exchange, LLC (''ISE'') submitted its proposal on February 7, 2008, the American Stock Exchange LLC (''Amex'') filed on February 20, 2008, the Philadelphia Stock Exchange, Inc. (''Phlx'') filed on February 28, 2008, and NYSE Arca, Inc. (''NYSE Arca'') filed on May 21, 2008 with the Commission the proposed rule changes as described in Items I and II below, which items have been prepared substantially by the Amex, ISE, NYSE Arca, and Phlx. On May 20, 2008, ISE and Phlx submitted Amendment No. 1 to their respective proposals. On May 21, 2008, ISE and Phlx submitted Amendment No. 2 to their respective proposals and Amex submitted Amendment No. 1 to its proposal. The proposals submitted by the Amex, ISE, NYSE Arca, and Phlx are substantively identical to CBOE's proposal. Pursuant to Section 19(b)(1) of the Act[5] and Rule 19b–4[6] thereunder, the Commission is publishing this notice to solicit comments on these four proposed rule changes, as modified, from interested persons and is approving the proposals, as modified, on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Amex, ISE, NYSE Arca, and Phlx each propose to amend certain of their respective rules to enable the listing and trading of Gold Trust Options on their markets. The text of the proposals is available at each of the respective exchanges, the Commission's Public Reference Room, and *http://www.amex.com, http://www.iseoptions.com, http://www.nysearca.com,* and *http://www.phlx.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In their filings with the Commission, the Amex, ISE, NYSE Arca, and Phlx included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item III below. These exchanges have prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organizations' Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Amex, ISE, NYSE Arca, and Phlx each state that the purpose of its proposed rule changes is to permit the listing and trading of Gold Trust Options.

Currently, the rules of these exchanges permit only certain ''Units'' (also referred to herein as exchange traded funds (''ETFs'')) to underlie options traded on their markets.[7] Specifically, to be eligible as an underlying security for options traded on the Amex, ISE, NYSE Arca, or Phlx, an ETF must represent: (i) Interests in registered investment companies (or series thereof) organized as open-end management investment companies, unit investment trusts or similar entities that hold portfolios of securities, and/or financial instruments including, but not limited to, stock index futures contracts, options on futures, options on securities and indexes, equity caps, collars and floors, swap agreements, forward contracts, repurchase agreements and reverse purchase agreements (''Financial Instruments''), and money market instruments, including, but not limited to, U.S. government securities and repurchase agreements (''Money Market Instruments'') comprising or otherwise based on or representing investments in indexes or portfolios of securities and/or Financial Instruments and Money Market Instruments (or that hold securities in one or more other registered investment companies that themselves hold such portfolios of securities and/or Financial Instruments and Money Market Instruments); or (ii) interests in a trust or similar entity that holds a specified non-U.S. currency deposited with the trust or similar entity when aggregated in some specified minimum number may be surrendered to the trust by the beneficial owner to receive the specified non-U.S. currency and pays the beneficial owner interest and other distributions on deposited non-U.S. currency, if any, declared and paid by the trust; or (iii) commodity pool interests principally engaged, directly or indirectly, in holding and/or managing portfolios or baskets of securities, commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or non-

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 57465 (March 11, 2008), 73 FR 14284.

[4] In Amendment No. 3, CBOE updated its proposed rule text to reflect the change in name, effective May 21, 2008, of the underlying trust from streetTRACKS Gold Trust to SPDR Gold Trust. This is a technical amendment and is not subject to notice and comment.

[5] 15 U.S.C. 78s(b)(1).

[6] 17 CFR 240.19b–4.

[7] *See* Amex Rule 915 Commentary .06; ISE Rule 5.2(h); NYSE Arca Rule 5.3; and Phlx Rule 1009 Commentary .06.

U.S. currency. The proposed rule change would expand the types of ETFs that may be approved for options trading on the Exchanges to include the SPDR Gold Trust.

Apart from allowing the SPDR Gold Trust to be an underlying for options traded on Amex, ISE, NYSE Arca, and Phlx as described above, the listing standards for ETFs would remain unchanged from those that apply under the current rules of these exchanges. ETFs on which options may be listed and traded would still have to be listed and traded on a national securities exchange and satisfy the other listing standards set forth in the respective rules of each of these exchanges.[8]

Specifically, in addition to satisfying the aforementioned listing requirements, Units would have to continue to: (1) Meet the criteria and guidelines under the exchanges' rules for underlying ETFs; or (2) be available for creation or redemption each business day from or through the issuer in cash or in kind at a price related to net asset value, and the issuer must be obligated to issue Units in a specified aggregate number even if some or all of the investment assets required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer, as provided in the respective prospectus.[9]

Amex, ISE, NYSE Arca, and Phlx each propose that the current continued listing standards for options on ETFs would apply to Gold Trust Options. Specifically, options on Units may be subject to the suspension of opening transactions as follows: (1) Following the initial twelve-month period beginning upon the commencement of trading of the Units, there are fewer than 50 record and/or beneficial holders of the Units for 30 or more consecutive trading days; (2) the value of the index or portfolio of securities, non-U.S. currency, or portfolio of commodities including commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or Financial Instruments and Money Market Instruments on which Units are based is no longer calculated or available; or (3) such other event occurs or condition exists that in the opinion of the exchanges makes further dealing on the exchange inadvisable.[10]

In addition, shares of the SPDR Gold Trust would not be deemed to meet the requirements for continued approval, and the Amex, ISE, NYSE Arca, and Phlx would not open for trading any additional series of option contracts of the class covering shares of the SPDR Gold Trust, if the shares of the SPDR Gold Trust cease to be an ''NMS stock'' as provided for in rules of these exchanges[11] or shares of the SPDR Gold Trust are halted from trading on their primary market.

Amex, ISE, NYSE Arca, and Phlx each represented that the addition of the SPDR Gold Trust to types of Units that may underlie listed options traded on the exchange would not have any effect on the rules pertaining to position and exercise limits[12] or margin.[13]

Amex, ISE, NYSE Arca, and Phlx also represent that the respective surveillance procedures applicable to Gold Trust Options would be similar to those applicable to all other options on ETFs currently traded on these exchanges. In addition, the Amex, ISE, NYSE Arca, and Phlx note that they may obtain information from the New York Mercantile Exchange, Inc. (''NYMEX'') through the Intermarket Surveillance Group (''ISG'') related to any financial instrument traded there that is based, in whole or in part, upon an interest in, or performance of, gold.[14]

2. Statutory Basis

Amex, ISE, NYSE Arca, and Phlx each state that amending its rules to accommodate the listing and trading of Gold Trust Options will benefit investors by providing them with valuable risk management tools. Accordingly, these exchanges believe that the proposed rule changes are consistent with the requirements of Section 6(b) of the Act[15] in general, and further the objectives of Section 6(b)(5)[16] of the Act in particular, in that they are designed to remove impediments to, and perfect the mechanism of, a free and open market in a manner consistent with the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

Amex, ISE, NYSE Arca, and Phlx each believe that the proposed rule changes will not 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

Amex, ISE, NYSE Arca, and Phlx each state that no written comments were solicited or received with respect to the proposed rule changes.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule changes are 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 Nos. SR–Amex–2008–15; SR–ISE–2008–12; SR–NYSEArca–2008–52; and SR–Phlx–2008–17 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 Numbers SR–Amex–2008–15; SR–ISE–2008–12; SR–NYSEArca–2008–52; and SR–Phlx–2008–17. 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

[8] *See* Amex Rule 916 Commentary .07; ISE Rule 502(h); NYSE Arca Rule 5.3(g); and Phlx Rule 1009 Commentary .06.

[9] *See* Amex Rule 915 Commentary .06; ISE Rule 502(h)(A)–(B); NYSE Arca Rule 5.3(g)(1)(A)–(B); and Phlx Rule 1009 Commentary .06.

[10] *See* Amex Rule 916 Commentary .07; ISE Rule 503(h); NYSE Arca Rule 5.4(k); and Phlx Rule 1010 Commentary .08.

[11] *See* Amex Rule 916 Commentary .07; ISE Rule 503(h); NYSE Arca Rule 5.4(b); and Phlx Rule 1010.

[12] *See* Amex Rules 904 and 905; ISE Rules 412 and 414; NYSE Arca Rules 6.8 and 6.9; and Phlx Rules 1001 and 1002.

[13] *See* Amex Rule 462; ISE Rule 1202; NYSE Arca Rules 4.15 and 4.16; and Phlx Rule 722.

[14] The Commission noted a surveillance arrangement between the New York Stock Exchange, Inc. and NYMEX in its order approving proposed rule changes to permit the listing and trading of shares of the SPDR Gold Trust. *See* Securities Exchange Act Release No. 50603 (October 28, 2004), 69 FR 64614 (November 5, 2004) (SR–NYSE–2004–22).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

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 available publicly. All submissions should refer to File Numbers SR–Amex–2008–15; SR–ISE–2008–12, SR–NYSEArca–2008–52; and SR–Phlx–2008–17 and should be submitted on or before June 26, 2008.

IV. Commission Findings

After careful consideration, the Commission finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange [17] and, in particular, the requirements of Section 6 of the Act.[18] Specifically, the Commission finds that the proposed rule changes are consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the rules of a national securities exchange be designed 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. In accordance with the Memorandum of Understanding entered into between the Commodity Futures Trading Commission (''CFTC'') and the Commission on March 11, 2008, and in particular the addendum thereto concerning Principles Governing the Review of Novel Derivative Products, the Commission believes that novel derivative products that implicate areas of overlapping regulatory concern should be permitted to trade in either or both a CFTC-or Commission-regulated environment, in a manner consistent with laws and regulations (including the appropriate use of all available exemptive and interpretive authority).

As national securities exchanges, each of Amex, CBOE, ISE, NYSE Arca, and Phlx is required under Section 6(b)(1) of the Act [20] to enforce compliance by its members, and persons associated with its members, with the provisions of the Act, Commission rules and regulations thereunder, and its own rules. In addition, brokers that trade Gold Trust Options will also be subject to best execution obligations and FINRA rules.[21] Applicable exchange rules also require that customers receive appropriate disclosure before trading Gold Trust Options.[22] Further, brokers opening accounts and recommending options transactions must comply with relevant customer suitability standards.[23]

Gold Trust Options will trade as options under the trading rules of each of the exchanges. These rules, among other things, are designed to avoid trading through better displayed prices for Gold Trust Options available on other exchanges and, thereby, satisfy each exchange's obligation under the Options Intermarket Linkage Plan.[24] Series of the Gold Trust Options will be subject to exchange rules regarding continued listing requirements, including standards applicable to the underlying SPDR Gold Trust. Shares of the SPDR Gold Trust must continue to be traded through a national securities exchange or through the facilities of a national securities association, and must be ''NMS stock'' as defined under Rule 600 of Regulation NMS.[25] In addition, the underlying shares must continue to be available for creation or redemption each business day from or through the issuer in cash or in kind at a price related to net asset value.[26] If the SPDR Gold Trust shares fail to meet these requirements, the exchanges will not open for trading any new series of Gold Trust Options.

The Amex, CBOE, ISE, NYSE Arca, and Phlx have all represented that they have surveillance programs in place for the listing and trading of options based on the SPDR Gold Trust. For example, these exchanges may obtain trading information via the ISG from the NYMEX related to any financial instrument traded there that is based, in whole or in part, upon an interest in, or performance of, gold. Additionally, the listing and trading of Gold Trust Options will be subject to the exchanges' rules pertaining to position and exercise limits [27] and margin.[28]

In addition, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[29] for approving the proposed rule changes of the Amex, ISE, Phlx, and NYSE Arca prior to the thirtieth day after the date of publication of notice in the **Federal Register**. The Commission notes that proposals of the Amex, ISE, Phlx, and NYSE Arca are substantively identical to the CBOE proposal, which was published for a 21-day comment period and generated no comments. Therefore, the Commission does not believe that the proposals of the Amex, ISE, Phlx, and NYSE Arca raise any new regulatory issues different from that of the CBOE proposal. Accordingly, the Commission finds that there is good cause, consistent with Section 6(b)(5) of the Act,[30] to approve the proposals by Amex, ISE, NYSE Arca, and Phlx on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[31] that the proposed rule change (SR–CBOE–2005–11), as modified, be and is hereby approved and that the proposed rule changes (SR–SR–Amex–2008–15; SR–ISE–2008–12, SR–NYSEArca–2008–52; and SR–Phlx–2008–17), as modified, be, and are hereby approved on an accelerated basis.

By the Commission.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–12520 Filed 6–4–08; 8:45 am]

BILLING CODE 8010–01–P

[17] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f.

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78f(b)(1).

[21] *See* FINRA Rule 2320.

[22] *See* Amex Rule 926; CBOE Rule 9.15; ISE Rule 616; NYSE Arca Rule 9.18(g); and Phlx Rule 1029.

[23] *See* FINRA Rules 2860, 2860–2 and 2310; Amex Rule 923; CBOE Rules 9.7 and 9.9; ISE Rules 608 and 610; NYSE Arca Rule 918(b)–(c); and Phlx Rules 1024 and 1026.

[24] *See* Amex Rule 942; CBOE Rule 6.83; ISE Rule 1902; NYSE Arca Rule 6.94; and Phlx Rule 1085. Specifically, each of the exchanges is a participant in the Options Intermarket Linkage Plan.

[25] 17 CFR 242.600.

[26] *See* Amex Rule 915 Commentary .06, Interpretation and Policy .06 to CBOE Rule 5.3; ISE Rule 502(a)–(b); NYSE Arca Rule 5.3(a)–(b); and Phlx Rule 1009 Commentary .06.

[27] *See* Amex Rules 904 and 905; CBOE Rules 4.11 and 4.12; ISE Rules 412 and 414; NYSE Arca Rules 6.8 and 6.9; and Phlx Rules 1001 and 1002.

[28] *See* Amex Rule 462; CBOE Rule 12.3; ISE Rule 1202; NYSE Arca Rules 4.15 and 4.16; and Phlx Rule 722. *See also* FINRA Rules 2860 and 2860–1.

[29] 15 U.S.C. 78s(b)(2).

[30] 15 U.S.C. 78s(b)(5).

[31] 15 U.S.C. 78s(b)(2).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57887; File No. SR–BSE–2008–31]

Self-Regulatory Organizations; Boston Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Exchange Fees and Charges

May 30, 2008.

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 May 28, 2008, the Boston Stock Exchange, Inc. (''BSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

BSE proposes to amend the Fee Schedule of the Boston Options Exchange facility (''BOX'') to modify the fees and credits associated with the Liquidity Make or Take Pricing Structure. While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange designated the changes operative for June 2, 2008. The text of the proposed rule change is available at BSE, the Commission's Public Reference Room, and *http://www.bse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 7 of the BOX Fee Schedule [5] to introduce Tier 1 and Tier 2 pricing for the Liquidity Make or Take Pricing Structure.[6] The proposed rule change will reduce the fees and credits that the Exchange charges and applies to transactions in the iShares Russell 2000® Index Fund (''IWM''), Powershares® QQQ Trust Series 1 (''QQQQ''), and the Standard & Poor's Depositary Receipts® (''SPY'') (collectively referred to as ''Tier 2 Classes'') by fifteen cents ($0.15). Under the proposal, Tier 2 Class transactions subject to the Liquidity Make or Take Pricing Structure will have a thirty cent ($0.30) fee and fifteen cent ($0.15) credit for Market Makers and thirty cent ($0.30) fee and ten cent ($0.10) credit for a firm or Public Customer. This will maintain the current fee/credit differential applied to each account type within the Liquidity Make or Take Pricing Structure, namely, fifteen cents ($0.15) for a Market Maker and twenty cents ($0.20) for a firm or Public Customer. Fees and credits for the proposed Tier 1 Classes will remain at the levels currently applied to transactions subject to the Liquidity Make or Take Pricing structure.[7] Tier 1 pricing will continue to apply to all classes that currently participate in the Penny Pilot,[8] other than the aforementioned Tier 2 Classes.

Tier 2 Classes are among the most liquid and most actively traded options on BOX. Due to the vast liquidity in the Tier 2 Classes, BOX's cost to trade these classes is less than the costs of other classes traded on BOX. The Exchange believes that such lower costs should therefore result in decreased fees for trading in these Tier 2 Classes.

Furthermore, BOX proposes to distribute a complete list of the classes included in Tier 1 and Tier 2 pricing to participants via Regulatory Circular. The Exchange believes that distributing a Regulatory Circular containing the Tier 1 and Tier 2 Classes is the best method of notifying and informing Participants of the relevant pricing structure.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[9] in general, and Section 6(b)(4) of the Act,[10] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

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 proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A)(ii)[11] of the Act and Rule 19b–4(f)(2)[12] thereunder, because it establishes or changes a due, fee, or other charge applicable only to a member imposed by the Exchange. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] The BOX Fee Schedule can be found on the BOX Web site at *http://www.bostonoptions.com.*

[6] Capitalized terms not otherwise defined herein shall have the meanings set forth in the BOX Rules.

[7] Pursuant to the BOX Fee Schedule, Market Makers are currently subject to a forty-five cent ($0.45) charge and receive a thirty cent ($.0.30) credit. Firms and Public Customers are subject to a forty-five cent ($0.45) charge and a twenty-five cent ($0.25) credit.

[8] The rules pertaining to the Penny Pilot Program on BOX can be found in Section 33 of Chapter V of the BOX Rules. The Exchange has notified Participants of the classes included within the Penny Pilot Program via Regulatory Circular. See Boston Options Exchange Regulation LLC Regulatory Circular 2008–06.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

[12] 17 CFR 240.19b–4(f)(2).

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–BSE–2008–31 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-BSE–2008–31. 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 such filing will also 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 No. SR-BSE–2008–31 and should be submitted on or before June 26, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–12481 Filed 6–4–08; 8:45 am]

BILLING CODE 8010–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57883; File No. SR–CBOE–2008–53]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Proposed Rule Change To Amend the Exchange's Rules Pertaining to the Imposition of Fines for Minor Rule Violations

May 29, 2008.

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 May 19, 2008, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the CBOE. 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 CBOE Rule 17.50, ''Imposition of Fines for Minor Rule Violations,'' to revise the provisions of CBOE Rule 17.50(g)(1) ''Violations of Position Limits Rules.'' The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/Legal*), at the CBOE'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 Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to increase and strengthen the sanctions imposed pursuant to its Minor Rule Violation Plan (''MRVP'') in connection with any member or customer who exceeds the Exchange's position limit in accordance with CBOE Rule 4.11. The Exchange believes that increasing the fine levels specified; consolidating individual members, member organizations, and customers into one category; and lengthening the surveillance period from a 12-month period to a rolling 24-month period will serve as an effective deterrent to such violative conduct.

In addition, the Exchange, as a member of the Intermarket Surveillance Group (''ISG''), as well as certain other self-regulatory organizations (''SROs'') on October 29, 2007 executed and filed with the Commission a final version of an Agreement pursuant to Section 17(d) of the Act (the ''17d–2 Agreement'').[3] The members of the ISG intend to enter into an amendment to the 17d–2 Agreement in the near future concerning the surveillance and sanctions of position limit violations. As such, the SROs have agreed that their respective rules concerning position limits regarding options contracts are common rules. As a result, the proposal to amend the CBOE's MRVP will further result in consistency in sanctions among the SROs that are signatories to the 17d–2 Agreement and the forthcoming amendment concerning position limit violations.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5) of the Act,[5] in particular, in that it is designed to 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, to protect investors and the public interest. Specifically, the Exchange believes that the proposed rule change will strengthen its ability to carry out its oversight responsibilities as

[3] *See* letter to Richard Holley, Senior Special Counsel, Division of Trading and Markets, Commission, from Nyieri Nazarian, Assistant General Counsel, American Stock Exchange LLC, dated October 29, 2007.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

an SRO and reinforce its surveillance and enforcement functions. Additionally, the Exchange believes that the proposed rule change will promote consistency in minor rule violations and respective SRO reporting obligations as set forth pursuant to Rule 19d–1(c)(2) under the Act,[6] which governs minor rule violation plans.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE 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 on the proposed rule change.

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 Exchange 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–CBOE–2008–53 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–CBOE–2008–53. 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 CBOE. 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–CBOE–2008–53 and should be submitted on or before June 26, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–12482 Filed 6–4–08; 8:45 am]

BILLING CODE 8010–01–P

[6] 17 CFR 240.19d–1(c)(2).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57895; File No. SR–OCC–2008–07]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, Relating to SPDR Gold Shares

May 30, 2008.

I. Introduction

On March 7, 2008, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–OCC–2008–07 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] Notice of the proposal was published in the **Federal Register** on March 17, 2008, and was republished on April 25, 2008.[2] On May 22, 2008, OCC filed Amendment No. 1 to the proposed rule change.[3] No comment letters were received. For the reasons discussed below, the Commission is granting approval of the proposed rule change, as amended.

II. Description

The rule change helps to clarify the manner in which options and security futures on SPDR Gold Shares will be treated and cleared by adding an interpretation to the definition of ''fund share'' in Article I, Section 1 of OCC's By-Laws.[4] Under the interpretation, OCC will clear and treat as securities options any option contracts on SPDR Gold Shares, which are traded on securities exchanges. Similarly, OCC will clear and treat as security futures any futures contracts on SPDR Gold Shares.[5]

In its capacity as a ''derivatives clearing organization'' registered with the Commodity Futures Trading Commission (''CFTC''), OCC also filed the proposed rule change with the CFTC for prior approval by the CFTC pursuant to provisions of the Commodity Exchange Act (''CEA'').[6]

III. Discussion

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[7] By amending its By-Laws to help clarify that options and security

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release Nos. 57466 (March 11, 2008), 73 FR 14297 and 57695 (April 21, 2008), 73 FR 22452. The Commission republished notice of the proposed rule change in order to add footnote 6 to Section IV, Solicitation of Comments.

[3] Although the proposed rule change was amended after it was noticed for comment in the **Federal Register**, republication of the notice is not necessary because the post-notice amendment made only a technical change to reflect that streetTRACKS Gold Trust has been re-named SPDR Gold Trust.

[4] The new interpretation replaces the interpretation that was added to OCC's By-Laws by File No. SR–OCC–2008–04, which was effective upon filing. At the request of the Commission, OCC withdrew SR–OCC–2008–04 from consideration by the Commission in conjunction with the submission of this filing, SR–OCC–2008–07.

[5] The exact language of the interpretation can be found at *http://www.optionsclearing.com/publications/rules/proposed_changes/sr_occ_08_07.pdf*.

[6] OCC's filing with the CFTC can be found at *http://www.cftc.gov/stellent/groups/public/@rulesandproducts/documents/ifdocs/rul030708occ001.pdf*.

[7] 15 U.S.C. 78q–1(b)(3)(F).

futures on SPDR Gold Shares will be treated and cleared as securities options or security futures, OCC's proposed rule change should help clarify the jurisdictional status of such contracts and accordingly should help to promote the prompt and accurate clearance and settlement of securities transactions. In accordance with the Memorandum of Understanding entered into between the CFTC and the Commission on March 11, 2008, and in particular the addendum thereto concerning Principles Governing the Review of Novel Derivative Products, the Commission believes that novel derivative products that implicate areas of overlapping regulatory concern should be permitted to trade in either or both a CFTC- or Commission-regulated environment, in a manner consistent with laws and regulations (including the appropriate use of all available exemptive and interpretive authority).

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.[8]

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–2008–07), as modified by Amendment No. 1, be and hereby is approved.

By the Commission.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–12519 Filed 6–4–08; 8:45 am]

BILLING CODE 8010–01–P

[8] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11256 and #11257]

Arkansas Disaster Number AR–00020

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Arkansas (FEMA–1758–DR), dated 05/20/2008.

Incident: Severe Storms, Flooding, and Tornadoes.

Incident Period: 05/02/2008 and continuing.

DATES: *Effective Date:* 05/23/2008.

Physical Loan Application Deadline Date: 07/21/2008.

EIDL Loan Application Deadline Date: 02/20/2009.

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 Presidential disaster declaration for the State of Arkansas, dated 05/20/2008 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Arkansas, Phillips.

Contiguous Counties: (Economic Injury Loans Only):

Arkansas: Desha, Lincoln, Monroe.

Mississippi, Bolivar, Coahoma.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12533 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11206 and #11207]

Arkansas Disaster Number AR–00018

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 8.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Arkansas (FEMA–1751–DR) , dated 03/28/2008.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 03/18/2008 through 04/28/2008.

DATES: *Effective Date:* 05/22/2008.

Physical Loan Application Deadline Date: 06/27/2008.

EIDL Loan Application Deadline Date: 12/29/2008.

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 Presidential disaster declaration for the State of Arkansas, dated 03/28/2008 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Perry.

All other counties contiguous to the above named primary county have previously been declared.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12536 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11269 and #11270]

Florida Disaster # FL–00034

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Florida dated 05/30/2008.

Incident: Wildland Fires.

Incident Period: 05/11/2008 through 05/13/2008.

Effective Date: 05/30/2008.

Physical Loan Application Deadline Date: 07/29/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 03/02/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Brevard.

Contiguous Counties:

Florida Indian River, Orange, Osceola,

Seminole, Volusia.

The Interest Rates are:

	Percent
Homeowners With Credit Available Elsewhere	5.375
Homeowners Without Credit Available Elsewhere	2.687
Businesses With Credit Available Elsewhere	8.000
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses And Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11269 5 and for economic injury is 11270 0.

The States which received an EIDL Declaration # are Florida.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008).

Dated: May 30, 2008.

Steven C. Preston,

Administrator.

[FR Doc. E8–12637 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11254]

Maine Disaster Number ME–00012

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Maine (FEMA–1755–DR), dated 05/14/2008.

Incident: Severe Storms and Flooding.

Incident Period: 04/28/2008 through 05/14/2008.

DATES: *Effective Date:* 05/23/2008

Physical Loan Application Deadline Date: 07/14/2008.

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, 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 Maine, dated 5/14/2008, is hereby amended to include the following areas as adversely affected by the disaster.

Primary County: Penobscot.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12568 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11237 and #11238]

Mississippi Disaster Number MS–00018.

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Mississippi (FEMA–1753–DR) , dated 05/08/2008.

Incident: Severe Storms and Flooding.

Incident Period: 03/20/2008 and continuing through 05/19/2008.

DATES: *Effective Date:* 05/19/2008.

Physical Loan Application Deadline Date: 07/07/2008.

EIDL Loan Application Deadline Date: 02/03/2009.

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 Mississippi, dated 05/08/2008 is hereby amended to establish the incident period for this disaster as beginning 03/20/2008 and continuing through 05/19/2008.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12532 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11266 and #11267]

Mississippi Disaster # MS–00016

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Mississippi (FEMA–1764–DR), dated 05/28/2008.

Incident: Severe Storms and Tornadoes.

Incident Period: 04/04/2008.

DATES: *Effective Date:* 05/28/2008.

Physical Loan Application Deadline Date: 07/28/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 03/02/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 05/28/2008, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Hinds.

Contiguous Counties (Economic Injury Loans Only):

Mississippi: Claiborne, Copiah, Madison, Rankin, Simpson, Warren, Yazoo.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	5.500.
Homeowners Without Credit Available Elsewhere	2.750.
Businesses With Credit Available Elsewhere	8.000.
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250.
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000.
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000.

The number assigned to this disaster for physical damage is 11266C and for economic injury is 112670.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12569 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11203 and #11204]

Missouri Disaster Number MO–00025.

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 Missouri (FEMA–1749–DR), dated 03/27/2008.

Incident: Severe Storms and Flooding.

Incident Period: 03/17/2008 through 05/09/2008.

DATES: *Effective Date:* 05/28/2008.

Physical Loan Application Deadline Date: 06/26/2008.

EIDL Loan Application Deadline Date: 12/23/2008.

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 Missouri, dated 03/27/2008 is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 06/26/2008.

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. E8–12538 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11249 and #11250]

Oklahoma Disaster Number OK–00020

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–1756–DR), dated 05/14/2008.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/10/2008 and continuing through 05/13/2008.

DATES: *Effective Date:* 05/13/2008.

Physical Loan Application Deadline Date: 07/14/2008.

EIDL Loan Application Deadline Date: 02/16/2009.

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 Oklahoma, dated 05/14/2008 is hereby amended to establish the incident period for this disaster as beginning 05/10/2008 and continuing through 05/13/2008.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12539 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11249 and #11250]

Oklahoma Disaster Number OK–00020

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–1756–DR), dated 05/14/2008.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/10/2008 and continuing.

DATES: *Effective Date:* 05/23/2008.

Physical Loan Application Deadline Date: 07/14/2008.

EIDL Loan Application Deadline Date: 02/16/2009.

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 Presidential disaster declaration for the State of Oklahoma, dated 05/14/2008 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Craig, Latimer, Pittsburg.

Contiguous Counties (Economic Injury Loans Only):

Oklahoma: Atoka, Coal, Haskell, Hughes, Le Flore, Mayes, Mcintosh, Nowata, Pushmataha, Rogers.

Kansas: Labette.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12540 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11268]

South Dakota Disaster # SD–00016

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of South Dakota (FEMA–1759–DR), dated 05/22/2008.

Incident: Severe Winter Storm and Record and Near Record Snow.

Incident Period: 05/01/2008 through 05/02/2008.

DATES: *Effective Date:* 05/22/2008.

Physical Loan Application Deadline Date: 07/21/2008.

ADDRESSES: Submit completed loan applications to : U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 05/22/2008, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Bennett, Butte, Harding, Jackson, Perkins.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses And Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11268.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–12567 Filed 6–4–08; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Clark County, WA

AGENCY: Federal Highway Administration (FHWA), USDOT.

ACTION: Notice of Intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Federal Highway Administration is issuing this notice to advise the public and Indian Tribes that an Environmental Impact Statement (EIS) will be prepared for the proposed SR 502 Corridor Widening Project in Clark County, Washington.

DATES: Written comments on the purpose and need, scope of alternatives, and impacts to be considered in the EIS must be received no later than June 10, 2008, and must be sent to the Washington State Department of Transportation (WSDOT) at the address indicated below.

Scoping Meeting Date: One public information meeting will be held on May 20, 2008, 4 p.m–7 p.m at the Cherry Grove Friends Church, 9100 NE 219th Street, Battle Ground, Washington.

Oral and written comments may be given at the public meeting. This and all other public meetings will be accessible to persons with disabilities who may also request this information be prepared and supplied in alternate formats by calling Chris Tams at (360) 759–1310 or 1(866) 279–0730 at least 48-hours in advance of the meeting for WSDOT to make the necessary arrangements. Persons who are deaf or hard of hearing may access Washington State Telecommunications Relay Service by dialing 7–1–1 and asking to be connected to (360) 759–1310.

ADDRESSES: Comments or questions concerning this proposal will be accepted at the public meeting or can be sent to Chris Tams, Area Engineer, Washington State Department of Transportation Southwest Region, P.O. Box 1709, Vancouver, WA 98668–1709; by Fax at (360) 905–2062; or by e-mail to *SWGorge@wsdot.wa.gov.*

FOR FURTHER INFORMATION CONTACT: Dean Moberg, Federal Highway Administration, 711 S. Capitol Way, Suite 501, Olympia, WA 98501, Telephone: (360) 534–9344 (direct) or (360) 753–9480 (general). Additional information on the SR 502 Corridor Widening Project can be found on the project Web site at: *http://www.wsdot.wa.gov/Projects/SR502/Widening/.*

SUPPLEMENTARY INFORMATION:

Proposed Action Background

The FHWA and WSDOT will prepare an EIS on the proposed widening of the SR 502 Corridor (NE 219th Street) in north Clark County from a two-lane roadway to a four-lane roadway with a median barrier separating westbound and eastbound travel. The SR 502 Corridor Widening is proposed between NE 15th Avenue and NE 102nd Avenue, for a length of approximately 5 miles. The project also proposes to construct paved shoulders for pedestrian and bicycle use, stormwater facilities, and three new signalized intersections on SR 502 at NE 29th Avenue, NE 50th Avenue, and NE 92 Avenue in addition to the existing signalized intersection on SR 502 at NE 72nd Avenue (Dollars Corner). These improvements are proposed to address the current and future deficiencies related to mobility and safety on the SR 502 corridor.

The SR 502 Corridor Widening Project began as an Environmental Assessment (EA) in early 2007. One agency scoping meeting and one public scoping meeting were held on February 22, 2007, to identify issues and concerns as well as provide input into establishing a range of alternatives for the project. A wide range of alternatives were considered between February and September 2007. Six ''on-corridor'' alternatives, including widening the existing facility directly to either the north or south of the existing facility, or equally on both sides from the centerline, were studied. Additionally, two ''off-corridor'' alternatives, which considered constructing a new roadway for SR 502 further north or south of the existing corridor, were studied. Four public open house meetings were held to gather public input on the range of alternatives being considered for the project on: March 27, 2007; May 9, 2007; June 14, 2007; and September 27, 2007. These public meetings resulted in strong public support for one ''on corridor'' alternative, which was forwarded for further detailed environmental study along with the no action alternative. As draft environmental discipline studies of the possible effects of the potential alternatives were conducted, it was determined that the widening of the SR 502 corridor may substantially affect the quality of the human and natural environment and may benefit from a more detailed analysis. Therefore, the FHWA and WSDOT elected to prepare an ETS.

Alternatives

The EIS will address, at a minimum, the no action alternative and the following action alternative:

On-corridor Widening Alternative: This alternative would widen the existing SR 502 facility to four general purpose travel lanes from just west of NE 15th Avenue to NE 102nd Avenue. Along the entire SR 502 corridor, two lanes would be constructed in each direction with a median barrier separating westbound and eastbound travel between the four signalized intersections at NE 29th Avenue, NE 50th Avenue, NE 72nd Avenue (Dollars Corner), and NE 92nd Avenue. Paved shoulders that could be used by pedestrians and bicyclists would also be constructed the length of the corridor. Curb and sidewalk would accommodate additional pedestrian travel through the Dollars Corner rural commercial center between roughly NE 67th Avenue and the 7600 block of SR 502. Except at the four signalized intersections, turns to and from SR 502 would be restricted to right-in/right-out turning movements. Stormwater treatment facilities would

collect, detain, treat, and discharge stormwater runoff from new impervious surface that results from the roadway widening.

Probable Effects

The FHWA and WSDOT will evaluate all transportation, environmental, social, and economic effects of the alternatives. Potential areas of impact include: Natural and cultural resources; land use; social and economic elements; and, traffic and noise. All effects will be evaluated for both the construction period and the long-term period of operation. Indirect and cumulative impacts will also be evaluated. Measures to avoid, minimize, and mitigate any significant effects will be developed.

Scoping

Agency Coordination: The project sponsors are working with the local, state and federal resource agencies to implement regular opportunities for coordination during the National Environmental Policy Act (NEPA) process. This process will comply with SAFETEA–LU section 6002.

Tribal Coordination: The formal Tribal government consultation will occur through government-to-government collaboration.

The date and address of the public scoping meeting is given in the **DATES** section above. The WSDOT assures full compliance with Title VI of the Civil Rights Act of 1964 by prohibiting discrimination based on race, color, national origin and sex in the provision of benefits and services. For language interpretation services please contact Chris Tams at (360) 759–1310 or 1 (866) 279–0730. For information on the WSDOT Title VI Program, please contact the Title VI Coordinator at (360) 705–7098.

To ensure that a full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from interested parties. Comments or questions concerning this proposal will be accepted at the public meeting or may be sent to the Washington State Department of Transportation Southwest Region at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal Programs and activities apply to this program.)

Issued on May 28, 2008.

Ingrid Allen,

FHWA Team Leader, Olympia.

[FR Doc. E8–12307 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Informational Filing

In accordance with Section 236.913 of Title 49 of the Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received an informational filing from the Northeast Illinois Regional Commuter Railroad Corporation (Metra) to permit field testing of the railroad's processor-based train control system. The informational filing is described below, including the requisite docket number where the informational filing and any related information may be found. The document is also available for public inspection; however, FRA is not accepting public comments.

Northeast Illinois Regional Commuter Railroad Corporation

[Docket Number FRA–2008–0057]

Metra has submitted an informational filing to permit field testing of the railroad's processor-based train control system identified as Electronic Train Management System (ETMS). The informational filing addresses the requirements under 49 CFR 236.913(j)(1).

Specifically, the informational filing contains a description of the ETMS product and an operational concepts document, pursuant to 49 CFR 236.913(j)(1). The ETMS is a locomotive-centric, non-vital system designed to be overlaid on existing methods of operation and to provide an improved level of railroad safety through enforcement of a train's authority limits and both permanent and temporary speed restrictions. An associated temporary waiver petition has also been submitted to support field testing of Metra's ETMS pursuant to 49 CFR Sections 211.7 and 211.51, and can be found in the same docket as this informational filing (FRA–2008–0057).

Metra desires to commence field testing on or about July 1, 2008, or as soon as practicable thereafter, contingent upon FRA's acceptance and approval of their informational filing. Metra intends to test and develop ETMS on its Rock Island District between Chicago, IL and Joliet, IL.

Interested parties are invited to review the informational filing and associated documents at DOT's Docket Management facility during regular business hours (9 a.m.–5 p.m.) at 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590. All documents in the public docket are available for inspection and copying on the internet at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications received into any of our dockets by name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC on May 30, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–12545 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received a request for temporary waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, and the nature of the relief being requested.

Northeast Illinois Regional Commuter Railroad Corporation

[Docket Number FRA–2008–0057]

The Northeast Illinois Regional Commuter Railroad Corporation (Metra) has submitted a temporary waiver petition to support field testing of its processor-based train control system, identified as Electronic Train Management System (ETMS), pursuant to 49 CFR Sections 211.7 and 211.51.

An informational filing, as required under 49 CFR Part 236, Subpart H, has also been prepared and submitted in conjunction with this waiver petition, and can be found in the same docket as this waiver petition (FRA–2008–0057).

ETMS is a locomotive-centric, non-vital system, designed to be overlaid on

existing methods of operation and to provide an improved level of railroad safety through enforcement of a train's authority limits and both permanent and temporary speed restrictions. Metra desires to commence field testing on or about July 1, 2008, or as soon as practicable thereafter, contingent upon FRA's acceptance and approval of the associated informational filing and this waiver petition. Metra intends to test and develop ETMS on its Rock Island District between Chicago, IL, and Joliet, IL.

Metra is seeking regulatory relief for development testing and demonstration purposes only. Specifically, Metra is requesting regulatory relief from the following FRA requirements:

- 49 CFR 216.13 (Special Notice for Repairs—Locomotive);
- 49 CFR 217.9 (Program of Operational Tests and Inspections—Recordkeeping);
- 49 CFR 217.11 (Program of Instruction on Operating Rules—Recordkeeping, Electronic Recordkeeping);
- 49 CFR Part 218, Subpart D (Prohibition against Tampering with Safety Devices);
- 49 CFR 229.7 (Prohibited Acts);
- 49 CFR 229.135 (Event Recorders);
- 49 CFR 233.9 (Reports);
- 49 CFR 235.5 (Changes Requiring Filing of Application);
- 49 CFR 240.127 (Criteria for Examining Skill Performance); and
- 49 CFR 240.129 (Criteria for Monitoring Operational Performance of Certified Engineers).

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. All communications concerning these proceedings should identify the appropriate docket number (Docket Number FRA–2008–0057) and may be submitted by one of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received within 30 days of the date of this notice will be considered by FRA before final action being taken. Comments received after this period will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the DOT Docket Management Facility, 1200 New Jersey Avenue, SE., Room W12–140, in Washington, DC. All documents in the public docket are also available for inspection and copying on the internet at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC on May 30, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–12544 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Privacy Act of 1974: System of Records

AGENCY: Federal Transit Administration (FTA).

ACTION: Notice to establish a system of records.

SUMMARY: DOT intends to establish a system of records under the Privacy Act of 1974. The Privacy Act of 1974, as amended, 5 U.S.C. 552a, requires that agencies that maintain a system of records publish a notice in the **Federal Register** of the existence and character of the system of records. In accordance with the Privacy Act, the Department of Transportation (DOT) is giving notice of a system of records to meet the Federal Transit Administration's (FTA's) needs for emergency contact information in case of illness or injury to its employees and contractors.

DATES: *Effective Date:* This notice will be effective, without further notice, on July 15, 2008, unless modified by a subsequent notice to incorporate comments received by the public. Comments must be received by July 7, 2008 to be assured consideration.

FOR FURTHER INFORMATION CONTACT: Habib Azarsina, Departmental Privacy Officer, S–80, United States Department of Transportation, Office of the Secretary of Transportation, 1200 New Jersey Ave, SE., Washington, DC 20590, telephone 202–366–1965 or *habib.azarsina@dot.gov.*

SUPPLEMENTARY INFORMATION: The Department of Transportation system of records notice subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, has been published in the **Federal Register** and is available from the above mentioned address.

SYSTEM NUMBER: DOT/FTA 802.

SYSTEM NAME:

The Operational Assets and Information Security (OASIS) System.

SECURITY CLASSIFICATION:

Unclassified, Non-Sensitive.

SYSTEM LOCATION:

This system of record is in the Office of Information Technology for the Department of Transportation/Federal Transit Administration, Integrated Communication Solutions data center located at 5260 Westview Drive, Frederick, MD 21703.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM OF RECORDS:

FTA employees and contractors

CATEGORIES OF RECORDS IN THE SYSTEM

Information maintained in this system consists of employee/contractor work information in the form of room number, work telephone number, and systems to which the employees have access. The system also stores employee/contractor home addresses and telephone numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

49 U.S.C. 321.

PURPOSES:

Employee/contractor personal information is encouraged in case of emergency where the individual's family may need to be reached. Input of this information is not mandatory and is provided at the individual's option. Also, no record subject is able to see the information of any other record subject.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See Prefatory Statement of General Routine Uses.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Documents are stored electronically in a SQL Server database on the internal network (behind departmental firewall).

RETRIEVABILITY:

Records are retrieved by searching on an individual's name or office symbol.

SAFEGUARDS:

OASIS is an FTA application that resides on the internal network behind the departmental firewall. Users are authenticated by their network user ID and password.

RETENTION AND DISPOSAL:

Data is kept in the system for the life of the system. Many of FTA's applications interface with OASIS and individuals who are no longer working for FTA are in an inactive status. This is necessary in order to maintain historical traceability in our applications.

SYSTEM MANAGER(S) AND ADDRESS:

Office of Information Technology (TAD–20), Federal Transit Administration, 1200 New Jersey Ave., SE., Washington, DC 20590.

NOTIFICATION PROCEDURE:

Same as ''System Manager.''

RECORD ACCESS PROCEDURES:

Same as ''System Manager.''

CONTESTING RECORD PROCEDURES:

Same as ''System Manager.''

RECORD SOURCE CATEGORIES:

Personal information is entered voluntarily by the individual at her/his own discretion for emergency procedures.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Habib Azarsina,

Departmental Privacy Officer, DOT / OST / S–83.

[FR Doc. E8–12615 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA–2008–0057]

Reports, Forms and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration, U.S. Department of Transportation.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below will be forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collections and their expected burden. A **Federal Register** Notice with a 60-day comment period was published on March 28, 2008 (73 FR 16740).

DATES: Comments must be submitted to OMB on or before July 7, 2008.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer.

FOR FURTHER INFORMATION CONTACT: Jennifer Timian, Recall Management Division (NVS–215), Room W46–324, NHTSA, 1200 New Jersey Ave., Washington, DC 20590. Telephone: (202) 366–0209.

SUPPLEMENTARY INFORMATION:

National Highway Traffic Safety Administration

Title: Defect and Noncompliance Reporting and Notification.

OMB Number: 2127–0004.

Type of Request: Revision of a currently approved information collection.

Affected Public: Businesses or individuals.

Abstract: This notice addresses NHTSA's proposed revision to approved collection of information OMB No. 2127–0004. This collection covers those requirements found within various provisions of the Motor Vehicle Safety Act of 1966 (Act), 49 U.S.C. 30101, *et seq.*, and implementing regulations found within 49 CFR parts 573 and 577, that require motor vehicle and motor vehicle equipment manufacturers to notify NHTSA and also owners, purchasers, dealers, and distributors, of safety-related defects and failures to comply with Federal Motor Vehicle Safety Standards (FMVSS) in products they manufactured. It also covers additional reporting, notification, and recordkeeping requirements related to those notifications and the ensuing free remedy programs, including the requirement(s):

- That a plan be filed explaining how the manufacturer intends to reimburse owners or purchasers who paid to remedy the defective or noncompliant product prior to its recall, and that this plan be explained in the notifications issued to owners and purchasers;
- That the manufacturer provide to NHTSA copies of communications pertaining to the recall campaign that they may issue to owners, purchasers, dealers, or distributors;
- That the manufacturer maintain a list of the owners, purchasers, dealers, and distributors it notified;
- That the manufacturer provide NHTSA with at least six quarterly reports detailing the progress of the recall campaign;
- Related to, in tire recall campaigns, the proper disposal of recalled tires, including requirements that the manufacturer submit a plan and provide certain information and instructions to certain persons (such as its dealers or retail outlets) addressing disposal, and a requirement that those persons report back deviations from that plan; and
- That any person who sells or leases a defective or noncompliant tire, knowing that the manufacturer has decided that tire is defective or noncompliant, report that sale or lease to NHTSA.

The statutory sections imposing these requirements include 49 U.S.C. 30118, 30119, 30120, and 30166. The regulatory sections implementing these statutory sections are found within 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports,* and 49 CFR 577, *Defect and Noncompliance Notification.*

NHTSA published a **Federal Register** notice providing more detailed information about this information collection's requirements and its annual burden hour and respondent calculations on March 28, 2008 (73 FR 16740). All interested persons are encouraged to review that notice for further information if needed in preparing comments.

Estimated annual burden: 21,370 hours.

Number of respondents: 175.

Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of

the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is most effective if OMB receives it within 30 days of publication.

Issued on: May 27, 2008.

Kathleen C. DeMeter,

Director, Office of Defects Investigation.

[FR Doc. E8–12491 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2007–0053]

Motley Rice, LLC, Denial of Petition for Compliance Investigation

Motley Rice, LLC (Motley Rice), counsel of record for the plaintiffs in the lawsuit styled *Day* v. *Ford Motor Company,* Civ. No. 04CVS–10181 (N.C., Guilford County), has petitioned National Highway Traffic Safety Administration (NHTSA) pursuant to 49 CFR 552.3 seeking an order finding that certain vehicles manufactured by Ford Motor Company (Ford) are not in compliance with Federal Motor Vehicle Safety Standard (FMVSS) No. 206,[1] *Door Locks and Door Retention Components.* In addition, petitioner seeks an order finding that Ford's use of the Modified Dynamic Test Method to demonstrate compliance was inappropriate or, stated alternatively, that Ford's use of the 1960 Severy acceleration pulse is not a uniform approved pulse that can be inserted into any test for the purpose of determining regulatory compliance. Petitioner asserts that the following Ford vehicles are non-compliant with FMVSS No. 206: (1) Model Year (MY) 1997–2000 F–150—PN–96, (2) MY 1997–2000 F–250—Light Duty, (3) MY 1997–2000 Ford Expedition, and (4) MY 1997–2000 Lincoln Navigator vehicles. Collectively, this notice refers to these vehicles as ''subject vehicles.''

Motley Rice contends that the identified vehicles are not in compliance with FMVSS No. 206. Specifically, the petitioner contends that the identified vehicles are not in compliance with the 30g (inertia load) requirement of FMVSS No. 206 as a result of a defect in the outside handle torsion spring. The spring tension in these handles, petitioner contends, is substantially below specification and may reduce the level for inertia activation of the system to approximately half that needed to meet the 30g calculation requirements of FMVSS No. 206 per the calculation referenced in Society of Automotive Engineers Recommended Practice J839 (SAE–J839).

Under the National Traffic and Motor Vehicle Safety Act, as amended and recodified, 49 U.S.C. 30112(a)(1), a person may not manufacture for sale or sell any motor vehicle manufactured on or after the date of an applicable motor vehicle safety standard takes effect unless the vehicle complies with the standard and is covered by a certification issued under 49 U.S.C. 30115. Except with regard to vehicles not manufactured to comply with the FMVSSs but later imported, the prohibition of section 30112(a) does not apply to the sale of a motor vehicle after the first purchase of the vehicle in good faith other than for resale. The FMVSSs generally apply to the manufacture and sale of new vehicles, as distinguished from used vehicles.

In general, NHTSA's enforcement of the FMVSSs is based on compliance testing of samples of new products conducted using the test procedures set forth in the relevant safety standard. However, manufacturers certifying compliance with FMVSSs are not required to follow exactly the compliance test procedures set forth in the applicable standard. Manufacturers are required to exercise reasonable care to assure compliance in making their certifications. 49 U.S.C. 30115(a). It may be simplest and is best for a manufacturer to establish that it exercised reasonable care if it has strictly followed NHTSA's test procedures. However, NHTSA has recognized that reasonable care might also be shown using modified procedures if the manufacturer could demonstrate that the modifications were not likely to have had a significant impact on test results. In addition, reasonable care might be shown using engineering analyses or computer simulations.

FMVSS No. 206, *Door Locks and Door Retention Components* contains a number of requirements. One is the inertia load requirement. S4.1.1.3 *Inertia Load,* provides:

> The door latch shall not disengage from the fully latched position when a longitudinal or transverse inertia load of 30g is applied to the door latch system (including the latch and its actuating mechanism with the locking mechanism disengaged).

The accompanying compliance provision states:

> S5.1.1.2. *Inertia Load.* Compliance with S4.1.1.3 shall be demonstrated by approved tests or in accordance with paragraph 6 of Society of Automotive Engineers Recommended Practice J839, *Passenger Car Side Door Latch Systems,* June 1991.

SAE–J839 paragraph 6 specifies a 30g-based calculation. Apart from the SAE calculation, the only NHTSA-approved test[2] for compliance with the transverse inertia load requirement of FMVSS No. 206 at the time the vehicles were produced was the 1967 General Motors Corporation (GM) dynamic pulse test. There, GM developed a side impact pulse in light of the 30g Federal requirement. GM used research on side impacts conducted by D. Severy in 1960 as well as some GM test data. Using the Severy and GM data, GM developed a characteristic pulse shape with a maximum value exceeding 30g and a duration from GM data. This pulse was duplicated on a sled by altering the variables of pin shape and air pressure. In a sled test using this pulse, on-board, high speed movie cameras monitoring the latch determine that unlatching does not occur.

Ford certified the subject vehicles to the inertia load requirements of FMVSS No. 206 by using the SAE–J839 calculation. According to the petition, Ford thereafter determined that compliance (to the transverse inertia load requirement) could be demonstrated by using a modified version of the 1967 GM Dynamic Pulse Test Method; Ford used a computer-simulated program that relied upon the 1960 Severy acceleration pulse.

If NHTSA were to grant the Motley Rice petition, the agency would proceed to conduct a compliance investigation that might or might not result in an order to Ford under 49 U.S.C. 30118(b). In deciding whether to open a compliance or defect investigation, NHTSA considers, among other factors, allocation of agency resources, agency priorities, and the likelihood of success in litigation that might arise from an order the agency may issue. 49 CFR 552.8. *See Center for Auto Safety* v. *Dole,* 846 F.2d 1532, 1535 (D.C. Cir. 1988).

In this case, as discussed in further detail below, Ford has a simulation

[1] Throughout this Notice, all references to FMVSS No. 206 are based on the version of the standard in effect for the applicable manufacturing dates of the subject vehicles.

[2] U.S. DOT Federal Highway Administration, National Highway Safety Bureau Letter Dated 12/22/1967, *http://isearch.nhtsa.gov/gm/67/nht67–1.26.html.*

purporting to show compliance using the approved GM test. To evaluate the compliance of the subject vehicles with FMVSS No. 206's transverse inertia load requirements based on the approved 1967 GM dynamic pulse test, NHTSA likely would test the vehicles using the approved GM test. However, the agency does not have an in-house test procedure for the 1967 GM dynamic pulse test and we likely would develop one to evaluate the latch on the subject vehicles. This effort would be time consuming, likely would involve some trials and subsequent refinements (and therefore would be expensive), and would be of no broad-based benefit to the agency.

Assuming that NHTSA were to undertake testing, there would be significant practical difficulties. The subject vehicles were sold to their first purchasers about eight or more years ago. Programmatically, NHTSA has tested new, rather than used, vehicles for compliance with FMVSSs because NHTSA's burden would be to demonstrate that the vehicle did not comply at the time of sale or offer for sale. It is extremely unlikely that new vehicles for the model years in question could be obtained. In view of these limiting circumstances, NHTSA could consider expending some of its limited funds to have a test vehicle or vehicle subassembly containing a new latch system assembly identical to the original Ford latch assembly manufactured. The specifics of the test assembly would have to be developed in conjunction with the development of the test procedure. Such an approach would be novel and might be challenged on various grounds, including whether testing was permissible and whether the test assembly replicated or was representative of latches in the subject vehicles.

Even if NHTSA decided to invest considerable resources and time in such an investigation, the agency could issue an order finding noncompliance only after giving Ford an opportunity for an administrative hearing, and the agency would have the burden of substantiating such an order in a *de novo* proceeding in Federal court. In any such proceeding, Ford likely would present its simulation analysis that used commercially available dynamic analysis software, Working Model™. Ford's Working Model™ simulation was detailed and based on the dimensional specifications of the components. The acceleration pulse used in the simulation analysis was based on the NHTSA approved GM dynamic pulse test for certification to the transverse inertia load requirements of FMVSS No. 206. The simulation analysis methodology also included conservative measures where spring forces and part masses were set to levels, based either on design or measured values, that would provide the least contribution to maintaining a latched position. The effects of friction were also eliminated since those forces would improve latch performance by tending to resist unlatching. Based on our preliminary review, NHTSA would be very unlikely to develop sufficient evidence to overcome the simulation analysis conducted by Ford. Even if NHTSA were somehow to prevail in making such a case, by the time such an order were upheld few if any of the subject vehicles would be within the 10-year age limit for a free remedy under 49 U.S.C. 30120(g).

We have also considered safety issues presented by the latches in our testing and in our database. Our review of available New Car Assessment Program (NCAP) vehicle side impact test data included results for the MY 1999 Ford F150, and MY 2000 Ford F150 extended cab. Each vehicle tested yielded the highest government safety rating of 5–Stars for side impact protection and none of the results from these tests indicated that door unlatching occurred.

Lastly, our review of consumer complaints filed with NHTSA for the model year motor vehicles identified in the subject petition yielded only two cases potentially related to inertia door opening, one of which involved a severe 50 mph rollover crash. Given the three million-plus sales volume for the subject vehicles, the number of years of exposure already experienced by these vehicles, and the low number of alleged incidents reported to the agency, it does not appear that these vehicles are experiencing performance issues in the field.

In view of the available safety-related information that does not indicate the existence of a safety problem, the plausible position taken by Ford with regard to the vehicle's compliance, the substantial resources that would be required to address this matter in detail, and the agency's need to allocate its resources carefully to address issues involving appreciable safety risks, NHTSA has concluded that no further action is warranted. Therefore, the petition is denied.

Authority: 49 U.S.C. 30162(d); delegations of authority at CFR 1.50 and 501.8.

Issued on: May 29, 2008.

Daniel C. Smith,

Associate Administrator for Enforcement.

[FR Doc. E8–12546 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[NHTSA Docket No. NHTSA–2008–0109]

Meeting Notice—Federal Interagency Committee on Emergency Medical Services

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Meeting Notice—Federal Interagency Committee on Emergency Medical Services.

SUMMARY: NHTSA announces a meeting of the Federal Interagency Committee on Emergency Medical Services to be held in Washington, DC. This notice announces the date, time and location of the meeting, which will be open to the public.

DATES: The meeting will be held on June 23, 2008, from 10 a.m. to 12 Noon.

ADDRESSES: The meeting will be held at the Department of Homeland Security (DHS), Office of Health Affairs, 1120 Vermont Avenue, NW., 4th Floor–Conference Room #1, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Drew Dawson, Director, Office of Emergency Medical Services, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., NTI–140, Washington, DC 20590; Telephone number (202) 366–9966; E-mail *Drew.Dawson@dot.gov.*

SUPPLEMENTARY INFORMATION: Section 10202 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy For Users (SAFETEA–LU), Public Law 109–59, provided that the FICEMS consist of several officials from Federal agencies as well as a State emergency medical services director appointed by the Secretary of Transportation. SAFETEA–LU directed the Administrator of NHTSA, in cooperation with the Administrator of the Health Resources and Services Administration of the Department of Health and Human Services and the Director of the Preparedness Division, Directorate of Emergency Preparedness and Response of the Department of Homeland Security, to provide administrative support to the Interagency Committee, including scheduling meetings, setting agendas, keeping minutes and records, and producing reports.

This meeting of the FICEMS will focus on addressing the requirements of SAFETEA–LU and the opportunities for collaboration among the key Federal

agencies involved in emergency medical services. The agenda will include:

- Consideration of the FICEMS Technical Working Group report and recommendations
- Evidence-based Practice Guidelines Process Conference
- Report to Congress discussion
- Briefing on and discussion of the National EMS Information System (NEMSIS)
- Reports, updates, recommendations from FICEMS members
- Report from the National EMS Advisory Council

This meeting will be open to the public. Individuals wishing to register must provide their name, affiliation, phone number, and e-mail address to Drew Dawson by e-mail at *Drew.Dawson@dot.gov* or by telephone at (202) 366–9966 no later than June 18, 2008. Pre-registration is necessary to comply with security procedures. Picture I.D. must also be provided to enter the DHS Building and it is suggested that visitors arrive 45 minutes early in order to facilitate entry.

Minutes of the FICEMS Meeting will be available to the public online through the DOT Document Management System (DMS) at: *http://www.regulations.gov* under the docket number listed at the beginning of this notice.

Issued on: June 2, 2008.

Jeffrey P. Michael,

Acting Associate Administrator for Research & Program Development.

[FR Doc. E8–12607 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2008–0103; Notice 1]

Chrysler, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

Chrysler, LLC (Chrysler) has determined that certain vehicles that it manufactured during the period of March 14, 2006 through March 20, 2008, do not fully comply with paragraph S4.3 of 49 CFR 571.110 (Federal Motor Vehicle Safety Standard (FMVSS) No. 110 *Tire Selection and Rims for Motor Vehicles With a GVWR of 4,536 Kilograms (10,000 Pounds) or Less).* Chrysler has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports.*

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Chrysler has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Chrysler's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Affected are approximately 1,886 model year 2007–2008 Jeep Wrangler right-hand drive (RHD) multipurpose passenger vehicles (MPV).

Paragraphs S4.3 of 49 CFR 571.110 requires in pertinent part that:

> S4.3 Placard. Each vehicle, except for a trailer or incomplete vehicle, shall show the information specified in S4.3 (a) through (g), and may show, at the manufacturer's option, the information specified in S4.3 (h) and (i), on a placard permanently affixed to the driver's side B-pillar. In each vehicle without a driver's side B-pillar and with two doors on the driver's side of the vehicle opening in opposite directions, the placard shall be affixed on the forward edge of the rear side door. If the above locations do not permit the affixing of a placard that is legible, visible and prominent, the placard shall be permanently affixed to the rear edge of the driver's side door. If this location does not permit the affixing of a placard that is legible, visible and prominent, the placard shall be affixed to the inward facing surface of the vehicle next to the driver's seating position. This information shall be in the English language and conform in color and format, not including the border surrounding the entire placard, as shown in the example set forth in Figure 1 in this standard. At the manufacturer's option, the information specified in S4.3 (c), (d), and, as appropriate, (h) and (i) may be shown, alternatively to being shown on the placard, on a tire inflation pressure label which must conform in color and format, not including the border surrounding the entire label, as shown in the example set forth in Figure 2 in this standard. The label shall be permanently affixed and proximate to the placard required by this paragraph. The information specified in S4.3 (e) shall be shown on both the vehicle placard and on the tire inflation pressure label (if such a label is affixed to provide the information specified in S4.3 (c), (d), and, as appropriate, (h) and (i)) may be shown in the format and color scheme set forth in Figures 1 and 2.

Chrysler stated that the noncompliance is that the required placard was installed on the passenger's side (left side) door on each of the subject RHD vehicles, not on the driver's side (right side) door or B-pillar as required by FMVSS No. 110.

Chrysler explains that the subject vehicles were sold primarily for use by rural postal carriers, since RHD makes it easier for the carriers to access mailboxes located along the right side of the roadway. The relevant portion of S4.3 of FMVSS No. 110, entitled ''Placard,'' provides as follows: ''Each vehicle, except for a trailer or incomplete vehicle, shall show the information specified in S4.3(a) through (g) * * * on a placard permanently affixed to the driver's side B-pillar. In each vehicle without a driver's side B-pillar and with two doors on the driver's side of the vehicle opening in opposite directions, the placard shall be affixed on the forward edge of the rear side door. If the above locations do not permit the affixing of a placard that is legible, visible and prominent, the placard shall be permanently affixed to the rear edge of the driver's side door.''

Chrysler further explained that the subject vehicles have placards that contain all of the tire and vehicle loading information required by the various subsections of S4.3. However, because of an inadvertent failure of the assembly plant work instructions to differentiate between RHD and left hand drive (LHD) vehicles in this respect, the placards were inadvertently affixed to the rear edge of the door on the left (passenger) side of the subject vehicles, as opposed to the driver's side door. (Chrysler notes that the subject vehicles do not have a B-pillar with a flat surface that would permit the affixing of a placard that is ''legible, visible, and prominent.'')

Chrysler states its belief that the fact that the placard required by paragraph S4.3 of the standard was affixed to the left hand door of these RHD vehicles—as opposed to the driver's side door—creates absolutely no risk to motor vehicle safety. All of the relevant tire and loading information is set forth on the placard, and therefore it is readily available to vehicle operators. Moreover, the placard is located at the place where United States drivers are used to looking for it.

Chrysler also states its belief that the operators of the subject vehicles will have almost certainly owned and driven conventional LHD vehicles, so they will have had experience in locating the tire and load information on the left side of their vehicles. And in the extremely unlikely event that an owner has difficulty locating the placard, the owner's manual provided with the subject vehicles shows the location of the placard on the left side door.

Chrysler also makes reference to several previous NHTSA inconsequential noncompliance decisions that in its opinion are similar to the instant one.

Chrysler also notes that it has not received any consumer complaints

regarding an inability to locate the placard or an unawareness of the relevant tire and loading information.

In addition, Chrysler states that it has corrected the problem that caused these errors so that they will not be repeated in future production and that it believes that because the noncompliance is inconsequential to motor vehicle safety that no corrective action is warranted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance.

Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. *By mail addressed to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

b. *By hand delivery to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. *Electronically:* by logging onto the Federal Docket Management System (FDMS) website at *http://www.regulations.gov/*. Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. Please note that we are allowing just 10 days for comment in order to expedite resolution of this matter. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: June 16, 2008.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8.

Issued on: May 29, 2008.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. E8–12548 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket ID PHMSA–RSPA–2004–19854]

Pipeline Safety: Installation of Excess Flow Valves into Gas Service Lines

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice; Issuance of Advisory Bulletin.

SUMMARY: This document advises operators of gas distribution pipeline systems of a statutory requirement for installation of excess flow valves in certain gas service lines.

FOR FURTHER INFORMATION CONTACT: Mike Israni by phone at (202) 366–4571 or by e-mail at *mike.israni@dot.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Pipeline Inspection, Protection, Enforcement, and Safety (PIPES) Act of 2006 (Pub. L. 109–468) addresses the installation of excess flow valves (EFV) in certain gas service lines. An EFV is a safety device that can terminate flow of gas through a pipeline when the flow rate exceeds its design level, such as when the pipe ruptures or is broken (e.g., by excavation damage) downstream of the valve. A service line is a small-diameter pipeline that carries gas from a distribution main (often located below city streets) to individual residences and businesses where gas is used. Thus, EFVs can protect individual gas customer properties from the consequences of a break in the service line associated with their property.

Section 9 of the PIPES Act directs PHMSA to require operators of natural gas distribution systems to install EFVs in selected service lines that are installed or entirely replaced after June 1, 2008. The requirement applies to those service lines that operate continuously throughout the year at a pressure not less than 10 pounds per square inch (psi), that are not connected to a gas stream with respect to which the operator has had prior experience of contaminants that could interfere with operation of an EFV, where the installation of an EFV is not likely to result in a loss of service or interference with required maintenance actions, and where a valve of appropriate size and performance is commercially available. The PIPES Act directs PHMSA to include this requirement in a regulation requiring that distribution pipeline system operators establish integrity management programs.

PHMSA is still working on its proposed regulation addressing distribution integrity management programs (DIMP). That regulation is complex and has taken longer than anticipated to develop. As a result, the regulation will not be in place before the June 1, 2008, deadline specified in the Act for installation of EFVs on the affected service lines. Nevertheless, gas distribution pipeline operators should be aware of the statutory requirement and are encouraged to install EFVs on service lines that are newly installed or completely replaced after June 1, 2008, and that meet the criteria specified in the PIPES Act.

II. Advisory Bulletin (ADB–08–04)

To: Operators of Gas Distribution Pipelines.

Subject: Installation of Excess Flow Valves into Gas Service Lines.

Purpose: To advise gas distribution pipeline operators of a statutory requirement to install excess flow valves in selected gas service lines.

Advisory: The Pipeline Inspection, Protection, Enforcement, and Safety (PIPES) Act of 2006 (Pub. L. 109–468) mandates that PHMSA require operators of natural gas distribution systems to install excess flow valves (EFV) on certain gas service lines. The statute directs that installation of EFVs will be required on single family residence service lines:

- That are installed or entirely replaced after June 1, 2008;
- That operate continuously throughout the year at a pressure not less than 10 psi gauge;
- That are not connected to a gas stream with respect to which the operator has had prior experience with contaminants the presence of which could interfere with the operation of an EFV, and
- For which an excess flow valve meeting the performance standards of 49 CFR 192.381 is commercially available.

The PIPES Act directs the Pipeline and Hazardous Materials Safety Administration (PHMSA) to include this requirement in a regulation addressing distribution integrity management programs (DIMP). PHMSA is working on its DIMP regulation and expects a proposed rule to be published shortly. PHMSA intends to analyze public comments and prepare a final rule in an

expeditious manner. It is apparent, however, that the final rule cannot be in place before the June 1, 2008, deadline for EFV installation that is in the Act.

PHMSA encourages all gas distribution pipeline operators to take actions to ensure that EFVs are installed on the appropriate service lines that are installed or completely replaced after June 1, 2008.

Issued in Washington, DC, on May 30, 2008.

William H. Gute,

Deputy Associate Administrator for Pipeline Safety.

[FR Doc. E8–12566 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 35143]

R.J. Corman Railroad Company/ Pennsylvania Lines Inc.—Acquisition and Operation Exemption—Line of Norfolk Southern Railway Company

R.J. Corman Railroad Company/ Pennsylvania Lines Inc. (RJCP), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire by purchase from Norfolk Southern Railway Company (NS) [1] a rail line extending between milepost 64.5 near Winburne, PA, and milepost 45.5 near Gillintown, PA, a distance of approximately 19 miles in Clearfield and Centre Counties, PA (the Snow Shoe Industrial Track).[2]

RJCP intends to operate rail service over the Eastern Segment.[3]

Based on projected revenues for the line being acquired, RJCP expects to remain a Class III rail carrier after consummation of the proposed transaction. RJCP certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier.

Because the projected annual revenues of the lines, together with RJCP's projected annual revenue, will exceed $5 million, RJCP is required, at least 60 days before an exemption is to become effective, to send notice of the transaction to the national and local offices of the labor unions with employees on the affected lines and post a copy of the notice at the workplace of the employees on the affected lines and certify to the Board that it has done so. 49 CFR 1150.42(e). However, RJCP has noted that there are no affected employees as there is no current rail line. Therefore, RJCP has filed for a waiver from the requirements of 49 CFR 1150.42(e). RJCP states in the waiver request that the track materials on the line have been removed, no rail operations have been conducted for at least 15 years, and no railroad workers have been employed on the line for at least the same period of time. RJCP's waiver request will be handled in a subsequent decision.

The Board will establish in the decision on the waiver request the earliest this transaction may be consummated. RJCP states that it intends to consummate the transaction only following approval of RJCP's petition for exemption in STB Finance Docket No. 35116.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions for stay must be filed no later than 7 days before the exemption becomes effective.

Pursuant to the Consolidated Appropriations Act, 2008, Public Law 110–161 section 193, 121 Stat. 1844 (2007), nothing in this decision authorizes the following activities at any solid waste rail transfer facility: collecting, storing, or transferring solid waste outside of its original shipping container; or separating or processing solid waste (including baling, crushing, compacting, and shredding). The term ''solid waste'' is defined in section 1004 of the Solid Waste Disposal Act, 42 U.S.C. 6903.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 35143, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Ronald A. Lane, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606–2832.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: May 30, 2008.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–12584 Filed 6–4–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[RITA 2007–27185 Paperwork Reduction Notice]

Research and Innovative Technology Administration; Agency Information Collection; Activity Under OMB Review; Report of Traffic and Capacity Statistics—The T–100 System

AGENCY: Research and Innovative Technology Administration (RITA), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, Public Law 104–13, the Bureau of Transportation Statistics invites the general public, industry and other governmental parties to comment on the continuing need for and usefulness of DOT requiring U.S. and foreign air carriers to file traffic and capacity data pursuant to 14 CFR 241.19 and Part 217, respectively. These reports are used to measure air transportation activity to, from, and within the United States.

DATES: Written comments should be submitted by August 4, 2008.

ADDRESSES: You may submit comments identified by DOT Docket ID Number

[1] NS succeeded to Consolidated Rail Corporation's (Conrail) ownership of the subject line as a result of the merger proceeding in *CSX Corp. et al.—Control—Conrail Inc. et al.,* 3 S.T.B. 196 (1998).

[2] This proceeding also is related to STB Finance Docket No. 35116, *R.J. Corman Railroad Company/ Pennsylvania Lines Inc.—Construction and Operation Exemption—in Clearfield County, PA,* in which RJCP seeks an exemption to construct and to operate over approximately 10.8 miles of abandoned Conrail right-of-way from Wallaceton Junction, at Conrail milepost 11.76, to Winburne, at milepost 64.5 (Conrail milepost 22.56), (the Western Segment), and to rebuild the track on a rail banked 9.3-mile portion of the Snow Shoe Industrial Track between milepost 64.5 near Winburne and milepost 55.2 near Gorton, PA (the Eastern Segment). RJCP takes the position that it does not need Board authority for construction with respect to the rail banked Eastern Segment and has filed a motion to dismiss that part of the construction petition for exemption that pertains to the Eastern Segment. The Western Segment connects at Wallaceton Junction with RJCP's existing rail line. Together, the Eastern and Western Segments would be operated by RJCP as the Beech Creek Branch Line.

[3] A Certificate of Interim Trail Use or Abandonment (CITU) was issued for the entire 19 miles of the Snow Shoe Industrial Track in *Conrail Abandonment of the Snow Shoe Industrial Track in Centre and Clearfield Counties, PA,* Docket No. AB–167 (Sub-No. 1004N) (ICC served Nov. 5, 1993) and remains in place. The Headwaters Charitable Trust (HCT) has been using the rail banked right-of-way as a recreational trail on an interim basis. RJCP has concurrently filed a petition in STB Docket No. AB–167 (Sub-No. 1004N), seeking vacation of the CITU with respect to the Eastern Segment. With respect to the remaining portion of the Snow Shoe Industrial track, from milepost 55.2 to milepost 45.5, RJCP states that it intends to maintain the agreement with HCT to allow continued recreational trail use.

RITA 2007–27185 by any of the following methods:

Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

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

Hand Delivery or Courier: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

Fax: 202–493–2251.

Instructions: Identify docket number, RITA 2007–27185, at the beginning of your comments, and send two copies. To receive confirmation that DOT received your comments, include a self-addressed stamped postcard. Internet users may access all comments received by DOT at *http://www.regulations.gov.* All comments are posted electronically without change or edits, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://DocketInfo.dot.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* or the street address listed above. Follow the online instructions for accessing the dockets.

Electronic Access

An electronic copy of this rule, a copy of the notice of proposed rulemaking, and copies of the comments may be downloaded at *http://www.regulations.gov*, by searching docket RITA 3 2007–27185.

FOR FURTHER INFORMATION CONTACT: Mr. Bernard Stankus, Office of Airline Information, RTS–42, Bureau of Transportation Statistics, Research and Innovative Technology Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001, Telephone Number (202) 366–4387, Fax Number (202) 366–3383 or E-mail *bernard.stankus@dot.gov.*

SUPPLEMENTARY INFORMATION:

OMB Approval No. 2138–0040.

Title: Report of Traffic and Capacity Statistics—The T–100 System.

Form No.: Schedules T–100 and T–100(f).

Type of Review: Extension of a currently approved collection.

Respondents: Certificated, Commuter and Foreign air carriers that operate to, from or within the United States.

Number of Respondents: 250.

Total Burden Per Response: 6 hours.

Total Annual Burden: 18,000 hours.

Needs and Uses:

Airport Improvement

The Federal Aviation Administration uses enplanement data for U.S. airports to distribute the annual Airport Improvement Program (AIP) entitlement funds to eligible primary airports, i.e., airports which account for more than 0.01 percent of the total passengers enplaned at U.S. airports. Enplanement data contained in Schedule T–100/T–100(f) are the sole data base used by the FAA in determining airport funding. U.S. airports receiving significant service from foreign air carriers operating small aircraft could be receiving less than their fair share of AIP entitlement funds. Collecting Schedule T–100(f) data for small aircraft operations will enable the FAA to more fairly distribute these funds.

Air Carrier Safety

The FAA uses traffic, operational and capacity data as important safety indicators and to prepare the air carrier traffic and operation forecasts that are used in developing its budget and staffing plans, facility and equipment funding levels, and environmental impact and policy studies. The FAA monitors changes in the number of air carrier operations as a way to allocate inspection resources and in making decisions as to increased safety surveillance. Similarly, airport activity statistics are used by the FAA to develop airport profiles and establish priorities for airport inspections.

Acquisitions and Mergers

While the Justice Department has the primary responsibility over air carrier acquisitions and mergers, the Department reviews the transfer of international routes involved to determine if they would substantially reduce competition, or determine if the transaction would be inconsistent with the public interest. In making these determinations, the proposed transaction's effect on competition in the markets served by the affected air carriers is analyzed. This analysis includes, among other things, a consideration of the volume of traffic and available capacity, the flight segments and origins-destinations involved, and the existence of entry barriers, such as limited airport slots or gate capacity. Also included is a review of the volume of traffic handled by each air carrier at specific airports and in specific markets which would be affected by the proposed acquisition or merger. The Justice Department uses T–100 data in carrying out its responsibilities relating to airline competition and consolidation.

Recently, the House and Senate Subcommittees on Aviation have reviewed market data in assessing possible mergers between major airlines.

Traffic Forecasting

The FAA uses traffic, operational and capacity data as important safety indicators and to prepare the air carrier traffic and operation forecasts. These forecasts are used by the FAA, airport managers, the airlines and others in the air travel industry as planning and budgeting tools.

Airport Capacity Analysis

The mix of aircraft type are used in determining the practical annual capacity (PANCAP) at airports as prescribed in the FAA Advisory Circular *Airport Capacity Criteria Used in Preparing the National Airport Plan.* The PANCAP is a safety-related measure of the annual airport capacity or level of operations. It is a predictive measure which indicates potential capacity problems, delays, and possible airport expansions or runway construction needs. If the level of operations at an airport exceeds PANCAP significantly, the frequency and length of delays will increase, with a potential concurrent risk of accidents. Under this program, the FAA develops ways of increasing airport capacity at congested airports.

Airline Industry Status Evaluations

The Department apprises Congress, the Administration and others of the effect major changes or innovations are having on the air transportation industry. For this purpose, summary traffic and capacity data as well as the detailed segment and market data are essential. These data must be timely and inclusive to be relevant for analyzing emerging issues and must be based upon 6 uniform and reliable data submissions that are consistent with the Department's regulatory requirements.

Mail Rates

The Department is responsible for establishing international and intra-Alaska mail rates. International mail rates are set based on scheduled operations in four geographic areas: Trans-border, Latin America, operations

over the Atlantic Ocean and operations over the Pacific Ocean. Separate rates are set for mainline and bush Alaskan operations. The rates are updated every six months to reflect changes in unit costs in each rate-making entity. Traffic and capacity data are used in conjunction with cost data to develop the required unit cost data.

Essential Air Service

The Department reassesses service levels at small domestic communities to assure that capacity levels are adequate to accommodate current demand.

System Planning at Airports

The FAA is charged with administering a series of grants that are designed to accomplish the necessary airport planning for future development and growth. These grants are made to state metropolitan and regional aviation authorities to fund needed airport systems planning work. Individual airport activity statistics, nonstop market data, and service segment data are used to prepare airport activity level forecasts.

Review of IATA Agreements

The Department reviews all of the International Air Transport Association (IATA) agreements that relate to fares, rates, and rules for international air transportation to ensure that the agreements meet the public interest criteria. Current and historic summary traffic and capacity data, such as revenue ton-miles and available ton-miles, by aircraft type, type of service, and length of haul are needed to conduct these analyses to: (1) Develop the volume elements for passenger/cargo cost allocations, (2) evaluate fluctuations in volume of scheduled and charter services, (3) assess the competitive impact of different operations such as charter versus scheduled, (4) calculate load factors by aircraft type, and (5) monitor traffic in specific markets.

Foreign Air Carriers Applications

Foreign air carriers are required to submit applications for authority to operate to the United States. In reviewing these applications the Department must find that the requested authority is encompassed in a bilateral agreement, other intergovernmental understanding, or that granting the application is in the public interest. In the latter cases, T–100 data are used in assessing the level of benefits that carriers of the applicant's homeland presently are receiving from their U.S. operations. These benefits are compared and balanced against the benefits U.S. carriers receive from their operations to the applicant's homeland.

Air Carrier Fitness

The Department determines whether U.S. air carriers are and continue to be fit, willing and able to conduct air service operations without undue risk to passengers and shippers. The Department monitors a carrier's load factor, operational, and enplanement data to compare with other carriers with similar operating characteristics. Carriers that expand operations at a high rate are monitored more closely for safety reasons.

International Civil Aviation Organization

Pursuant to an international agreement, the United States is obligated to report certain air carrier data to the International Civil Aviation Organization (ICAO). The traffic data supplied to ICAO are extracted from the U.S. air carriers' Schedule T–100 submissions.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501 note), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Issued in Washington, DC, on May 28, 2008.

Marianne Seguin,

Acting Assistant Deputy Director, Airline Information, Bureau of Transportation Statistics.

[FR Doc. E8–12604 Filed 6–4–08; 8:45 am]

BILLING CODE 4910–HY–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 2005–26

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 Revenue Procedure 2005–26, Revenue Procedure Regarding Extended Period of Limitation for Listed Transaction Situations.

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, 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:* Revenue Procedure Regarding Extended Period of Limitations for Listed Transaction Situations.

OMB Number: 1545–1940.

Revenue Procedure Number: Revenue Procedure 2005–26.

Abstract: This revenue procedure provides procedures that taxpayers and material advisors may use to disclose a listed transaction that the taxpayer previously failed to disclose.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households and business or other for-profit institutions.

Estimated Number of Respondents: 859.

Estimated Time per Respondent: 5 hours.

Estimated Total Annual Burden Hours: 430.

The following paragraph applies to all 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: May 23, 2008.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–12547 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 637

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 637, Application for Registration (For Certain Excise Tax Activities).

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, 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: Application for Registration (For Certain Excise Tax Activities).

OMB Number: 1545–0014.

Form Number: Form 637.

Abstract: Form 637 is used to apply for excise tax registration. The registration applies to a person required to be registered under Revenue code section 4101 for purposes of the federal excise tax on taxable fuel imposed under Code sections 4041 and 4071; and to certain manufacturers or sellers and purchasers that must register under Code section 4222 to be exempt from the excise tax on taxable articles. The data is used to determine if the applicant qualifies for the exemption. Taxable fuel producers are required by Code section 4101 to register with the Service before incurring any tax liability.

Current Actions: There are no changes being made to the form at this time. Line items, attachments, and code references were recounted, however, to more accurately show burden.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and not-for-profit institutions, and farms.

Estimated Number of Respondents: 2,000.

Estimated Time per Respondent: 13 hr., 31 min.

Estimated Total Annual Burden Hours: 27,020.

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: May 27, 2008.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E8–12549 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 2005–41

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 Notice 2005–41, Guidance Regarding Qualified Intellectual Property Contributions.

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of notice 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: Guidance Regarding Qualified Intellectual Property Contributions.

OMB Number: 1545–1937.

Notice Number: Notice 2005–41.

Abstract: Notice 2005–41 explains new rules governing charitable contributions of intellectual property made after June 3, 2004. The notice explains the method by which a donor of qualified intellectual property may notify the donee that the donor intends to treat the contribution as a qualified donation under section 170(m). Donors of qualified intellectual property will use the required notification as evidence that they have satisfied the section 170(m) notification requirement.

Current Actions: There are no changes being made to the notice at this time.

Type of Review: This is a new collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 30.

Estimated Average Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 30.

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: May 23, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–12550 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8697

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 8697, Interest Computation Under the Look-Back Method for Completed Long-Term Contracts.

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, 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 6512, 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: Interest Computation Under the Look-Back Method for Completed Long-Term Contracts.

OMB Number: 1545–1031.

Form Number: Form 8697.

Abstract: Taxpayers who are required to account for all or part of any long-term contract entered into after February 28, 1986, under the percentage of completion method must use Form 8697 to compute and report interest due or to be refunded under Internal Revenue Code section 460(b)(3). The IRS uses Form 8697 to determine if the interest has been figured correctly.

Current Actions: There are no changes being made to the Form 8697 at this time. The number of revenue code references has been recounted.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 3,333.

Estimated Time per Respondent: 12 hrs, 10 minutes.

Estimated Total Annual Burden Hours: 40,557.

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: May 23, 2008.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–12552 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 12884

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 12884, Survey Questionnaire.

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms 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: Survey Questionnaire.

OMB Number: 1545–1922.

Form Number: Form 12884.

Abstract: This form will be completed by applicants to collect statistical data regarding advertising media and to collect RNO information that is recorded in the TIMIS database for EEO statistics and reporting.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved submission.

Affected Public: Individuals and households and Federal Government.

Estimated Number of Respondents: 33,085.

Estimated Time per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 2,757.

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: May 20, 2008.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–12553 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–DIV

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 1099–DIV, Dividends and Distributions.

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, 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: Dividends and Distributions.

OMB Number: 1545–0110.

Form Number: 1099–DIV.

Abstract: Form 1099–DIV is used by the IRS to insure that dividends are properly reported as required by Internal Revenue Code section 6042, that liquidation distributions are correctly reported as required by Code section 6043, and to determine whether payees are correctly reporting their income.

Current Actions: There are no changes being made to the form at this time. We did, however make a correction to the previous burden to properly reflect the latest filing figures that were not accounted for in the previous submission.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 111,922,150.

Estimated Time per Response: 18 minutes.

Estimated Total Annual Burden Hours: 34,695,867.

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: May 14, 2008.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–12555 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 12854

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 12854, Prior Government Service Information.

DATES: Written comments should be received on or before August 4, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms 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: Prior Government Service Information.

OMB Number: 1545–1919.

Form Number: Form 12854.

Abstract: Form 12854 is used to record prior government service, annuitant information and to advise on probationary periods.

Current Actions: There are currently no changes to this form.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 24,813.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 6,203.

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: May 27, 2008.

Allan Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–12556 Filed 6–4–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Low Income Taxpayer Clinic Grant Program; Availability of 2009 Grant Application Package

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This document contains a Notice that the IRS has made available the grant application package and guidelines (Publication 3319) for organizations interested in applying for a Low Income Taxpayer Clinic (LITC) matching grant for the 2009 grant cycle (the 2009 grant cycle runs January 1, 2009, through December 31, 2009). The application period shall run from May 27, 2008, through July 7, 2008.

The IRS will award a total of up to $6,000,000 (unless otherwise provided by specific Congressional appropriation) to qualifying organizations, subject to the limitations of Internal Revenue Code section 7526, for matching grants. A qualifying organization may receive a matching grant of up to $100,000 per year. Qualifying organizations that provide representation for free or for a nominal fee to low income taxpayers involved in tax controversies with the IRS or that provide education on taxpayer rights and responsibilities to taxpayers for whom English is a second language can apply for a grant for the 2009 grant cycle.

Examples of qualifying organizations include: (1) Clinical programs at accredited law, business or accounting schools, whose students represent low income taxpayers in tax controversies with the IRS, and (2) organizations exempt from tax under I.R.C. § 501(a) which represent low income taxpayers in tax controversies with the IRS or refer those taxpayers to qualified representatives.

DATES: Grant applications for the 2009 grant cycle must be electronically filed or postmarked by July 7, 2008.

ADDRESSES: Send completed grant applications to: Internal Revenue Service, Taxpayer Advocate Service, LITC Grant Program Administration Office, TA:LITC, 1111 Constitution Avenue, NW., Room 1034, Washington, DC 20224. Copies of the *2009 Grant Application Package and Guidelines,* IRS Publication 3319 (Rev. 5–2008), can be downloaded from the IRS Internet site at *http://www.irs.gov/advocate* or ordered by the IRS Distribution Center by calling 1–800–829–3676. Applicants can also file electronically at *http://www.grants.gov.* For applicants applying through the Federal Grants Web site, the Funding Number is TREAS–GRANTS–052009–001.

FOR FURTHER INFORMATION CONTACT: The LITC Program Office at (202) 622–4711 (not a toll-free number) or by e-mail at *LITCProgramOffice@irs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 7526 of the Internal Revenue Code authorizes the IRS, subject to the availability of appropriated funds, to award organizations matching grants of up to $100,000 per year for the development, expansion, or continuation of qualified low income taxpayer clinics. Section 7526 authorizes the IRS to provide grants to qualified organizations that represent low income taxpayers in controversies with the IRS or inform individuals for whom English is a second language of their taxpayer rights and responsibilities. The IRS may award grants to qualifying organizations to fund one-year, two-year or three-year project periods. Grant funds may be awarded for start-up expenditures incurred by new clinics during the grant cycle.

The *2009 Grant Application Package and Guidelines,* Publication 3319 (Rev. 5–2008), outlines requirements for the operation of a qualifying LITC program and provides instructions on how to apply for a grant.

The costs of preparing and submitting an application are the responsibility of each applicant. Each application will be given due consideration and the LITC Program Office will mail notification letters to each applicant.

Selection Consideration

Applications that pass the eligibility screening process will be numerically ranked based on the information contained in their proposed program plan. Please note that the IRS Volunteer Income Tax Assistance (VITA) and Tax Counseling for the Elderly (TCE) Programs are independently funded and separate from the LITC Program. Organizations currently participating in the VITA or TCE Programs may be eligible to apply for a LITC grant if they meet the criteria and qualifications outlined in the *2009 Grant Application Package and Guidelines,* Publication 3319 (Rev. 5–2008). Organizations that seek to operate VITA and LITC Programs, or TCE and LITC Programs, must maintain separate and distinct programs even if co-located to ensure proper cost allocation for LITC grant funds and adherence to the rules and regulations of the VITA, TCE and LITC Programs, as appropriate.

Comments

Interested parties are encouraged to provide comments on the IRS's administration of the grant program on an ongoing basis. Comments may be sent to Internal Revenue Service, Taxpayer Advocate Service, Attn: Shawn Collins, LITC Program Office, TA:LITC, 1111 Constitution Avenue, NW., Room 1034, Washington, DC 20224.

Nina E. Olson,

National Taxpayer Advocate, Internal Revenue Service.

[FR Doc. 08–1318 Filed 6–2–08; 8:45am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

[AC–22: OTS Nos. 00057, H4139, H4138, and H4513]

Home Federal Savings and Loan Association, Home Federal Mutual Holding Company of Louisiana, Home Federal Bancorp, Inc. of Louisiana, and (new) Home Federal Bancorp, Inc. of Louisiana, Shreveport, Louisiana; Approval of Conversion Application

Notice is hereby given that on May 14, 2008, the Office of Thrift Supervision approved the application of Home Federal Mutual Holding Company of Louisiana and Home Federal Savings and Loan Association, Shreveport, Louisiana, to convert to the stock form of organization. Copies of the application are available for inspection by appointment (phone number: 202–906–5922 or e-mail: *Public.Info@OTS.Treas.gov*) at the Public Reading Room, 1700 G Street, NW., Washington, DC 20552, and OTS Midwest Regional Office, 225 E. John Carpenter Freeway, Suite 500, Irving, Texas 75062.

Dated: May 28, 2008.

By the Office of Thrift Supervision,

Sandra E. Evans,

Federal Register Liaison.

[FR Doc. E8–12270 Filed 6–4–08; 8:45 am]

BILLING CODE 6720–01–P

Federal Register

Thursday,
June 5, 2008

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare and Medicaid Programs: Hospice Conditions of Participation; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–3844–F]

RIN 0938–AH27

Medicare and Medicaid Programs: Hospice Conditions of Participation

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The final conditions address the comments that we received on the proposed rule published on May 27, 2005. This final rule focuses on the care delivered to patients and their families by hospices and the outcome of that care. The final requirements continue to reflect the unique interdisciplinary view of patient care and allow hospices flexibility in meeting quality standards. These changes are an integral part of the Administration's efforts to achieve broad based improvements in the quality of health care and our efforts to improve the quality of care furnished through the Medicare and Medicaid programs.

EFFECTIVE DATE: These regulations are effective on December 2, 2008.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 2, 2008.

FOR FURTHER INFORMATION CONTACT: Steve Miller, (410) 786–6656; Mary Rossi-Coajou, (410) 786–6051; Danielle Shearer, (410) 786–6617; or Jeannie Miller, (410) 786–3164.

SUPPLEMENTARY INFORMATION:

I. Background

Hospice care is an approach to caring for the terminally ill individual that provides palliative care rather than traditional medical care and curative treatment. Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other issues. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family, and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. A hospice uses an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of caregivers.

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Public Law 97–248, added section 1861(dd) to the Social Security Act (the Act) to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, and these conditions are set forth at 42 CFR part 418. The CoPs apply to a hospice as an entity as well as to the services furnished to each individual under hospice care. Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under hospice care. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

The hospice CoPs were originally published on December 16, 1983 (48 FR 56008) and were amended on December 11, 1990 (55 FR 50831) largely to implement provisions of section 6005(b) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239). However, many of the current CoPs have remained unchanged since their inception.

As the single largest payer for health care services in the United States, the Federal Government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. These problems would either be corrected or would lead to the exclusion of the provider from participation in the Medicare or Medicaid programs. However, we have found that this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in quality of care.

In order to take advantage of continuing advances in the health care delivery field, incorporate changes made to the Act, and incorporate recommendations made by various government agencies we are revising the Medicare hospice CoPs, which are also used by Medicaid. The revised CoPs focus on a patient-centered, outcome-oriented, and transparent process that promotes quality patient care for every patient every time.

We have developed a set of core requirements for hospice services that encompass the following: Patient rights, comprehensive assessment, patient care planning and coordination by a hospice interdisciplinary group (IDG). Overarching these requirements is a quality assessment and performance improvement program that builds on the philosophy that a provider's own quality management system is key to improved patient care performance. The objective is to achieve a balanced regulatory approach by ensuring that a hospice furnishes health care that meets essential health and quality standards, while ensuring that it monitors and improves its own performance.

We are revising the CoPs based on four main considerations. First, we considered the recommendations from the Secretary's Advisory Committee on Regulatory Reform. In an effort to make regulations more predictable and responsive to relevant stakeholders, the Committee heard public testimony on a variety of hospice-related topics and developed recommendations to address key issues that were highlighted. The Committee recommended that we clarify the relationship between nursing facilities and hospices (found in our final rule at § 418.112); change the requirements for 24-hour nursing services for hospices providing respite care (§ 418.108 of the final rule); and clarify that all qualified individuals, including nurses, are permitted to furnish dietary counseling (§ 418.64(d)(2) of the final rule).

Second, we considered the Balanced Budget Act of 1997 (Pub. L. 105–33) because it made changes to the hospice statute that must now be incorporated into the CoPs. Specifically, the Balanced Budget Act of 1997 (BBA) permitted hospices to provide physician services, including those of a medical director, under contract (§ 418.64 and § 418.102 of the final rule). It also allowed hospices located in non-urbanized areas to receive a waiver of the requirement that physical therapy, occupational therapy, speech-language pathology, and dietary counseling be available on a 24-hour as needed basis (§ 418.74 of the final rule). Additionally, the

legislation allowed hospices located in non-urbanized areas to receive a waiver of the requirement that dietary therapy be provided by hospice employees (§ 418.74 of the final rule).

Third, we considered section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 946 of the MMA amended section 1861(dd) of the Act, to permit a hospice to enter into an arrangement with another hospice to provide core hospice services or to provide the highly specialized services of a registered professional nurse, in certain circumstances (§ 418.64 of the final rule).

Finally, this revision is part of a larger effort to bring about improvements in the quality of care furnished to hospice patients and their families through an outcome-oriented approach to patient care. The revised CoPs focus on the core elements of hospice care that are necessary to achieve positive patient outcomes to meet the growing challenges associated with the changing hospice care environment such as increasingly diverse patient populations and care settings.

Before developing the proposed CoPs for hospices, published in the **Federal Register** on May 27, 2005, we analyzed our hospice survey data, and received advice and suggestions from the hospice industry, professional associations, practitioner communities, consumer advocates, and State and other governmental agencies with an interest in, or responsibility for, hospice regulation and oversight. Based on the data and suggestions, we developed the following principles:

- Focus on the continuous, integrated health care process that a patient/family experiences across all aspects of hospice care, and on activities that center around patient assessment, care planning, service delivery, and quality assessment and performance improvement;
- Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the patient's needs;
- Incorporate an outcome-oriented quality assessment and performance improvement program;
- Facilitate flexibility in how a hospice meets performance expectations;
- Require that patient rights are ensured; and
- Use performance measurement systems to evaluate and improve care.

Based on these principles and the public comments that were submitted regarding the May 2005 proposed rule, we are setting forth this final rule.

II. Provisions of the Proposed Regulations and the Analysis and Responses to Public Comments

On May 27, 2005, we set forth proposed rules for hospices that choose to participate in Medicare and Medicaid. We proposed to revise all of the existing conditions of participation (CoPs), and to add several new CoPs to address aspects of hospice care that we believe need attention. This section will briefly describe the content of each CoP in the proposed rule.

We proposed no changes to Subparts B (Eligibility, Election and Duration of Benefits), G (Payment for Hospice Care), or H (Coinsurance) of 42 CFR part 418.

We received 205 timely items of correspondence that raised numerous issues. These comments, detailed below, came from accrediting bodies, consumer advocacy organizations, hospices, individuals, national health care provider organizations, State agencies, and State health care provider organizations.

1. Scope of the Part (§ 418.2)

We proposed to revise § 418.2 to reflect the reorganization of the part and to include an introductory statement describing the purpose of the part. We did not receive any comments on this section. Therefore, we are adopting the provisions as proposed.

2. Definitions (§ 418.3)

We proposed to remove, revise, and add numerous definitions to this section in order to clarify the meaning of the proposed rule. We proposed to move the definitions of ''physician'' and ''social worker'' from the definitions section to the personnel requirements section at § 418.114 because the definitions set forth the standards that these individuals must meet in order to function in a hospice. In addition, as it is not a condition of participation, and is only used for hospice payment purposes, we proposed to maintain the existing definition of the term ''cap period.''

We proposed to revise the definitions of the terms ''attending physician'', ''bereavement counseling'', ''employee'', ''hospice'', ''representative'', and ''terminally ill''. Finally, we proposed to add definitions for the following terms: ''clinical note'', ''drug restraint'', ''hospice care'', ''licensed professional'', ''palliative care'', ''physical restraint'', ''progress note'', ''restraint'', ''satellite location'', and ''seclusion''.

We proposed to add nurse practitioners to the definition of ''attending physician'' because section 408 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the statutory definition of ''attending physician'' to include nurse practitioners with respect to some (but not all) aspects of hospice services.

The terms ''drug restraint'', ''physical restraint'', and ''seclusion'' were presented for the first time in the proposed rule. Seclusion and restraint requirements were proposed because anecdotal evidence suggested that there are occasions when hospice inpatient facilities must use seclusion and/or restraints for patient and/or staff safety. Moreover, Section 591 of the Public Health Service (PHS) Act, as added by the Children's Health Act (Pub. L. 106–310), prohibits the use of restraint and seclusion, except under specific circumstances, in any health care facility, that receives support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency.

We proposed to define the term ''satellite location'' to codify long-standing Medicare survey and certification policies that permit hospices to operate multiple locations under a single provider number. Multiple locations were not an issue when the hospice CoPs were originally implemented, and, as such, were not addressed. We believed that the proposed definition would help hospices determine when they do or do not need to obtain Medicare approval for a new location and what criteria would be used by Medicare in approving or denying a multiple location application.

Comment: Many commenters requested that changes be made to the proposed definition of ''attending physician.'' Some of these commenters requested that, in addition to ''nurse practitioner,'' we also add ''advanced practice nurse,'' ''clinical nurse specialist,'' and ''physician's assistant'' to the definition of ''attending physician'' in order to broaden the category of individuals who could receive payment in that capacity. A single commenter suggested that we defer to the States to determine training, education and experience requirements for nurse practitioners. Another commenter suggested that the definition of ''attending physician'' should be divided into two definitions, one for physicians and one for nurse practitioners. Still another commenter requested that we delete the

requirement that an attending physician must be legally authorized to practice surgery by the State in which he or she performs that function because surgery is not a specialty necessary to be considered qualified as an attending physician. Several other commenters requested that we specify in the definition of ''attending physician'' that a patient's attending physician may be a hospice employee. Another commenter suggested that we add a statement that a nurse practitioner may cover for an attending physician in the attending physician's absence.

Response: Section 408(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA) amended the term ''attending physician'' at section 1861(dd)(3)(B) of the Act specifically for hospices to allow nurse practitioners to function as a patient's attending physician if the patient identifies the nurse practitioner as such. Following publication of the proposed rule, CMS published two final rules (70 FR 45144 and 72 FR 50214) on other matters that, among other things, modified the definition of the term ''attending physician'' to incorporate changes made by the MMA. We are deferring to these final rules. Furthermore, Section 1861(r)(1) of the Act specifically defines a physician as ''a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action.'' We believe that this statutory definition is appropriate for hospice providers, as well as for the many other health care providers for which it is used. We do not have the authority to delete the term ''and surgery'' from this definition.

We do not believe that it is necessary to state in the definition that an attending physician may be an employee of the hospice. The decision as to who is or is not the attending physician belongs to the patient regardless of that individual's employment relationship (or lack thereof) with the hospice. We do not prohibit attending physicians from being hospice employees as long as it is the patient's choice to decide whether or not to have an attending physician and who that attending physician will be during the patient's hospice care. In addition to consulting with the hospice interdisciplinary group (IDG) regarding the patient's hospice care, the attending physician retains responsibility for meeting the patient's needs that are not related to the terminal illness and that terminal illness's related conditions. The attending physician is typically someone with whom the patient had a relationship before electing to receive hospice care. The role of the attending physician is to provide a long term perspective on the patient and family that takes into account their medical and personal history. The attending physician is not typically an individual provided by the hospice to fill this role because a patient does not have an attending physician, although we recognize that this does occur at times.

We also do not believe that it is necessary to state that a nurse practitioner may act on behalf of the attending physician in the attending physician's absence. If the attending physician is unable to fulfill his or her duties, then the hospice physicians are responsible for fulfilling the attending physician's duties in his or her absence in accordance with § 418.64(a)(3) of the final rule. Therefore, there is no need for the attending physician to designate another individual to cover his or her hospice patients. The role and function of the nurse practitioner is also addressed in CMS hospice payment policies (see, for example, 42 CFR 418.304(e)).

Comment: A commenter requested that we revise the definition of ''bereavement counseling'' to reflect the fact that bereavement counseling begins before the patient dies. The commenter noted that the proposed rule even required the initial step of bereavement counseling to begin before the patient's death by requiring that the initial bereavement assessment be completed at the time of the comprehensive assessment. Another commenter questioned the qualifications of persons providing bereavement counseling and indicated that we should consider adding language to address this question within the definition of ''bereavement counseling.'' Another commenter requested that we specify, in the definition of bereavement counseling, that the counseling only applies to the patient's immediate family members as set out in the Act.

Response: We agree that effective bereavement counseling must begin before the patient's death and that the proposed rule and this final rule reflect this practice by requiring a bereavement assessment early in the patient's hospice stay. To clarify our intent, at section § 418.3 of this final rule, we are revising the definition of ''bereavement counseling'' to specify that it occurs both before and after the patient's death.

With respect to counseling immediate family members, current practice in many hospices is expanding this activity. Many hospice programs have extensive bereavement programs that extend beyond immediate family members to embrace other caregivers, friends, and the larger community. As the commenter pointed out, the statute at section 1861(dd)(2)(A)(i) of the Act mandates bereavement counseling for the immediate family of the terminally ill individuals, but does not explicitly limit counseling to only such family members. We believe that limiting counseling to immediate family members would disregard the work that many hospices do for other persons whose relationship with the patient is important. To restrict bereavement counseling to a select few would discourage hospices from providing this service, thus harming the bereaved and the larger community. Therefore, we did not insert language limiting the definition of ''bereavement counseling'' to immediate family members. Bereavement counseling is part of the hospice's bundled daily payment rate.

In order to facilitate bereavement counseling services beginning at an early time and being furnished to whomever the hospice assesses as needing services, we believe that it is necessary to allow hospices flexibility in deciding who is qualified to provide bereavement services in accordance with their own policies, current standards of practice, and other applicable Federal, State, and local laws and regulations. In the proposed and final rule at § 418.64(d), we require that counseling services, including bereavement counseling, are provided by or under the supervision of a qualified individual with experience in grief or loss counseling. Some hospices may use a social worker while other hospices may choose to use chaplains or volunteers to provide this service. This flexibility allows hospices to meet the needs of their patients and families in a manner that works best for their needs and resources. Therefore, we are not prescribing who may or may not furnish bereavement counseling services.

Thus, the revised definition for ''bereavement counseling'' is as follows: ''*Bereavement counseling* means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.''

Comment: Numerous commenters indicated that the proposed definitions for the terms ''clinical note'' and ''progress note'' were either unnecessary or redundant. The commenters suggested that these definitions either be deleted or further clarified to distinguish their purpose. In addition, many commenters suggested that the terms ''psychosocial'' and ''spiritual note'' be added to the definition of

''clinical note'' to reflect the fact that individuals who furnish psychosocial and spiritual care such as social workers, counselors and chaplains also write notations in the patient's clinical record.

Response: Notations in a patient's clinical record by individuals furnishing services on behalf of a hospice are standard practice. They are a primary and crucial means of communication between various care providers who are in the patient's home at different times while furnishing different services. Therefore, we believe that it is important to acknowledge their use in the hospice environment by requiring their presence in the patient's clinical record. At the same time, we agree that having two separate definitions for notations is not necessary and may even be confusing. Therefore, at § 418.3, we are using a single definition, ''clinical note,'' that addresses notations regarding both the patient and the family. We also added the terms ''psychosocial'' and ''spiritual'' to the definition to reflect the need for this important information in the patient's clinical record. The condensed and revised definition is as follows:

''*Clinical note* means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional, psychosocial or spiritual condition during a given period of time.''

We would like to point out that the term ''clinical note'' does not limit the notations only to those individuals who are clinicians. Clinical notes may be written by any individual furnishing care and services to a patient, including volunteers, homemakers, vendors, etc. Indeed, we would expect that clinical notes from all individuals would be included in the clinical record because the goal of the clinical note is to include as much information as possible to ensure that all hospice care providers have complete and correct information to use in making care decisions and furnishing care.

Comment: Many commenters were confused by the terms ''initial assessment'' and ''comprehensive assessment'' as they are used in § 418.54, ''Initial and Comprehensive assessment of the patient.'' The commenters requested definitions for these terms in order to help clarify the difference between the two assessment requirements to ensure that the proper information was being gathered within the stated timeframes.

Response: We agree that adding definitions of these two terms will help ensure that patients are being assessed in a timely fashion. We are clarifying that the initial assessment is to determine the patient's immediate care needs. Hospices must complete this abbreviated assessment in 48 hours. The comprehensive assessment must assess in-depth all of the patient's areas of need and will ensure that hospices are fully aware of the patient's current status. Hospices will be able to use these assessments to establish an individualized hospice plan of care that meets the patient's needs. We did not, as some commenters suggested, specify which disciplines must complete the comprehensive assessment. Hospices provide many different services and not every patient will require an assessment by a provider of each of those services. If, upon completion of the initial assessment, it is determined that a patient may benefit from physical therapy services, then we would expect a physical therapist to complete a physical therapy assessment as part of the comprehensive assessment. However, if there is no indication that the therapy services may benefit the patient, then a therapy assessment by a therapist would be unnecessary. The new definitions for ''initial assessment'' and ''comprehensive assessment'' are added at § 418.3 as follows:

''*Initial assessment* means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs.''

''*Comprehensive assessment* means a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.''

Comment: A number of commenters asked us to define the terms ''dietary counseling'' and/or ''dietitian'' to help clarify what type of counseling hospices are required to provide to their patients, and who may furnish this service. A few commenters further suggested that we should differentiate between dietary counseling furnished by a dietitian and dietary counseling furnished by a qualified individual such as a nurse or nutritionist.

Response: Section 1861(dd)(1)(H) of the Social Security Act (the Act) requires hospice facilities to provide ''counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death.'' However, the term ''dietary counseling'' has never been defined for hospices, and there is a great deal of confusion in the hospice industry regarding exactly what constitutes ''dietary counseling.'' Therefore, we agree that a definition of ''dietary counseling'' is necessary. The definition at § 418.3 reads as follows:

''*Dietary counseling* means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care.''

We do not agree that we should prescribe what type of counseling must be provided by a dietitian. We would expect that, based on an assessment of the patient's dietary needs, a hospice would furnish dietary counseling services through an individual whose skills best meet the patient's identified needs. We believe that the needs of the individual patient, rather than preset rules, should be the determining factor relative to services and staff. We do not believe it is appropriate to define the term ''dietitian'' or establish personnel requirements for dietitians because we believe that hospices should have the flexibility to employ an individual that would meet the needs of their patients in accordance with all other applicable Federal, State, and local laws and regulations.

Comment: A few commenters submitted suggestions for the proposed definition of the term ''employee.'' A single commenter asked that we replace the definition of the term ''employee'' with a definition of the term ''staff.'' Another commenter suggested that, through the definition of the term, hospice employees should be required to be appropriately trained in death and dying.

Response: The term ''employee'' is singular and is used throughout the regulation to refer to the direct relationship between the hospice and the individual in terms of furnishing services (that is, a direct employee), supervision, and lines of authority and responsibility. The term ''staff,'' on the other hand, is plural and may include individuals who are contracted through an outside entity, supervised by that outside entity, and primarily responsible to that outside entity. ''Staff,'' as a broader term, is not an appropriate substitution for the term ''employee'' in these definitions.

Additionally, it is not appropriate to require in the definition of the term ''employee'' that an employee must be trained in issues related to death and dying. We agree that thorough training in issues related to death and dying is necessary for all individuals furnishing patient care services, including clinicians and patient care volunteers. In final § 418.100(g)(1) we now require hospices to educate all hospice employees who have patient contact in the hospice philosophy. Education in the hospice philosophy would, we believe, encompass issues related to death and dying, as the commenter suggested. It is not necessary for office employees with no patient contact to be trained in issues relating to death and dying. To require the training for all employees, regardless of their role within the hospice organization, would unnecessarily burden hospices and divert resources from more critical patient care activities. Therefore, we are not requiring all hospice employees to receive such training.

Comment: A commenter suggested that, in the definition of ''hospice care,'' we should specify that hospice care may be provided in the home, the community, or a facility.

Response: Hospice care is currently being furnished in a variety of settings, and we do not believe that it is necessary or appropriate to specify in this rule where hospice care may be provided. To do so may unintentionally preclude hospices from providing services in settings that are appropriate but that are outside of an established definition.

Comment: Numerous commenters requested changes to the definition of ''licensed professional.'' Many of those commenters suggested that dietary therapy should be added to the list of examples of services that should be furnished by a licensed professional. Another commenter suggested deleting the list of examples because the examples may inadvertently limit the types of services that should be provided by licensed professionals. Yet another commenter suggested that medical social services should be deleted from the list of examples because not all States license social workers. Therefore, in those States where no State licensure for social workers exists, medical social services, CMS presumes, that the commenter is advocating that such services be furnished by a professional without a license.

Response: We agree that the proposed definition needs to be clarified. While the commenters are correct in suggesting that dietary therapy should be provided by a licensed professional, whether a nurse, dietitian or nutritionist, we agree with the commenter who suggested that the mere presence of the list of services is limiting. Therefore, while we agree that dietary therapy should be provided by a licensed professional, we are not adding dietary therapy to the list of examples. Rather, at § 418.3, we are deleting the entire list of examples because they are unnecessary and may be confusing. Deleting the list of examples also addresses the commenter's concern regarding the licensure status of social workers. We recognize that some States may not license social workers or other health care disciplines, and we do not intend to imply that States must provide licensure for all health care disciplines furnishing hospice services. Rather, our intent, as proposed at § 418.116(a) and finalized at § 418.114(a) is that if a State licenses a particular health care discipline, then any individual working within that discipline in the hospice environment must obtain and maintain that State license. If no State license exists for a particular discipline, and if that individual meets all other personnel and training requirements as required by this rule and any other applicable Federal, State, or local laws, regulations, policies, and requirements, then it is acceptable for that individual to furnish services to hospice patients absent a State license.

Comment: Numerous commenters requested clarification on the definition of the term ''satellite location.'' Specifically, hospices requested that the definition include: Concrete criteria that hospices must meet in order to be considered satellite locations, information about the approval and survey process, and information about the type of services furnished by satellite locations.

Response: The term ''satellite location'' is now referred to as ''multiple locations,'' and § 418.3 has been modified to reflect this change. We believe that this new terminology more accurately describes those entities that furnish a full array of services from two or more locations. We have also clarified our intent by stating that multiple locations are those locations ''from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number.'' We note that the term ''certification number'' is now used in place of the term ''provider number.'' This change reflects a change in the terminology used by CMS to describe the number issued to a hospice to identify it in certain Medicare systems.

We believe that clarifying that a multiple location provides the same full array of services as the hospice location originally issued the certification number will alleviate commenter concerns that convenience sites where staff stop in to complete paperwork or check messages, or warehouse sites where equipment is stored would need to be approved by Medicare as multiple locations. We note that although we do not require hospices to obtain approval for warehouse and other single function sites, States may still require hospices to receive approval from State or local authorities. The requirement that multiple locations must share administration, supervision, and services with the hospice that was issued the certification number is relocated from the definition of the term at § 418.3 to the paragraph addressing multiple locations at § 418.100(f)(1)(ii). We continue to believe that it is the level of control and supervision exercised by the hospice that was issued the certification number over the multiple location, rather than mileage limitations or staffing levels, which determines whether or not a site is a multiple location of an existing hospice or a completely separate hospice.

We do not believe that it is appropriate to add specific criteria or procedures for the approval of multiple locations in the regulatory definition because this level of specificity may reduce our ability to adapt to rapid changes in the hospice industry related to the use of multiple locations. Rather, we will continue to address specific criteria and procedures for multiple locations in sub-regulatory guidance such as the State Operations Manual.

Comment: A commenter requested clarification about the definition of ''palliative care'' and its relationship to the requirement that, in order for a Medicare beneficiary to qualify for the Medicare hospice benefit, the beneficiary must be certified as being terminally ill. Specifically, the commenter asked if palliative care could be provided by a hospice to individuals who are not terminally ill or who have not elected the Medicare hospice benefit.

Response: Hospice care is a very specific type of care provided within a defined timeframe at the end of life. Palliative care, on the other hand, can be provided at any time of life when there is a need to anticipate, prevent and treat suffering to optimize a patient's quality of life. Hospices have a long history of providing palliative care and are often in a position to provide

the care either on a direct or contract basis to patients who either do not qualify for the Medicare hospice benefit (or another health care insurer's hospice benefit) or who do not choose to forgo curative treatment in order to elect the Medicare hospice benefit. We do not prohibit hospices from providing these palliative care services to patients that do not elect or qualify for hospice care, as long as the hospices are primarily engaged in furnishing hospice care as required by section 1861(dd) of the Act.

Comment: A few commenters requested that we define the term ''physician designee'' as it was proposed in § 418.102, ''Medical director.'' The commenters believed that a definition would help to clarify this individual's role.

Response: We agree that defining this term will help clarify what responsibilities this individual has as well as when those responsibilities are assumed. The purpose of the physician designee role is to ensure that, if the medical director is unavailable, there is a predetermined, qualified individual who can assume all of the medical director's responsibilities. Having a predetermined individual who is ready and able to assume the medical director responsibilities will help to ensure that patients receive high quality hospice care even when the usual medical director is not available to perform his or her duties. With this in mind, we are adding a definition for ''physician designee'' at § 418.3 to read as follows:

''*Physician designee* means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical director when the medical director is not available.''

Comment: Several commenters asked us to clarify the definition of the term ''representative'' by recognizing case law, common law, and health care powers of attorney in determining whether or not an individual is a patient's representative.

Response: The proposed definition of ''representative'' states that a representative is an individual who has the authority under State law to authorize or terminate care on the patient's behalf. In the context of this definition, we are deferring to State law in its entirety, including statutes, agency regulations, and binding court rulings. Since designations of health care powers of attorney are deemed to appoint legal representatives by most, if not all states, our proposed definition would include individuals granted health care powers of attorney. Thus, case law, common law, and health care powers of attorney are subsumed within the definition of the term ''representative'', and there is no need to amend it.

Comment: A majority of commenters requested that we revise the proposed definition of ''drug restraint'' to remove the stigma associated with the term ''drug.'' A minority of commenters requested that we delete the definition of ''drug restraint'' completely, and suggested that the hospice industry at large or hospices individually should be allowed to determine a definition.

Response: Drugs have long played a prevalent role in hospice care. They are used to relieve pain, calm anxiety, improve breathing and support the patient. However, the idea of drugs used as restraints is relatively new in hospice care and has provoked much anxiety in the hospice industry. We understand that hospices are concerned about an overly restrictive definition of the term ''drug restraint.'' We also understand that hospices are concerned about State surveyors applying the drug restraint regulations applicable to other health care providers to hospices. We believe that these regulations clearly apply only to hospice inpatient facilities (hospice programs do not have outpatient facilities). Deleting the definition of ''drug restraint'' will not resolve providers' uncertainty, and will only leave hospices and patients in the untenable position of not knowing what is and is not a drug restraint; and simply renaming the definition as ''chemical restraint'' will not resolve the ambiguity either. While we acknowledge that the term ''drug'' may have a negative connotation among patients, we are not requiring hospices to use this term when discussing medications or chemicals with patients. Hospices are free to refer to drugs used for any purpose within the hospice in a manner that suits their patients and their representatives, families, other caregivers, and the hospice. Moreover, section 591(d)(1)(B) of the PHS Act prohibits the use of drugs ''used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition.'' This provision of the Act applies to any health care facility that receives any financial support from any program receiving Federal dollars.

Comment: Many commenters suggested that we narrow the definition of ''drug restraint'' to tailor it to the hospice environment. Specifically, commenters requested that we indicate, in the definition, that a drug is only considered a restraint if it is not an accepted treatment within a hospice program. The commenters expressed concern that drugs that may be considered restraints in other health care settings (for example, long term care facilities) are not restraints in hospice care because those drugs are used to treat distressing symptoms (for example, terminal restlessness). A single commenter requested that we not consider a drug to be a restraint if that drug is requested by the patient or the patient's representative while another commenter suggested that drugs should only be considered restraints if they are used inappropriately.

Response: Narrowing the definition of ''drug restraint'' by specifying that a drug is not a restraint if it is a ''standard treatment within a hospice program'' may hinder hospices from adopting new symptom management drugs in the future because they may have not yet met the ''standard treatment within a hospice program'' criteria. Our final language states that drugs used as a restraint are drugs that are not standard treatment or dosage for the patient's condition, and we believe that this will afford adequate protection to the hospice patient population. Therefore, we are not adding this additional limitation to the definition.

Similarly, narrowing the definition by adding a provision that a drug is not a restraint if it is requested is not appropriate. Requesting a drug does not alter its status as a restraint. In fact, there are times when a patient, representative or family member may request that a drug be administered to protect a patient from his or her own behavior. The requestor would, in essence, be asking for a restraint. Once the drug is administered, the patient would require the increased level of supervision required by this rule in order to ensure the patient's safety and well being at all times. Therefore, we are not adding a provision to exclude drugs from the definition of ''drug restraint'' if those drugs are requested by the patient or family.

Furthermore, narrowing the definition of ''drug restraint'' to those drugs that are used inappropriately is not suitable. There are drugs commonly used in the hospice environment for symptom management that can also be used appropriately as drug restraints under limited circumstances when warranted by the patient's condition and needs as documented in the patient's clinical record.

Comment: A few commenters suggested that we should use the same definition of ''chemical restraint'' for hospices as we do for other provider types.

Response: We agree that using the same definition will help to ensure that

hospice patients receive the same level of care and protection regardless of where they receive health care services. In addition, we agree that using the same definition will help to ensure that employees moving from another provider type to the hospice setting will more likely be familiar with the regulatory requirements. Therefore, at § 418.3, we are adopting the same definition and definitional format for drug restraints as is used in the Hospital Conditions of Participation. We are deleting the definitions of ''drug restraint'' and ''physical restraint'' in favor of a more expansive definition of ''restraint'' that encompasses both drug and physical restraints. We believe that having a single definition, rather than three separate definitions, will simplify the regulation and increase the public's understanding of the requirements. The specific section of the new ''restraint'' definition that applies to drug restraints is as follows:

''A drug or medication when it is used as a restraint to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.''

Comment: Many commenters suggested changes for the definition of ''physical restraint'' ranging from a suggestion to delete the definition to a suggestion that devices adjacent to the patient's body also be considered physical restraints.

Response: As with ''drug restraints,'' we understand that there is a great deal of apprehension and uncertainty regarding physical restraints. In the preamble to the proposed rule we asked for public comments regarding instances when physical restraints may or may not be appropriate and necessary. We heard from a few commenters that bedrails and positional devices are used for patient safety, and for assisting patients in functioning independently. No commenters described a single instance where physical restraints have been, or to their knowledge, are now used, whether appropriately or inappropriately, for patient safety, behavior management or any other purpose. The lack of specific comments leads us to conclude that this is an issue that most hospices choose not to discuss. Without this input, we are unable to gauge the level of physical restraint utilization in the hospice industry or the purposes of that utilization.

The Children's Health Act (CHA) requires us to promulgate regulations concerning the use of restraints in hospices. Deleting the definition of ''physical restraint'' would be in conflict with the requirements of the CHA and will not alleviate the concern about the safe and proper use of physical restraints. Indeed, deleting the definition will only leave hospices wondering whether their practices constitute physical restraint and what precautions should be taken to ensure patient safety and well being. We do not believe that this is in the best interest of patients or hospices; therefore we are including a definition to address physical restraints. Moreover, section 591 of the PHS Act sets forth a statutory definition, which is the basis for enforcing regulations on the use of restraints.

At the same time, however, we are sensitive to commenters' concerns that the definition of ''physical restraint,'' as was proposed, could include bedrails and positional devices. Bedrails and positional devices may have the effect of restraining one patient but not another, depending on the individual patient's condition and circumstances. For example, a partial bedrail may assist one patient to enter and exit the bed independently while acting as a restraint for another patient. Patients who attempt to exit a bed through, between, over, or around bedrails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised bedrails than from a fall from a bed where bedrails are not used. Bedrails also potentially increase the likelihood that the patient will spend more time in bed and fall when attempting to transfer from the bed. To address these potential hazards, many long term care facilities have replaced the use of bedrails with lower beds, perimeter mattresses, alarms, and sitters for restless individuals. We encourage hospices to have a dialogue with their long term care facility colleagues about the safe and appropriate use of bedrails for hospice patients, as we believe that both parties can learn from their successes. To reflect the fact that it is the function and effect of a device, rather than a device itself, that determines whether or not the device is a physical restraint, we have revised the definition at § 418.3 as follows:

''Restraint means: (a) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).''

This language almost precisely tracks 591(d)(1)(A) of the PHS Act, and matches the definition in the Hospital Conditions of Participation. As a commenter suggested, physical restraint applies to any device that has a restrictive effect, regardless of whether the device is attached to or adjacent to a patient's body. It is the effect of the device, rather than its location, that makes it a restraint. Using the same definition for hospices as is used for other provider types will help ensure that patients are consistently provided the same quality of care and supervision when restraints are used, regardless of whether those patients are in a hospital or a hospice inpatient facility. At the same time, using the same definition will make staff transitions between different provider types easier because the same set of restraint rules will apply to some other provider types. This may be particularly helpful to hospices that have occasion to furnish services under contract where a nurse or other practitioner may be more familiar with the rules governing restraints in hospitals. Having the same definition will help to ensure that there is no conflict between the practitioner's previous background and training and the applicable hospice rules.

Comment: Several commenters noted that the proposed definition of the term ''seclusion'' implies that any placement of patients in private rooms would constitute seclusion. One commenter suggested that the term should be completely removed.

Response: While it was not our intent, we agree that the proposed definition of ''seclusion'' could embrace private rooms. Therefore, at § 418.3, we have revised the definition of ''seclusion'' by adding the term ''involuntary.'' Patients who request private rooms do so voluntarily, and therefore would not be in seclusion. However, if a patient is placed alone in a private room against his or her will and is not permitted visitors or egress from that room, then the patient would be considered to be in seclusion. We also believe that it is essential for the term ''seclusion'' to remain in this rule. Seclusion, as defined in section 591(d)(2) of the PHS Act, may only be used under circumstances described at 591(b). Deleting the term ''seclusion'' will not assist hospices in complying with the statutory requirement, and will only leave hospice facilities and patients in the untenable position of not knowing

what situations do and do not qualify as ''seclusion'' and whether they may be in violation of the Children's Health Act. We do not believe that this is in the best interest of hospices or their patients.

Comment: A few commenters requested that we delete the definition of the term ''terminally ill'' because it is a term that may discourage patients from accepting hospice care.

Response: Section 1861(dd) of the Act establishes the Medicare hospice benefit for beneficiaries who are terminally ill with a prognosis of 6 months or less if the illness runs its normal course. The definition that we proposed is the same definition that is used in the Act. We believe that this is necessary to maintain the definition in this rule because this term is used in the hospice payment rules.

Comment: A number of commenters requested that we define the term ''family'' using a very broad, patient-directed approach that allows the patient to identify those who are considered to be his or her ''family.''

Response: We do not believe that a single definition of the term ''family'' would benefit beneficiaries or hospices. The meaning of ''family'' can change depending on circumstances and availability of persons close to the patient. While allowing the patient to identify his or her ''family'' would be ideal, this may not be possible for patients who cannot communicate and who do not have written information available for the hospice. We have decided that it would be most appropriate to allow each hospice to establish its own policy on what ''family'' means in its community and with its own patients.

Comment: A single commenter requested that we add a definition for the term ''unnecessary drugs'' to include drugs used in excessive dosages, for excessive durations, without adequate monitoring, without adequate indications for use, or in the presence of adverse events.

Response: The term ''unnecessary drugs'' did not appear within the proposed rule. The concept is very interesting and may be useful to hospices when assessing a patient's drug therapy regimen as required by § 418.54(c), Content of the comprehensive assessment. We have incorporated some of the commenter's concerns in our final rule at section 418.54(c)(6). This section requires hospices to review a patient's prescription and over-the-counter drugs in use at the time of the assessment, including, but not limited to, an identification of the effectiveness of the drug therapy regimen, any potential or existing drug side effects, any potential or existing drug interactions, any duplicate drug therapies, and any drug therapy requiring laboratory monitoring. Excessive dosages or durations, or inadequate monitoring would likely lead to effectiveness and side effect issues that will be assessed during the comprehensive assessment and subsequent updates. The IDG, in conference with an individual who has specialized education and training in drug management, such as a pharmacist, will be required to address these issues in the patient's individualized hospice plan of care.

Comment: A commenter suggested that we should define the term ''adverse event'' using the Joint Commission patient safety event taxonomy. Another commenter suggested that we should define the term as an, ''unanticipated, non-therapeutic response or injury''.

Response: While we agree that using the Joint Commission patient safety taxonomy or suggested definition may be helpful for some hospices, we do not believe that a single definition of ''adverse event'' would meet the needs of all hospices at this time. In general, an adverse event would be any action or inaction by a hospice that causes harm to a hospice patient. We believe that hospices are capable of determining what is or is not an adverse event based on the characteristics and needs of their patient populations and staff. We recognize that hospices are seeking further guidance on this issue, and we plan to provide such guidance in future sub-regulatory guidance, such as the State Operations Manual and Interpretive Guidelines.

Comment: A few commenters requested that we define the term ''homemaker services'' with specific references to the Medicaid personal care benefit that many states offer to Medicaid beneficiaries. Commenters asked for clarification about the role of homemakers in hospice care, their relationship to Medicaid personal care aides, and the qualifications for individuals who furnish homemaker services.

Response: Section 418.202(g) in subpart F of the current hospice regulations states, ''[h]omemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.'' We believe that this language adequately describes the role that homemakers play in hospice care, and we are making no changes to it in this final rule.

Each State establishes its own Medicaid personal care aide benefit, pursuant to our regulations at 42 CFR 440.167, including its own eligibility criteria, scope of services to be provided, and personnel qualifications. Medicaid regulations impose only minimal restrictions on the state's discretion regarding these services. Hospice care is meant to supplement the care provided by the patient's caregiver. If the individual(s) furnishing Medicaid personal care services is functioning as the patient's caregiver, then the hospice would not be expected to replace the Medicaid personal care providers with its own homemaker services on a round-the-clock basis. The Medicare hospice benefit is not meant to be a caregiver benefit and should not be expected to function as such. Hospices should work with their respective State Medicaid agencies if they have questions about who pays for services provided to patients eligible for both Medicare and Medicaid.

With regard to who is qualified to furnish homemaker services on behalf of a hospice, we proposed in § 418.76(j) that a homemaker must have either completed home health aide training requirements or must have successfully completed a hospice's orientation addressing the needs and concerns of patients and families coping with a terminal illness. We continue to believe that either home health aide (now referred to as a hospice aide) training or hospice orientation provides sufficient knowledge for an individual to function as a homemaker under the supervision of the IDG, and our final requirements at § 418.76(j) and § 418.76(k) reflect this.

Comment: Several commenters requested that we define the term ''nursing services.'' Most of these commenters defined the term to include those services furnished by a registered nurse, licensed practical nurse (LPN), licensed vocational nurse (LVN), nurse practitioner or other advanced practice nurse. However, the commenters were divided on whether or not services should be allowed to be delegated by a nurse to a hospice aide and whether these delegated services should be considered nursing services.

Response: The intent of section 1861(dd) of the Act has always been to require hospices to furnish nursing services to their patients as part of the Medicare hospice benefit. Hospices have complied with this requirement for the past two decades using the services of a variety of different categories of nurses ranging from nurse practitioners to licensed vocational nurses to registered nurses. Hospices have not, to our knowledge, had any difficulty in determining what constitutes nursing services and we see no reason to

establish a definition for the term at this time.

It is important to point out that if we had included delegated services in the definition of the term ''nursing services,'' then the inclusion would effectively prohibit hospices from contracting for hospice aide services. We believe that this de facto prohibition would occur because those contracted hospice aides would routinely be furnishing delegated nursing services, and section 1861(dd) of the Act requires that substantially all nursing services should be furnished by direct hospice employees. We do not think that the commenters intended to establish this de facto prohibition on contracting for hospice aide services.

Comment: A commenter asked us to define the term ''covering physician'' as a physician acting on behalf of the attending physician.

Response: The term ''covering physician'' did not appear in the proposed rule. If the patient's attending physician is not available to care for his or her patients, then a hospice physician would assume care responsibilities. In accordance with the proposed and final rule at § 418.64(a)(3), a hospice is responsible for providing an alternate physician to meet the medical needs of the patient in the attending physician's absence.

Comment: A few commenters asked us to add a definition for the term ''social worker.'' Some commenters proposed maintaining the current definition as an individual with a Bachelors degree in Social Work from an accredited university. Others suggested raising the requirement to a Masters degree in Social Work from an accredited university.

Response: We believe that the commenters raise important issues, which are discussed in a subsequent portion of the preamble. We are relocating the credential requirements for social workers from the definitions section to the new personnel requirements section (§ 418.114). We believe that this new, central location for all credentialing requirements is the appropriate location for the social work credentialing requirements as well. Therefore, we are addressing these suggestions in the personnel qualifications section of this rule.

Comment: Several commenters asked us to add definitions for the four levels of care provided in hospice (routine home care, continuous home care, respite care, and general inpatient care). A few commenters even provided their own definitions for these levels of care.

Response: These ''levels of care'' are payment rather than health and safety issues, and therefore we are not addressing them in this rule. These terms are used specifically in reference to our hospice payment rules found at 42 CFR 418 Subpart F ''Covered Services'' and Subpart G ''Payment for Hospice Care.'' In these two subparts, specific criteria for these payment levels are detailed, and these criteria constitute the definitions for these payment terms.

Comment: Some commenters asked us to define the term ''plan of care,'' and suggested the plan of care should be defined as a written document that addresses the patient and family needs identified in the comprehensive assessment and is updated as needed.

Response: We agree with the commenters that the plan of care must be a written document and that it must address the status of the patient and family as identified in the comprehensive and updated assessments. We also agree that the plan of care should be updated as frequently as necessary based on changing status and needs. We do not believe that it is necessary to define ''plan of care'' because pertinent issues are being specified in this final rule at § 418.56, ''Interdisciplinary group, care planning, and coordination of services.'' Section 418.56 requires that a hospice IDG ''prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.'' In addition, § 418.56(d) will require that the plan of care be updated by the IDG ''as frequently as the patient's condition requires, but no less frequently than every 15 calendar days.'' We believe that these requirements adequately address the commenters' concerns.

Comment: A commenter requested that we define the term ''spiritual assessment'' to ensure that these assessments address more than a person's religious affiliation.

Response: Our inclusion of ''spiritual assessments'' in hospices should not be solely related to religious affiliation (or lack thereof). These assessments might focus on a patient's sense of peace, purpose, beliefs, etc., but may not be warranted for all patients, particularly if they already have an available spiritual/emotional support system. Therefore, we do not believe that it is in the best interest of hospice patients and hospice providers to prescribe exactly what constitutes a spiritual assessment. A definition may unintentionally interfere with the individualized, patient-centered hospice care that we require hospices to furnish. We do not intend for this regulation to suggest that any spiritual counseling or services be provided to a hospice patient or family against their wishes.

Comment: Many commenters asked us to define the phrase ''patient's home'' or ''patient's residence'' as a house, apartment, SNF/NF, ICF/MR, assisted living facility, adult home, shelter, foster home or any other place where a patient lives.

Response: We are unable to develop a single definition of the terms ''home'' or ''residence'' at this time. We will consider these suggestions for future rulemaking.

Comment: Many commenters requested a definition of the term ''facility'' as it is used in proposed and final § 418.112.

Response: The general term ''facility'' has been removed from this condition of participation (CoP) in favor of a more specific list of the facility types to which § 418.112 applies. As the general term no longer appears in the rule in the context of § 418.112, it is no longer necessary to define it.

Comment: A commenter suggested that we define the term ''hospice patient'' as a patient who has been certified as being terminally ill and who has accepted the care of a hospice agency.

Response: There is no single definition of ''hospice patient'' that can encompass all types of patients treated by a hospice and all eligibility criteria for all payment sources. Certifying a patient's terminally ill status is a Medicare and Medicaid payment requirement that does not necessarily apply to other health insurance or private pay patients. To say that un-certified patients are not ''hospice patients'' by excluding them from the definition would be inappropriate. However, ''hospice patients'' for Medicare payment purposes are those Medicare beneficiaries certified under § 418.22 and electing hospice services under § 418.24. Furthermore, we note that the term ''hospice patient'' does not appear in statute or regulation, and, as such, we do not believe that it requires a definition in this rule.

3. Condition of Participation: Patient's Rights (Proposed § 418.52)

We proposed to replace the existing CoP, Informed consent, at § 418.62, with a new patient rights CoP. The proposed patient rights CoP was divided into five standards. The first standard, ''(a) Notice of rights,'' would have required hospices to develop a notice of rights, including information about advance directives and the hospice's controlled

drug policies. Under the proposed requirement, hospices would have been required to present the notice of rights verbally (meaning spoken) and in writing to patients and families in a language and manner that they are able to understand. This would have occurred before the hospice furnished care to a patient and family. Hospices would also have been required to document the patient's or representative's understanding of the notice of rights.

In standard (b), ''Exercise of rights and respect for property and person,'' we proposed that the patient would be able to exercise his or her rights, be respected, voice grievances, and not be subjected to discrimination or reprisal. We also proposed that hospices would investigate and report all alleged violations of patient rights, and take appropriate corrective action where necessary.

The third standard, ''(c) Pain management and symptom control,'' proposed that patients would have the right to receive effective pain management and symptom control from the hospice.

Standard (d), ''Confidentiality of clinical records,'' proposed that hospices would be required to maintain the confidentiality of clinical records in accordance with the Privacy Rule published in the **Federal Register** on December 28, 2000 (65 FR 82461) as amended on August 14, 2002 (67 FR 53182) and set out at 45 CFR parts 160 and 164.

Finally, the fifth standard, ''(e) Patient liability,'' proposed that patients would be informed about the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other sources, verbally and in writing in a language that the patient was able to understand. This standard proposed that this information would be provided to patients before care was furnished. The intent of this standard was to ensure that patients were aware of their potential out-of-pocket costs for hospice care, such as co-payments, so that they would not be surprised by financial concerns at this stressful time.

Comment: A majority of commenters on this issue expressed concern about the proposed requirement that hospices provide a notice of the patient's rights and responsibilities verbally, as well as in writing, in a language and manner that the patient would understand. Many of these commenters requested that hospices not be required to furnish written notices in obscure or otherwise uncommon languages. Other commenters requested that the choice of language(s) used to communicate be left to the discretion of each hospice or that the communication be done in accordance with guidance issued by the Department of Health and Human Services (HHS) related to Title VI of the Civil Rights Act of 1964, Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons. Still other commenters requested that we specifically recognize in the regulation that interpreters, family or otherwise, be permitted to facilitate communication of the notice of rights to patients and families.

Response: We recognize that this is an area of concern for hospices, as it may be challenging for hospices to communicate with patients who speak languages other than English. However, ensuring that patients are aware of their rights and how to exercise them are vital components of improving overall hospice quality and patient satisfaction. If patients are unaware of their rights or the methods and protections available for exercising those rights, then hospices cannot expect to receive valid feedback from patients on ways to improve their services. Without the valid feedback, true quality measurement and improvement cannot exist. Therefore, we believe it is in the interest of patients and hospices to ensure that all patients, regardless of their communication needs, are informed of their patient rights.

Even so, we are sensitive to the concerns of hospice providers. The HHS guidance on Title VI (August 8, 2003, 68 FR 47311) applies to those entities that receive federal financial assistance from HHS, including hospices. This guidance presents four areas for hospices to consider when developing and implementing strategies to meet the needs of limited English proficient persons. The guidance recognizes the role of professional translation services, as well as family and friends of the patient, in communicating important information to patients, including the notice of rights. Hospices are already expected to comply with the HHS guidance, and doing so will enable them to comply with the requirements of the proposed rule.

Using family and friends as translators should not be the communication plan of choice for the hospice for its patients who do not speak English, unless the patient specifically requests this approach. Hospices should make all reasonable efforts to secure a professional, objective translator for hospice-patient communications, including those involving the notice of patient rights. Furthermore, hospices should make all reasonable efforts to have written copies of the notice of rights available in the language(s) that are commonly spoken in the hospice's service area. For those patients who speak uncommon languages in areas where professional translators for those languages are not readily available, using family and friends of the patient is an acceptable option.

Comment: A commenter asked that we explicitly specify in § 418.52(a)(2) that patients have the right to refuse to formulate advance directives.

Response: Under this final rule, hospices are required to comply with 42 CFR part 489 Subpart I, ''Advance directives.'' Patients may choose to develop advance directives in accordance with applicable State requirements. Likewise, they may choose to not formulate advance directives. We believe that 42 CFR part 489 adequately addresses all aspects of advance directives, including patient choice. Therefore, we are not adding the commenter's suggestion.

Comment: Some commenters asked that we clarify what type of documentation would be necessary to demonstrate that the hospice provided patients with a notice of rights and that the patient or representative demonstrated an understanding of the rights. A majority of commenters noted that language in the proposed rule, ''demonstrated an understanding of,'' was imprecise and difficult to measure. Additional commenters suggested that language from the home health agency CoPs at 42 CFR 484.10 should be used in the hospice CoPs. Section 484.10 states that ''the HHA must maintain documentation that it has complied with the requirements of this section.'' This language, commenters noted, would allow hospices to determine in their own policies how the documentation would be handled. Several other commenters suggested that hospices be required to obtain the patient's or family's signature, confirming that they received the notice of rights.

Response: We agree that a more precise requirement will help hospices ensure that patients and families are fully informed about the notice of rights. Furthermore, we agree that more precise language will help hospices ensure that they are in compliance with our documentation requirements. Therefore, this final rule at § 418.52(a)(3) states, ''The hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.''

Comment: Some commenters noted that State practices and laws may

govern a legal representative's exercise of a patient's rights as described in § 418.52(b)(3). The commenters requested that we add the phrase ''and practice'' at the end of this requirement so it would read: ''If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law and practice.''

Response: Without more specific information from the commenters regarding what practices states may unofficially have in place, we do not believe that it is appropriate for us to add the phrase ''and practice'' to the requirement at this time. If more specific information is made available at a future time, we will reconsider this suggestion.

Comment: Many commenters had concerns about the scope of the responsibilities of hospices when investigating and reporting violations of patient rights by hospice staff. In addition, the commenters had concerns about the proposed timeframes for investigating and reporting alleged violations to local authorities and State survey agencies. Specifically, the commenters noted that it would not be necessary to notify State and local bodies having jurisdiction about unverified violations. The commenters also noted that alleged violations may occur several days before the hospice becomes aware of them, and indicated that the reporting timeframe should not begin before a hospice even becomes aware of the alleged violation. Numerous commenters suggested that the patient rights requirement in the home health agency regulations at § 484.10 might be more appropriate, while others suggested that the investigation and reporting requirements be deleted in their entirety.

Response: Requiring hospices to investigate potential violations of patient rights by hospice staff (including contracted or arranged services) will protect patients and their families. Reporting violations (when verified in accordance with hospice policies and procedures and any applicable State and local laws and regulation) is an integral part of improving the quality of hospice care provided to Medicare beneficiaries. At the same time, adopting regulations more in line with those currently in the home health agency rules would not, we believe, be appropriate for the hospice industry because hospices typically care for more fragile patients and families in a wider variety of patient care settings, such as private homes, long term care facilities, and hospice inpatient units. The home health agency requirements are narrower than what we are requiring. We believe that a broader framework in these hospice regulations, coupled with a hospice's own policies and procedures, will allow hospices to adapt the requirements to the particular needs and concerns of their patient populations now and in the future.

However, we agree that further clarifications are warranted to ensure that a hospice assumes full responsibility for its staff, while not overwhelming the hospice with responsibilities beyond its control. To that end, we are requiring hospice staff that discover alleged violations to immediately report such allegations involving anyone furnishing services on behalf of the hospice, including contracted and arranged services, to the hospice's administrator. The hospice administrator must investigate violations involving anyone furnishing services on behalf of the hospice and, if verified, the hospice must report the violation to State and local bodies having jurisdiction within 5 working days of any member of the hospice staff (including those furnishing contracted or arranged services) becoming aware of the violation in accordance with the hospice's own policies and procedures. We would expect that significant violations, such as illegal actions by hospice staff, would be reported to State and local bodies. We believe that these modifications will ensure that violations are fully addressed while not overburdening hospices.

Comment: A single commenter requested that we defer to State requirements for violation reporting.

Response: If State requirements for reporting violations are stricter than our Federal requirements, then those stricter State requirements would take precedence. Stricter State requirements may be those that require violations to be reported regardless of whether they are verified or not, or requirements that verified violations be reported in less than 5 days. However, if State requirements are less stringent than Federal requirements, then the Federal requirements will take precedence. We believe that the scope and timeframes contained in this final rule are the minimum health and safety requirements with which facilities could reasonably be expected to comply.

Comment: Several commenters specifically focused their concerns on the implementation of proposed § 418.52(b)(4) in the context of the dual and possibly overlapping responsibilities of hospices that provide services to residents of long term care facilities. In particular, commenters suggested that hospices should only be held responsible for those individuals functioning on behalf of the hospice and that concerns pertaining to individuals functioning on behalf of the long term care facility should be the responsibility of that facility.

Response: We agree that hospices should only be held responsible for investigating and reporting violations pertaining to their own employees and contractors. To address this comment, at § 418.112(c)(8), we are setting forth a requirement that the written agreement between the hospice and the SNF/NF or ICF/MR must contain a provision whereby the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the facility administrator within 24 hours of the hospice becoming aware of the alleged violation.

This requirement will assure that the SNF/NF or ICF/MR is made aware of the alleged violation in a timely manner so that it can begin its own investigation and implement its own intervention(s). A hospice may also want to consider incorporating a provision in the contract to require a SNF/NF or ICF/MR to notify the hospice if any of its staff become aware of a potential patient rights violation involving hospice staff. Such a provision may enhance hospice-facility communication and cooperation. In addition, we will consider this issue when developing complementary regulations for long term care facilities.

Comment: A few commenters asked that we define the term ''immediately'' as it applies to the timeframe for reporting alleged violations to the hospice's administrator. The commenter recommended that the timeframe for reporting alleged violations be based on an assessment of the patient's needs.

Response: It is in the patient's best interest to involve the hospice administrator at the time that the potential violation is noted to assure that the situation is adequately and expeditiously dealt with. Once notified, it is up to the hospice's policies and procedures and the hospice administrator's judgment, in accordance with this rule, to handle the allegation. The hospice administrator is the designated leader of the hospice and assumes responsibility for the care and services furnished by the hospice, whether directly or under contract. This is a 24-hour a day responsibility, and it

applies to incidences of alleged violations.

Comment: Some of commenters expressed concern regarding the manner in which the terms ''mistreatment'' and ''injury'' are used in the proposed patient's rights CoP. They believe the terms to be vague and too difficult to judge objectively.

Response: The terms ''mistreatment'' and ''injury'' encompass two important areas that affect patient safety and satisfaction. While other terms such as ''abuse'' and ''neglect'' imply actual harm to a patient, ''mistreatment'' is a broader term that encompasses quality of life issues that are crucial as patients and families cope with death and dying. We understand that the broad nature of the term makes it difficult to judge. This judgment difficulty is exactly why we are requiring hospices to conduct their own internal investigation into the potential patient rights violation. We are leaving these terms mostly undefined so that hospices may determine whether ''mistreatment'' or ''injury'' have occurred on a case-by-case basis. State tort liability laws may serve as a guide for hospices in determining whether ''mistreatment'' or ''injury'' have occurred. Through a thorough investigation, hospices can determine, in accordance with their own policies and procedures, whether mistreatment occurred and what steps need to be taken to resolve the mistreatment and prevent future occurrences.

The presence of the term ''injury'' is also important in this standard because it addresses other issues that may not constitute ''abuse'' or ''neglect'' but that nonetheless impact a patient's well-being. We understand that some relatively minor injuries such as skin tears may be perceived as injuries. By maintaining the term ''injury'' in this standard, hospices are required to fully investigate incidents of minor injuries (like skin tears) to determine if they constitute a violation of a patient's rights. If the internal investigation reveals that all appropriate steps were taken to prevent the minor injury, then the hospice may determine that the injury is not a violation of a patient's rights. However, if the investigation reveals that reasonable precautions were not taken, then the hospice may determine that the injury is a violation of patient rights. In setting forth a standard in the final rule that requires hospices to report patient injuries to the hospice administrator, hospices have the opportunity to conduct a self assessment to determine if care processes need to be changed to improve the consistent delivery of quality care.

Comment: Some commenters asked for clarification regarding proposed § 418.52(c), which reads, ''The patient has a right to receive effective pain management and symptom control from the hospice.'' While the commenters supported the intent of this standard, they questioned its scope. One commenter wanted to know whether this standard would require hospices to furnish continuous home care, while another questioned if hospices were supposed to be responsible for pain and symptom management unrelated to the terminal and related conditions. Still another commenter suggested that hospices should be allowed to refer patients to other providers for pain and symptom management.

Response: Effective pain and symptom management have long been the hallmark of hospice care, and we appreciate that the commenters recognized the importance of this patient right. We agree that hospices are required to furnish pain and symptom management for the terminal illness for which the patient is receiving hospice care and conditions related to the terminal illness. We have revised this standard and clarified this point at § 418.52(c)(1). The continuous home care level of care described in the payment and coverage sections at 42 CFR 418.204 and 418.302 may or may not be the most effective way to provide effective pain management and symptom control while maintaining a patient at home.

It is acceptable for hospices to refer pain and symptom control issues unrelated to the terminal illness and related conditions to other providers. If a hospice were to make a referral, we would expect the hospice to coordinate its efforts with the other provider to avoid duplicative or contradictory therapies in accordance with final § 418.56(e)(5). The goal of this coordination is to ensure that the patient's hospice plan of care is implemented, and that the hospice care is furnished in concert with other care sources to ensure that all patient needs are met. In accordance with § 418.100(c) hospices are responsible for pain and symptom management related to the terminal illness and related conditions and should not refer patients to other providers for these issues. If a hospice does not have the expertise to handle pain and symptom management issues related to the terminal and related conditions, it is responsible for procuring the expertise for the patient as part of its regular hospice services.

Comment: Many commenters suggested that we should add provisions stating that patients have the right to refuse treatment and the right to be involved in developing their plans of care.

Response: We agree that these are important patient rights that should be included in this final rule. We believe that including these rights, at new § 418.52(c)(2) and § 418.52(c)(3) respectively, will help to ensure that the patient's goals and needs are consistently reflected in the hospice's plan of care and actions.

Comment: A few commenters requested that we add a provision requiring hospices to provide patients with a written statement of the scope of care and services that will and will not be provided. One commenter requested that we add a provision stating that patients have the right to receive information about the services covered under the hospice benefit.

Response: We agree that providing a patient with general information about his or her hospice benefit is an important step in ensuring that hospice patients are educated about their rights. Therefore, we are establishing section 418.52(c)(7), which requires hospices to provide this general benefit information.

We also agree that providing a patient with general information about the scope of services that the hospice provides, as well as any limitations on those services, will further empower hospice patients and their caregivers to take an active role in hospice care planning. Providing the patient and family a list of services that the hospice may provide gives the patient and family an opportunity to request specific services that the IDG had not considered. Simply knowing that help is available may lead patients and families to reach out for it. For this reason, we are establishing section § 418.52(c)(8), which requires hospices to provide information about the scope of services that the hospice will provide to its patients, and specific limitations on those services.

Comment: A single commenter requested that we add a specific provision stating that patients have the right to continue to maintain a relationship with their attending physician once they elect the hospice benefit.

Response: It is understood and widely accepted throughout the health care community, including in the hospice industry, that patients should be allowed, even encouraged, to continue to work with their attending physicians as they transition from one health care provider or setting to another. The goal of this practice is to enhance continuity and quality of care by actively including the attending physician, who knows

that patient's medical and family history, in planning and delivering the patient's hospice care. We believe that this is in the best interest of patients and providers. Explicitly identifying a patient's right to choose his or her attending physician without undue influence from a hospice will help ensure that hospices and patients continue to benefit from the knowledge of attending physicians. Therefore, we have added this patient right at § 418.52(c)(4).

Comment: A commenter requested that we add a provision stating that patients have the right to access, request amendments to, and receive an accounting of disclosures regarding their health information.

Response: Patient rights regarding their health information are explicitly addressed in the HIPAA regulations at 45 CFR 164.502(a)(2)(i) and 164.524. Hospices are already required to comply with these extensive regulations, and we see no need to duplicate the HIPAA patient rights requirements in this rule. Therefore, we are not adding this suggested provision.

Comment: Many commenters expressed confusion and concern about our proposed requirement that hospices notify patients of the extent to which payment may be expected from the patient before care is initiated. Commenters sought clarification on how this requirement would dovetail with the Advanced Beneficiary Notice (ABN), long term care facility payments, and private health insurance payment rules. In addition, commenters wanted to know if, before care is initiated, hospices would be required to advise patients of those services that would not be covered by the hospice because those items would not be in the plan of care, even though the plan of care had not yet been formulated. Some commenters suggested that, rather than providing exact dollar amounts for patient liability, we should require a more general description about co-pays, Medicaid spend down requirements, etc. Other commenters requested that this notice not be in writing or that it be provided at the time of the initial assessment rather than before any care is provided. A single commenter requested that the requirement be phased in over a period of time.

Response: The original intent of this proposed standard was to educate patients and families about their potential liability in consideration of all available payment sources. Patients and families often come to hospice after long illnesses with pressing financial concerns. In requiring hospices to provide information when services are first provided (particularly on Medicare's comprehensive benefit with minimal co-pays) we sought to alleviate some of those financial worries. However, as many commenters noted, hospices regularly provide this payment overview as part of their patient intake process when patients are choosing whether or not to elect the hospice benefit. We encourage hospices to continue this practice. Furthermore, commenters noted that financial liability for long term care facility residents becomes very complicated and uncertain because of the patient's residential status. Information provided before the start of care is likely to be inaccurate because hospices do not control the resident's long term care facility liability. The proposed timing of the notification and its all-encompassing nature make it impractical for hospices to implement and would likely not increase the benefit of hospice services to patients and families. Therefore, we are deleting this requirement. We believe that the existing ABN requirements at 42 CFR 411.404, which require hospices to notify patients should a particular service or item potentially not be covered by Medicare, provide the most timely and accurate information to patients and families. The ABN should be delivered far enough in advance that the patient or representative has time to consider the options and make an informed choice. The ABN should be verbally reviewed with the patient or representative and any questions raised during that review should be answered before it is signed.

Comment: A commenter requested that we add a provision to the patient's rights CoP stating that patients have the right to refuse to participate in experimental research.

Response: Ethical research practices dictate that patients must choose to participate in experimental research and that their participation or lack thereof may not negatively impact their well-being. In addition, although we acknowledge that it may occur at times, experimental research in palliative care is not, to our knowledge, a common occurrence. We believe that the existing patient opt-in research standard, combined with the rarity of the situation, does not warrant us issuing a new standard within this CoP.

Comment: A few commenters suggested that we should add a provision, either in the ''Patient's rights'' requirement or other requirements, that ensures that long term care facility residents are provided a choice of which hospice furnishes their care.

Response: We are aware of concern within the hospice industry about long term care facilities that choose to not contract with hospice providers, or to only contract with a single hospice provider to furnish hospice services to residents. However, authority to govern long term care facilities' actions is not contained in the hospice regulations found in 42 CFR part 418. Therefore, we are not adding the suggested requirement. We will however, take these comments into consideration as we review the long term care CoPs for possible future revisions that would address this aspect of long term care facility responsibility relative to the care of residents.

Comment: Some commenters requested that we require hospices to recognize board-certified chaplains as advocates for patient rights in hospices.

Response: We expect that all hospice employees and contractors should be patient rights advocates with the best interest of the patients in mind at all times. We are not requiring that hospices use patient advocates. However, if hospices choose to designate specific patient rights advocates, they are free to do so, and are free to select those individuals who are best suited for the task. Board-certified chaplains may serve well in the patient rights advocate capacity, and hospices are free to explore this option.

Comment: Another commenter requested that we add a provision stating that patients should not be denied hospice care based on the cost of their reasonable and necessary palliative care.

Response: Decisions about admission to hospice fall outside of the purview of this rule, which focuses on ensuring the safe and effective provision of quality care to patients and their families once the patient is admitted to a hospice. Although we take this issue very seriously, we are not incorporating the suggested provision in this rule. We note that providers, in general, cannot be required to provide services to Medicare patients (see Section 1802(a) of the Social Security Act).

Comment: A single commenter suggested that patients should be required to demonstrate their willingness to comply with the plan of care.

Response: We understand that patient noncompliance is occasionally an obstacle for hospices in providing safe and effective hospice care. However, we have no authority to mandate patient compliance. It is the hospice's responsibility to fully educate the patient and family regarding hospice care, as well as hospice policies and

procedures for handling plan of care disagreements, emergencies and other situations that may prompt patient noncompliance. For these reasons we are not adding a patient compliance provision.

Comment: A single commenter suggested that hospices be required to comply with any additional State reporting requirements for elder abuse.

Response: We agree that hospices should be required to comply with all health and safety related Federal, State and local laws and regulations, which would include reporting requirements for elder abuse. This rule finalizes § 418.116, ''Compliance with Federal, State and local laws and regulations related to the health and safety of patients,'' which requires hospices to comply with State elder abuse reporting requirements.

4. Condition of Participation: Initial and Comprehensive Assessment of the Patient (Proposed § 418.54)

The proposed assessment requirement identified the general areas that would be included in a patient assessment and the timeframes for completing the assessments to help hospices ensure that they were identifying needs in all areas in a timely fashion.

The proposed comprehensive assessment requirement was divided into five standards. The first standard, (a), ''Initial assessment,'' would require a registered nurse to make an initial assessment visit within 24 hours of receiving a physician's admission order for care, unless ordered otherwise by the physician. The purpose of this initial assessment was to determine the patient's immediate care and support needs. In the proposed rule we differentiated this initial assessment from the hospice's evaluation of a patient's appropriateness for hospice care. We stated that visiting a patient to determine his or her appropriateness for hospice care does not constitute an initial assessment.

The second standard, (b), ''Timeframe for the completion of the comprehensive assessment,'' proposed that the hospice IDG and the patient's attending physician complete the comprehensive assessment no later than four calendar days after the patient elected the hospice benefit. The four day timeframe was proposed because many hospice patients are admitted to hospice late in their terminal illness and often require intensive hospice services at the beginning of their hospice stay. A hospice must assess a patient to identify his or her needs before it can develop and implement a plan of care to meet those needs. Therefore, a timely assessment is necessary to properly care for a patient.

In the third standard, (c), ''Content of the comprehensive assessment,'' we proposed that hospices identify the physical, psychosocial, emotional, and spiritual needs of the patient related to the terminal illness and related conditions. As proposed, the comprehensive assessment would include information about the terminal condition, complications and risk factors, an initial bereavement assessment, a drug profile review, and any further referrals or evaluations, as appropriate. We did not propose that hospices use a specific assessment form or tool.

Under proposed standard (d), ''Update of the comprehensive assessment,'' the hospice IDG would be required to update each patient's comprehensive assessment no less frequently than every 14 days and at the time of each recertification. The proposed comprehensive assessment update would document changes that had occurred since the last assessment, including the patient's progress toward desired outcomes and the patient's response to the care furnished by the hospice. We proposed these update timeframes because the condition of a hospice patient is expected to change over the course of hospice care, and often does so quite rapidly, considering that the median length of a hospice stay is about 26 days.

The final standard in this proposed CoP, (e), ''Patient outcome measures,'' would require hospices to include, as part of the information gathered by the comprehensive assessment, data elements to allow hospices to measure patient outcomes. This standard proposed that the data elements would be collected and documented in the same manner for all patients in order to ensure the accuracy and consistency of the data. Hospices would be required to use the data in individual care planning and the quality assessment and performance improvement program described in proposed § 418.58. We did not propose to require hospices to use any specific patient outcome measures or data elements.

Comment: Many commenters requested that we clarify in the opening paragraph of the CoP that hospices are not required to assess a patient's condition beyond the patient's need for hospice care and services related to the terminal illness and related conditions. Commenters suggested that we delete the phrase ''but is not limited to'' because it implies that hospices are required to assess and address areas beyond the boundaries of the terminal illness and related conditions.

Response: The Medicare hospice benefit covers all care provided by hospices for the palliation and management of an individual's terminal illness and related conditions. Hospices are required to furnish these services; however, they are not required to furnish services for needs unrelated to the terminal illness and related conditions. Our intent in specifying that hospices are not limited to assessing the patient's status and needs associated with the terminal and related conditions was to explicitly permit hospices to look beyond the terminal and related conditions to gain a complete picture of the patient. We did not intend to imply that hospices would be required to provide care for those issues that are outside of the scope of hospice care under the hospice benefit. In order to clarify our intent in the second sentence of the CoP, we have removed the phrase ''but is not limited to'' and we have replaced the word ''care'' with ''assessment''. The final sentence of the introductory paragraph at 418.54 now reads, ''This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.''

Modifying the requirement does not mean that hospices are prohibited from identifying and/or addressing issues and areas of patient need outside of the hospice benefit, even though hospices are not responsible for providing services for these issues. Indeed, not gathering the information may make it more difficult for hospices to effectively plan to care for a patient because important information would not be available when making care planning decisions.

Comment: The majority of commenters who submitted comments in this section expressed concern about the timing of the initial assessment. Commenters seemed unclear about the proposed requirement that hospices would have 24 hours from the time that a physician order is received to make the assessment. Additionally, commenters were concerned that the proposed rule, as written, would not allow hospices to adjust the initial assessment timeframe based upon patient and family wishes. Many commenters specifically requested that we replace the term ''physician's order for care'' with ''physician's certification'', which would require the assessment to be completed after the physician has certified that the patient is terminally ill and thus an appropriate candidate for hospice care. A few commenters explicitly disagreed with

this suggestion. Several other commenters questioned the role that the patient's election to receive hospice care played in determining when to begin the timeframe for completing the assessment.

Response: We agree that a more definitive time point needs to be established and that patient and family wishes should be taken into account when establishing this timeframe. We recognize that some patients are self-referred and therefore may not have a physician's order for hospice care. These patients could create uncertainty in hospices because hospices would not know when to begin the 24 hour period for completion of the initial assessment. This uncertainty could lead to situations of non-compliance that are out of the hospice's control. We do not believe that this would be in the best interest of patients or hospices; therefore, we are revising the timeframe language as requested by many commenters.

In order to clarify the length of time that hospices have to complete the initial assessment, we have referenced language used in Subpart B, Eligibility, election and duration of benefits, of the existing hospice regulations, into the initial assessment requirement at § 418.54(a). Once a hospice has obtained an election statement for a particular Medicare or Medicaid patient in accordance with the requirements of Subpart B, the hospice has 48 hours to complete the initial assessment, unless the patient, his/her representative, and/or physician request an expedited timeframe. Since election requirement is particular to the Medicare and Medicaid hospice benefits, hospices are free to establish a similar starting point for non-Medicare and Medicaid patients in their own policies, based on the needs of the hospice, its community, and any applicable State and local laws and regulations.

We also agree that the needs of patients or their representatives should be taken into consideration when completing the initial assessment. There are times when patients or representatives may want to expedite the initial assessment, and their wishes, along with the health status of the patient, should be taken into account when scheduling and completing the initial assessment. For example, a patient's representative may request that the hospice complete the initial assessment in a shortened timeframe because the patient is in acute distress and requires immediate hospice assistance. We would expect the hospice to consider the patient's or representative's request for a change in the initial assessment timeframe when scheduling the necessary visit(s) to complete the initial assessment. Therefore, we have modified the language to state that the patient or representative may request that the initial assessment be completed in less than 48 hours.

If a patient or representative wishes to delay the completion of the initial assessment, it would not be appropriate to have that patient or representative elect the hospice benefit. When a patient elects the hospice benefit she waives the right to receive all other Medicare covered services for the terminal illness and related conditions. If the patient may not receive all other Medicare covered services for the terminal illness and related conditions, and that patient cannot receive hospice services because she has not received an initial assessment to determine her immediate care needs, then the terminally ill patient is effectively without health care for the intervening time period. We do not believe that this is an acceptable situation.

Standard (a), ''Initial assessment,'' now states, ''The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with § 418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours).''

Comment: A few commenters expressed support for separating the initial assessment from the comprehensive assessment.

Response: We agree that separating the assessment requirements will enable hospices to quickly assess the most critical areas of need and begin furnishing appropriate care while ensuring that all areas of need are assessed by the appropriate disciplines in a timely manner.

Comment: Some commenters requested that we replace the requirement that hospices complete initial assessments within 24 hours with a requirement that hospices make or make available an initial patient contact within 24 hours of receiving a referral. In addition, commenters requested that any hospice employee, or at least an RN or social worker, be permitted to make this initial contact.

Response: We understand there may be some confusion in the hospice community about the purpose of the initial assessment. The purpose of the initial assessment is to gather the critical information necessary to treat the patient's immediate care needs. The initial assessment is not a ''meet and greet'' visit whereby the hospice introduces itself to the patient and begins to evaluate the patient's interest in and appropriateness for hospice care. As the commenters stated, the initial patient contact takes place before the hospice assumes responsibility for the patient's care. Hospices may choose the timeframe and appropriate individual for completing this initial contact.

It is not appropriate to substitute an initial contact for an initial assessment. Merely requiring an initial contact within 24 hours would not be sufficient to meet the needs of critical patients. Patients often come to hospice in moments of crisis. An initial contact when a patient is in need of timely assistance would be a disservice to the patient and family and would not lead to effective, high quality care. Hospices may choose to send a social worker or other discipline to complete the initial assessment along with the RN, and this may lead to better patient outcomes and satisfaction. Because other disciplines do not have the skills necessary to independently complete the initial assessment, we are not incorporating the commenters' suggestions.

Comment: Several commenters suggested that we change the phrase ''RN must make an initial assessment visit'' to ''RN must complete an initial assessment.'' Similarly, another commenter suggested that we require that ''the hospice registered nurse must perform and document an initial assessment visit.'' The commenters stated that their proposed revised language would clarify our intent that, rather than simply making a visit to begin the initial assessment, the initial assessment must be fully complete within the specified timeframe.

Response: The commenters are correct in their assertion that the initial assessment must be completed, not just started, within the timeframe. Completing the initial assessment, which means that it is both performed and documented, enables the hospice to determine the patient's immediate care and support needs in a timely manner. An accurate determination of care and support needs cannot be made until the initial assessment is complete; therefore, we agree that it is necessary that it be completed within 48 hours. We have clarified the requirement to read, ''The hospice registered nurse must complete an initial assessment within 48 hours * * *.''

Comment: A few commenters questioned the role of the hospice physician in completing the initial assessment.

Response: The initial assessment completed by hospice staff must address the patient's critical physical, psychosocial and emotional status

related to the terminal and related conditions. It is likely not the most efficient use of a physician's time to complete a task (the initial assessment) that can be fully handled by a registered nurse. Therefore, we continue to require that a registered nurse complete the initial assessment. This requirement in no way prevents a hospice from using the knowledge and skills of both a registered nurse and a physician to complete the initial assessment. A physician who is employed by or under contract with a Medicare hospice cannot bill separately for the initial and comprehensive assessments.

Comment: Several commenters requested that we revise the timeframe for completing the initial assessment. Suggestions included 48 hours, 72 hours, the close of the day following the day the patient is referred, and 24 hours ''when reasonably possible.'' Other commenters requested that the timeframe be deleted completely.

Response: Establishing a clear and consistent timeframe for completing the initial assessment is essential to ensuring that patients benefit from hospice care early in their stay. Completing the initial assessment within 48 hours will help hospices gather the essential information to begin a plan of care that addresses the patient's needs before those needs escalate and become extremely difficult to address.

Overall, many commenters stated that the 24 hour timeframe for the initial assessment, as we proposed, was too restrictive. In this final rule we have effectively increased the length of the timeframe by changing its starting point from the time the physician's order is received to the time that the election statement is complete in accordance with the applicable requirement of Subpart B. Under the proposed rule, hospices would have been required to complete the initial assessment within 24 hours of the physician's order to begin hospice care, even if the hospice was unable to schedule a visit with the patient and family within that timeframe. Under the revised final rule language, hospices have 48 hours after the patient elects the hospice benefit to complete the initial assessment. At times, a patient, representative, or physician may request that the comprehensive assessment be completed in a timeframe less than 48 hours, and we expect hospices to accommodate such requests when they are made.

Comment: Many commenters questioned the role of the patient's attending physician in completing the comprehensive assessment. Some commenters explicitly requested that hospices should not be required to involve attending physicians. Other commenters requested that a provision be added permitting attending physicians to ''opt out'' of participating in the assessment. Still others indicated that we should require attending physicians to approve, in writing, the content of the comprehensive assessment.

Response: The scope of public comments submitted regarding the role of the attending physician in hospice care suggested that there is no single model that applies. Some commenters indicated that community-based attending physicians provide a leading role in hospice care, actively participating in the IDG, writing orders, and even making visits. Some commenters, however, indicated that community-based attending physicians preferred to step back once a patient has elected hospice, typically transferring their patients to the hospice physician's care. While we are pleased to know that there are many attending physicians who wish to stay involved in caring for their patients, these physicians should not assume that their attending physician service role is part of the hospice benefit. Likewise, while we are pleased to know that hospices are fully prepared to care for all of their patients needs, including those needs unrelated to the terminal illness and related conditions that the attending physician would be responsible for, it would be inappropriate for a hospice to influence a patient to relinquish his or her attending physician.

At the same time, we are sensitive to the concerns expressed by the hospices. Some patients do not have attending physicians. Some patients do not want to continue seeing their attending physicians. Some attending physicians may be unresponsive to, or uncooperative with, the hospice. We do not want to place patients in a position where they must choose between receiving services from their attending physician and their hospice, nor do we want to place hospices in a position where they are forced to handle difficult attending physicians who disrupt their operations.

In light of these considerations, we are maintaining the requirement that hospices consult with the patient's attending physician when completing the comprehensive assessment. Involving the attending physician to the extent possible will allow hospices to gain additional information about the patient. Attending physicians can often provide a lengthy history of the patient's disease process and family dynamics can help the hospice make better care planning decisions that result in improved patient outcomes. In recognition of the fact that not all patients have willing attending physicians, we have added a caveat that this consultation need only occur if there is an attending physician to consult with. In this way, attending physicians may, with the patient's agreement, opt out of following the patient's care through the patient's hospice stay. We are not, as some commenters suggested, requiring that the attending physician sign a document approving the content of the comprehensive assessment. Rather, we leave it to hospices to define in their own policies and procedures how they will document that they have conferred with the attending physician. We believe that this will give hospices the ability to structure their communication and coordination system in a way that meets their needs for timely information sharing and documentation.

Comment: Several commenters wanted to know if the consultation with the attending physician to complete the comprehensive assessment could be accomplished over the telephone or through electronic communication methods.

Response: A hospice would need to consult with willing attending physicians in accordance with its own policies and procedures. If a hospice's policies and procedures permitted it to consult with attending physicians on the telephone or through electronic communications, then that would be an acceptable practice. Rather than dictate what is or is not an acceptable communication method, this rule seeks to ensure that these communications occur. Effective communication between the hospice and attending physician in completing the comprehensive assessment will enable a hospice to develop a more complete understanding of the patient and family in order to develop a plan of care that addresses all areas of need related to the terminal illness and related conditions.

Comment: A majority of commenters addressed the issue of the length of time necessary to complete the comprehensive assessment. As with the initial assessment, some commenters questioned the exact time that the timeframe began. Some commenters expressed strong support for the proposed four-day timeframe, with a few commenters even suggesting that, in the future, we should move to a two- or three-day timeframe. Other commenters suggested that the timeframe should be lengthened to five, seven, eight, or even 14 days. Some suggested that no

timeframe be established at all. Still other commenters suggested that we should add a caveat that completion of the comprehensive assessment should be dependent upon the patient's condition.

Response: Completing the comprehensive assessment is an integral step in hospice care. The information gathered in the comprehensive assessment is the basis for completing the plan of care. If the information is not gathered in a timely manner, then completing the plan of care is delayed. This results in patients and families not receiving all of the services they need in order to maximize comfort and dignity and achieve the patient's and family's hospice care goals. Comprehensive assessment plays an important role in hospice care and a reasonable time is needed for its completion. The timeframes suggested by the commenters varied greatly, with some being so short as to potentially preclude hospices from conducting a truly thorough assessment and some being so long as to virtually ensure that hospices would never be required to complete comprehensive assessments for more than 30 percent of their patients. Neither extreme would successfully meet the needs of patients and hospices.

In the middle are the commenters who suggested maintaining the four-day requirement, lengthening it to five days, or lengthening it to seven days. While we appreciate the support from commenters who agreed with the proposed four-day timeframe, we agree with those commenters who suggested that a longer timeframe would be more appropriate due to the scheduling demands of hospice providers. We have lengthened the timeframe from four days to five days. Allowing hospices another day to complete the comprehensive assessment will allow more time to schedule the necessary contacts.

While we have lengthened the timeframe, we note that it is a maximum, a length of time that should not be exceeded. The timeframe should not be misinterpreted to prevent hospices from completing the comprehensive assessment earlier than five days after the patient or representative elects the hospice benefit. Indeed, we encourage hospices to complete comprehensive assessments in less than five days if at all possible. This is particularly true for patients who enter hospice in crisis. While the initial assessment will provide the necessary information to begin the plan of care for these critical patients, it is the comprehensive assessment that will fill in important pieces of information to be used to maximize the patient and family's physical, emotional and spiritual comfort. While we recognize that a portion of patients enter hospice at the end stage of the disease process and may die in less than five days after electing the hospice benefit, their physical condition does not necessarily absolve hospices of the responsibility to comprehensively assess these patients. The hospice is still responsible for taking all appropriate steps to complete the comprehensive assessment as that assessment is tailored to the patient's areas of need. The ability of hospices to tailor the exact content of the comprehensive assessment, and the individuals who complete it, to the needs of patient and families addresses concerns about extremely short stay patients who may not be contacted by all disciplines before death. We do not expect or require designated disciplines to complete assessments if those assessments are not indicated as being necessary during the initial assessment and any subsequent contacts.

Comment: A few commenters suggested that we eliminate certain areas from the comprehensive assessment. In particular, commenters suggested that we eliminate the requirement that hospices assess spiritual or potential bereavement issues as part of the comprehensive assessment. Commenters noted that eliminating either of these areas from the comprehensive assessment would make it easier to complete the comprehensive assessment within the required timeframe. The commenters acknowledged that these areas would still need to be assessed, and stated that completing the assessments by the time of the first IDG meeting would be sufficient.

Response: As discussed above, we agree that fully assessing all areas may require more than the four days we initially proposed for this process. For this reason, we have extended the timeframe from four days to five days. We believe that this approach, rather than carving out certain sections of the comprehensive assessment, best meets the flexibility needs of hospices and the care needs of patients. In maintaining both the spiritual and bereavement assessment requirements, hospices will be required to ensure that patient and family specific information about these important areas is gathered in a timely manner to inform the care planning decisions. At the same time, allowing hospices more time to schedule the necessary contacts to gather this information will ensure that hospices have the flexibility to incorporate new patients into existing workloads and schedules. We believe that this solution accommodates the concerns of the commenters without separating these two key areas from the comprehensive assessment.

Comment: Some commenters requested that the final sentence of the introductory paragraph of standard (c) be revised. The commenters stated that characterizing the comprehensive assessment as a description does not fully capture the role of the comprehensive assessment. Commenters suggested that we use either the phrase, ''[t]he comprehensive assessment must take into consideration the following factors,'' or the phrase, ''[f]actors that must be considered in developing the individualized care plan interventions include'' in its place.

Response: We agree that more expressive language is useful in introducing the elements that the comprehensive assessment must contain. Since both of the suggested phrases achieve the same goal, we chose to incorporate the more concise statement because it will likely lead to less confusion. Therefore, the final sentence of the introductory paragraph at § 418.54(c) states, ''[t]he comprehensive assessment must take into consideration the following factors.''

Comment: Several commenters suggested that we should add a new element to standard 418.54(c), ''Content of the comprehensive assessment,'' which would address the issue of the patient's functional status and the impact of that status on the patient's ability to understand and participate in care planning and implementation.

Response: We agree that the functional status of the patient, both physically and mentally, impacts the patient's ability to participate in his or her own care and the hospice's ability to furnish that care. Furthermore, we agree that this information should be collected as part of the comprehensive assessment. Therefore, we have added a new element at § 418.54(c)(3) that requires hospices to assess the patient's ''[f]unctional status, including the patient's ability to understand and participate in his or her own care.''

Comment: Several commenters suggested that we add a new element to standard 418.54(c), ''Content of the comprehensive assessment,'' which would address the issue of the imminence of death.

Response: We agree that assessing the imminence of the patient's death is an important part of the comprehensive assessment. A certain portion of hospice patients have extremely short hospice stays of three days, and sometimes less

than that. The imminence of a patient's death will often drive the type and frequency of services provided to a patient. Published studies and reports (Medpac, ''Report to the Congress: Increasing the Value of Medicare,'' Chapter 3, June 2006; Huskamp, H., Buntin, M.B., Wang, V., and Newhouse, J., ''Providing Care at the End of Life: Do Medicare Rules Impede Good Care?'', Health Affairs, 2001) have noted that hospice per-patient expenditures are highest in the last few days of life. This indicates that the pattern of care for a patient in the last days of life will likely be different than for a patient who is expected to receive hospice services for several weeks or months. Identifying the imminence of death as part of the comprehensive assessment will allow hospices to more accurately tailor the plan of care to the patient's status. We are adding this element as new § 418.54(c)(4).

Comment: Numerous commenters suggested that we add a new element to the comprehensive assessment standard (c), which would address severity of symptoms.

Response: We agree that the severity of a patient's symptoms is an important aspect of the comprehensive assessment that should be assessed for all patients, and we have added this requirement as new § 418.54(c)(5). Gathering accurate information about symptom severity will allow hospices to make more accurate care planning decisions. We are not prescribing how hospices must assess symptom severity. There are numerous pain and distress scales available for use and we do not endorse one scale over another. Hospices have the discretion to identify the manner in which they will assess and document symptom severity for their patients. We anticipate, over time, that useful tools for patient assessment will emerge, and that the hospice industry will select the most effective and efficient assessment tools to use as part of a standard patient assessment practice. We may revisit the patient assessment requirements in the future to ensure that the requirements reflect current standards of practice.

Comment: Many commenters supported our proposed requirement that hospices complete a medication review for each patient as part of the comprehensive assessment. The commenters suggested that further clarification was needed with regard to the requirement that hospices include a review of a patient's prescription and over-the-counter drugs. Commenters suggested that this review should include all drugs and alternative therapies, even those unrelated to the terminal illness and related conditions. Furthermore, some commenters suggested that hospices should be required to differentiate in their documentation of this review which drugs were and were not related to the terminal illness and related conditions. Some commenters noted that hospices should not be held responsible for not being aware of drugs that they were not informed of by the patient, family, physician, or other health care provider.

Response: We thank the commenters for their support and agree that the drug profile review should include all drugs, herbal remedies and other alternative treatments that could affect drug therapy, whether those drugs and remedies are related to the terminal illness and related conditions or not. This thorough review must document all substances which the patient is using. While we understand that patients and families may be unwilling to disclose the use of certain substances, we expect hospices to use all available and appropriate methods to develop a complete list. These efforts may include asking the patient, family, attending physician, and any other health care providers. Efforts may also include asking to look at all medications in the home, being attentive to tell-tale odors, and looking for medication-specific equipment in the home. Hospices may choose how to document the drug profile review and the efforts made to complete it in the manner that best suits their individual needs. While we agree that it may be helpful for hospices to note the relationship of a drug and therapy to the terminal illness and related conditions, we do not believe that it is necessary to prescribe this level of documentation detail in regulation.

Comment: A few commenters suggested that we restructure the comprehensive assessment standard to de-emphasize the bereavement and drug therapy sections of the comprehensive assessment. The commenters acknowledged that these are important areas to assess; however, they believe that their placement within the standard appeared to place more value on these two elements than on the other elements of the standard.

Response: We agree that neither bereavement nor drug therapy should appear to take precedence over the other comprehensive assessment elements. The drug therapy requirements, now referred to as drug profile requirements, are now codified at § 418.54(c)(6) and the bereavement requirements are now codified at § 418.54(c)(7), on par with the other elements of the standard.

Comment: Many commenters suggested that we should rephrase the requirement that hospices identify ''ineffective drug therapy'' as a requirement that hospices assess the ''effectiveness of drug therapy.'' A single commenter suggested that this requirement should be removed because it is not within the nurse's scope of practice.

Response: We agree that the phrase ''effectiveness of drug therapy'' is more inclusive and will help to capture the range of effectiveness of different drugs and therapies. For example, rather than noting that drug B is ineffective and remaining silent on the effectiveness of drugs A and C, this new requirement will require hospices to note for example, that drug A is fully effective, but only for a few hours, drug B is completely ineffective, and drug C is consistently minimally effective. The additional level of detail required by this new provision will help hospices develop a more complete overall assessment from which to make more accurate care planning decisions. This new provision is located at § 418.54(c)(6)(i). If a nurse is unable to complete this part of the assessment, then it is appropriate for a hospice to use another discipline to complete the drug profile assessment.

Comment: Some commenters suggested that we require hospices to identify all drug side effects, rather than only those side effects that are not wanted. In addition, the commenters suggested that we delete the term ''toxic'' because the phrase ''drug side effects'' would include issues of toxicity.

Response: Our original intent was to ensure that bothersome side effects were noted in the drug assessment so that they could be addressed in the care planning process. However, as the commenters noted, all side effects should be noted, even if they are desirable. Identifying desirable, as well as undesirable, side effects will help ensure that the desired side effects are not negatively impacted by other drugs and their side effects. Additionally, as the commenters noted, the term ''toxic'' is unnecessary. Any toxic effects would already be recorded as side effects, rendering the term ''toxic'' duplicative. Therefore, we are deleting the terms ''unwanted'' and ''toxic'' from § 418.54(c)(6)(ii), and are simply requiring that the hospice review the patient's drug profile for side effects.

Comment: Several commenters suggested that we require hospices to evaluate potential as well as actual drug interactions.

Response: We agree that more specificity is needed to clarify our intent. We agree that hospices must identify drug interactions that have

occurred in the past or are occurring at the time of the assessment if at all possible, and must identify drug interactions that have the potential to occur if the patient continues using the same drugs. The lack of a drug interaction to date does not mean that an interaction will never occur as long as the patient continues to use the potentially interacting drugs. The individual completing the drug profile must document the existence of the potential interaction so that the entire IDG is made aware of the potential problem and can then make an informed decision about the patient's drug regimen. For these reasons, we are revising the drug profile requirement at § 418.54(c)(6)(iii), to require the hospice to evaluate both actual and potential drug interactions.

Comment: A commenter suggested that we require hospices to determine whether the patient is using duplicate medications or medications that require laboratory monitoring.

Response: We agree that adding these provisions will help hospices gather more detailed information from which to make accurate care decisions. Patients often come to hospice with a long list of medications prescribed by several different doctors. It is very possible that some of these medications have overlapping effects, in which case one or more medications may be safely and appropriately discontinued. Identifying unnecessary/duplicate drugs and subsequently eliminating them will make it easier for patients to follow their drug regimens. Identifying drugs that currently require laboratory monitoring during the assessment will also help patients and hospices. Some patients come to hospice with the explicit desire to forgo more laboratory tests. It is imperative that hospices identify any drugs that the patient is currently taking that may require these tests so that patients know about the situation and the options available to them to help achieve their goals. Identifying drugs that require laboratory testing will enable patients to make informed decisions and may lead patients to forgo the use of certain drugs. For these reasons, we have incorporated these two suggestions at § 418.54(c)(6)(iv) and § 418.54(c)(6)(v).

Comment: A commenter suggested that, as part of the drug review, hospices should be required to identify:

Medications that are unnecessary or are not consistent with patient therapy goals; Medications requiring dosage optimization; Medications that are inappropriate according to evidence based guidelines; and Missing medications that are necessary to prevent or address symptoms experienced by the patient.

Response: The purpose of the drug profile assessment is to gather the information necessary to enable the hospice to make appropriate care decisions, and it is the role of the individual completing this portion of the assessment to collect this information. Several of the commenter's suggestions (1, 3 and 4) require the individual completing the drug profile portion of the assessment to draw conclusions. We believe that these conclusions should be made by the IDG during care planning, rather than by a single member of the IDG who is completing this portion of the assessment. Suggestion 2 is already captured by the requirement that hospices review the effectiveness of drug therapy at § 418.54(c)(6)(i). If a drug dosage needs adjustment, then that need will be reflected in its level of effectiveness. For these reasons, we are not incorporating these suggestions.

Comment: Numerous commenters expressed concern about the role of the initial bereavement assessment in the comprehensive assessment and in the bereavement plan of care. In particular, commenters noted that the information gathered in the initial bereavement assessment may not remain accurate when the patient dies and may unintentionally result in poor decision making in the final bereavement plan of care. For this reason, some commenters requested clarification of the role that the initial bereavement assessment plays in the final bereavement plan of care. Other commenters suggested that we substitute the hospice plan of care for the bereavement plan of care. This would require hospices to use the information gathered in the initial bereavement assessment when developing the plan of care, but not when developing the bereavement plan of care. Still other commenters suggested that the initial bereavement assessment be completely removed from the comprehensive assessment.

Response: We appreciate the valuable insight that the commenters provided about the role of the initial bereavement assessment in hospice. The comments validated our understanding that hospices already assess patients and families for actual and potential bereavement issues before the patient's death rather than waiting until after death to begin this process.

We also appreciate the suggestions to help clarify the role of the bereavement assessment within the comprehensive assessment. We agree that the information gained in the initial bereavement assessment should be incorporated into the hospice plan of care. Issues identified in the initial bereavement assessment such as anticipatory grief and previous experiences with loss should inform care planning decisions long before the patient dies. By requiring hospices to incorporate bereavement assessment information into the plan of care, hospices will be able to develop a more complete picture of the patient and family.

Likewise, we agree that feelings can change over time, rendering the information gathered in the initial bereavement assessment moot at the time of the patient's death. For this reason, we are no longer requiring that information gathered from the initial bereavement assessment be incorporated into the bereavement plan of care. Rather, we are requiring that the information from the initial bereavement assessment be considered in the bereavement plan of care. This change still requires hospices to begin the bereavement assessment process early in the patient's stay. However, the change reflects that fact that the bereavement assessment will change as it is updated. Furthermore, the change allows hospices to use the most accurate bereavement assessment information, regardless of when it was obtained, in developing the bereavement plan of care.

Comment: A single commenter suggested that we require, as part of the comprehensive assessment, that hospices assess the family's needs along with the patient's needs.

Response: One of the most unique aspects of hospice, and one of the most valued, is that it treats the patient and family as a single unit of care. Hospices recognize that patients do not live in a vacuum. Rather, patients are continually affected by the well-being, or lack thereof, of the people who surround and care for them. We in no way want to discourage this holistic practice. However, comprehensively assessing all of the needs of the patient's family, as we require for the patient, is beyond the scope of the Medicare and Medicaid hospice benefits. Therefore, we are not incorporating this suggestion.

Comment: A few commenters suggested that we should add the phrase ''consistent with patient self-determination'' to the description of the elements that must be included in the comprehensive assessment. The commenters expressed that adding this phrase would convey to hospices that the comprehensive assessment is patient-driven.

Response: We agree that, within the broad outline provided in this rule, the

comprehensive assessment is a patient-driven process. Hospice has a long history of tailoring patient care, including assessments, to the needs and desires of the patient. We do not believe that the new comprehensive assessment requirement will alter this existing practice because it provides broad outlines that allow hospices to continue tailoring their care. Therefore, we do not believe that adding the phrase ''consistent with patient self-determination'' is necessary.

Comment: A single commenter suggested that we should add a new element to Standard (c), which would address the issue of the need for hospices to assess pain and symptom management as well as emotional and spiritual support.

Response: We agree that these are important areas to be assessed; however, we do not agree that they need to be separated out as new elements. Standard (c) already requires hospices to ''identify the physical, psychosocial, emotional, and spiritual needs'' of the patient. The specific issues of pain and symptom management and emotional and spiritual support are addressed by these broader categories, and therefore do not require separate elements in the assessment. To do so would be duplicative.

Comment: A few commenters asked us to specify which disciplines and providers within those disciplines must complete the comprehensive assessment. For example, one commenter asked us to specify the type of personnel who are qualified to provide a spiritual assessment. Many other commenters wanted us to specify that only certified chaplains should perform this function. Another commenter questioned whether MSWs should be required to complete social work assessments and whether, based on those assessments, patients could then be assigned to a baccalaureate degree prepared social worker.

Response: A comprehensive assessment, in the context of this rule, is not a single document that all hospice providers are required to use. Instead, it is a flexible evaluative process that could be different for each hospice based on the hospice's own needs. If a hospice chooses to implement a policy that an MSW must assess the status and needs of all patients, then we would expect the hospice to follow its own policy. Likewise, if a hospice chooses to implement a policy that certified chaplains must be used to assess all patients who do not have existing spiritual support systems while community religious leaders must be used to assess all patients who have existing spiritual support systems, then we would expect the hospice to follow its own policy. These examples illustrate the flexible nature of the assessment requirement. To prescribe who may or may not complete different elements of the comprehensive assessment, or even what areas of care must be assessed, would remove this flexibility. We do not believe that removing flexibility is in the best interest of patients or hospices; therefore we are not adopting these suggestions.

Comment: A single commenter observed that the plan of care could not be completed until the comprehensive assessment was completed.

Response: The commenter is correct; however, the initial assessment would already have gathered the most critical clinical and psychosocial information, which would enable the hospice to begin completing the plan of care. Once the comprehensive assessment is complete, the hospice must then finish the plan of care based on the needs identified in the comprehensive assessment. Hospices may not wait until the comprehensive assessment is complete to begin to formulate the plan of care and provide services, as the commenter seemed to imply. Such waiting, when the hospice has assumed responsibility for caring for the patient and the patient has forgone all other services related to the terminal illness, would be a disservice to the patient and would likely lead to negative patient outcomes, patient and family complaints, and numerous other undesirable effects.

Comment: Several commenters expressed confusion about who would be responsible for completing the comprehensive assessment, how it would have to be completed, and who would review its content. Specifically, commenters suggested that the hospice registered nurse be required to complete the comprehensive assessment and that the IDG be required to review its content. Other commenters questioned whether all disciplines were required to make in-person visits or whether phone contacts could be used to complete the assessment.

Response: The comprehensive assessment is not a single static document, a symptom and severity checklist, or a set of generic questions that all patients are asked. It is a dynamic process that needs to be documented in an accurate and consistent manner for all patients. While the comprehensive assessment often begins with a nursing assessment that is focused on the patient's physical status and conducted by a registered nurse, it does not end there. The comprehensive assessment must also focus on the patient's psychosocial and emotional status and needs, and this piece is often assessed by a social worker. In addition, the comprehensive assessment must address the patient's spiritual status and needs, which is often the domain of the pastoral or other counselor who is a member of the patient's IDG. Furthermore, the comprehensive assessment must focus on identifying any other needs that fall into the scope of the physical therapist, speech language pathologist, occupational therapist, dietitian, or any number of other disciplines that a hospice may provide. A nurse is not qualified to provide detailed assessments in all of these areas; therefore we cannot place the burden of completing the comprehensive assessment on the nurse alone. The broad nature of the comprehensive assessment requires the active involvement of all of the members of the IDG in order to ensure that a complete and accurate picture of the patient and family is obtained.

The active involvement can occur in any number of ways depending on the patient's needs and preferences. Some families may need a face-to-face visit from a social worker to help them sort through myriad insurance papers or simply provide a supportive presence, while other families may find it easier to discuss difficult issues by phone. If families need or prefer in person visits, then those needs should be met. If they prefer the limited anonymity afforded by the telephone, then their preference should be accommodated. We cannot provide the clear cut answer that commenters are seeking because each patient, family, and situation is different. Decisions about who assesses and how they assess need to be based on the needs of the patient and family and the hospice's own policies and procedures.

Comment: A single commenter suggested that we should create a separate standard for assessing patients with short lengths of stay. The commenter stated that a separate standard would avoid overwhelming patients and families.

Response: We agree that patients and families should not be overwhelmed in the last days of life. However, we do not agree that a separate short stay assessment standard is necessary. We are finalizing a requirement that hospices complete an initial, abbreviated patient assessment within 48 hours of the patient or representative electing the hospice benefit. This assessment, conducted by the hospice

nurse in conjunction with other appropriate hospice staff, will provide hospices with the essential information to formulate a plan of care to address the patient's immediate care and support needs without overwhelming the patient and family. We believe that patients who stay for a short time in hospice will be well served by this initial assessment. Length of stay should not be the determinant of the quality of care that is to be furnished. For those patients who stay for a longer period of time, we are requiring hospices to complete a comprehensive assessment within five days of the patient or representative electing the hospice benefit. We are not prescribing what areas of hospice care must be assessed (that is, nursing, social work, therapies, etc.) or who must complete those assessments. Allowing hospices to make these choices allows them to strike a balance between the need for assessment information and the desire to not overwhelm patients and families. We believe that this built-in flexibility accomplishes the commenter's goal without adding a separate short stay assessment standard. Therefore, we are not adopting the comments as suggested.

Comment: A commenter suggested that standard (d), ''Update of the comprehensive assessment'' should be renamed ''Ongoing assessment'' to clarify that the entire assessment does not need to be redone every 15 days.

Response: We do not believe that renaming the standard will accomplish the stated goal. Renaming the standard as ''Ongoing assessment'' would imply that every single change, regardless of how minute it was, would need to be documented on the comprehensive assessment, as these minute changes would be identified in the day-to-day clinical assessments of the patient. We believe this would add an unnecessary burden to hospice staff and would not advance patient care.

Comment: Many commenters supported the goal of requiring hospices to regularly update the comprehensive assessment. Most of these commenters suggested changes to the proposed 14-day timeframe for updating the comprehensive assessment. Some commenters suggested that we delete the timeframe completely, while other commenters suggested that the timeframe be every two weeks or at the beginning of each new benefit period.

Response: We appreciate the support for regularly updating the comprehensive assessment, as this support generally reflects our understanding that most hospices already update patient assessments in accordance with some sort of self-imposed timeframe. We believe that establishing a standard comprehensive assessment timeframe in this rule will help those hospices ensure that their update timeframe is consistent with patient needs and standards of practice. Deleting or greatly extending the timeframe, as a few commenters suggested, would be out of step with current standards of practice and would likely lead to negative patient outcomes. Updating the comprehensive assessment at reasonable regular intervals ensures that hospices have the most recent information about the patient from which to make accurate care planning decisions. Without the timely updated assessment information, care planning decisions are likely to be inaccurate, inappropriate, and possibly harmful to the patient. This is not an acceptable outcome.

We also appreciate the many timeframe suggestions that we received. We agree that the proposed 14-day timeframe, while within reason and in the realm of acceptable standards of practice, may not be the best match between patient and hospice needs. Numerous commenters suggested that updating the comprehensive assessment at least every 15 days was the proper match, as the 15-day timeframe would correspond with the 60- and 90-day Medicare Hospice Benefit election periods described in § 418.21. Corresponding the update timeframe length to the benefit period length would help hospices avoid completing separate assessments for the routine comprehensive assessment update and the update to re-certify that the patient is terminally ill. Two separate assessments within a few days of each other would be overwhelming for the patient and burdensome for the hospice. Thus, we agree that requiring hospices to update the comprehensive assessment at least every 15 days is preferable to the proposed 14-day timeframe. We believe that the new 15-day timeframe accomplishes the flexibility goals of those commenters who suggested twice monthly, bi-weekly, and every 14- to 16-day updates as well. We note that hospices are still required to complete the comprehensive assessment update more frequently than every 15 days as the patient's status changes. We also note that hospices are permitted to update the assessment more frequently than every 15 days if the 15th day falls on a holiday or if day-to-day hospice operations are scheduled to be suspended for any reason on the 15th day.

Comment: Several commenters suggested that we should either delete the requirement that hospices must update the comprehensive assessment at the time of each recertification, or allow a grace period at the time of each recertification to ensure that the assessment is not unnecessarily updated twice within a few days to meet the every 14-day and recertification timeframes.

Response: As discussed above, we replaced the 14-day timeframe with a 15-day timeframe. The 15-day timeframe would coincide with the length of the benefit periods and the recertification timeframes. Since the assessment and recertification timeframes are now coordinated, we agree that it is appropriate to delete the recertification assessment requirement.

Comment: Several commenters expressed confusion about the nature of the comprehensive assessment update. A few commenters wanted to know if we expected hospices to complete an entire new set of comprehensive assessment forms each time an update is due. Other commenters wanted to know if the update of the comprehensive assessment referred to the regularly scheduled IDG meetings. Another commenter noted that the medical director should not be required to update the assessment.

Response: We understand that some hospices are confused by the proposed requirement that patient-specific comprehensive assessments should be updated at regular intervals. To clarify, we are requiring hospices to update those sections of the comprehensive assessment that require updating. As a patient's condition changes the comprehensive assessment must be updated to reflect these changes. For example, if a patient had a normal blood pressure reading at the time of the initial assessment and at a nursing visit nine days later the patient's blood pressure becomes elevated for a period of time, this new elevated blood pressure must be documented. This becomes an update to the comprehensive assessment. A significant change in the patient's condition must be documented and the assessment must then be updated to reflect the patient's revised status. As in the case of the comprehensive assessment, hospices are not required to use specific forms or formats. However, there have to be dedicated documents that contain assessment information and that are easily identified. Hospices are free to choose the method that best suits their needs when documenting the comprehensive assessment and the updates to that assessment. The purpose of updating the assessment is to ensure that the hospice IDG has the most recent

accurate information about the patient in order to make accurate care planning decisions. We are not requiring hospices to complete, in full, those documents which they identified as comprising their comprehensive assessment every 15 days, although hospices are free to do so if they choose. Likewise, we are not requiring hospice medical directors to assume total responsibility for updating the comprehensive assessment, although we do expect to see the physician member of the IDG actively involved in all aspects of furnishing care, including updating the comprehensive assessment.

Comment: Many commenters expressed confusion about the role of patient outcome measures in the comprehensive assessment. Some commenters stated that data elements should be in the plan of care rather than in the assessments. Others stated that including data measures in the assessments may limit the amount of useful data available for a hospice's quality assessment and performance improvement (QAPI) program.

Response: In the QAPI CoP hospices are required to identify patient outcome measures that they will apply to all patients. These measures should help the hospice identify areas of strength and weakness in patient and family care delivery. Once the measures are identified, hospices must choose which data elements they will collect in order to measure their performance. For example, a hospice may choose to focus on pain control as one of its QAPI domains. Within the pain control domain, that hospice may choose an outcome measure that identifies the percentage of patients whose pain was controlled within 48 hours of admission to hospice. In order to measure this outcome, that hospice may choose to incorporate a data element in its initial assessment that identifies those patients who are experiencing uncontrolled pain upon admission as well as a data element in its comprehensive assessment to identify patients who experienced uncontrolled pain upon admission and had that pain controlled within 48 hours of admission. The information gathered by these data elements during the comprehensive assessment can then be collected, aggregated, and used to identify areas of strength and weakness within the hospice's care delivery system. Without these individual pieces of information gathered during the assessments, the hospice does not have the information it needs to make effective judgments of its quality and to make appropriate performance improvement project decisions. Therefore, QAPI-related data elements must be included in the patient assessments completed by the hospice.

At the same time, we do not expect hospices to limit their QAPI-related data collection efforts to the data collected in the patient assessments. Data collection must look beyond patient assessment data to examine all facets of a hospices operation, from contract services to volunteer retention rates to adverse events. Rather than limiting the amount of useful data available to hospices, this requirement simply ensures that patient level data are included as part of the broader data collection program.

For additional discussion of public comments regarding patient outcome measures and the proposed QAPI CoP, please refer to the quality assessment and performance improvement section in the preamble of this rule.

Comment: A commenter requested that we change the timing of the medical director's certification of the terminal illness to coincide with the completion of the comprehensive assessment.

Response: The commenter did not provide any particular rationale for this request. The timing of the certification of the terminal illness for Medicare beneficiaries is based on specific Medicare payment requirements. Since payment requirements are not within the scope of this rule, we are not accepting this suggestion.

Comment: Numerous commenters expressed varying levels of confusion regarding the exact sequence and timing of the initial assessment, comprehensive assessment, updated assessments, plan of care, and updated plans of care. Commenters believed that some of these elements would occur simultaneously while other elements, such as orienting patients to hospices and evaluating patients for hospice appropriateness do not appear in the regulation at all.

Response: We appreciate the opportunity to explain how the finalized requirements will function in the hospice environment. First, hospices will obtain a signed election statement in accordance with § 418.24. Next, the hospice registered nurse must complete an initial assessment of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions in order to evaluate the patient's immediate care and support needs within 48 hours of completing the election form. This assessment need not go into great detail in each of these areas. Rather, it needs to gather key information, as identified in the hospices policies and procedures, about the patient that will enable the hospice IDG accurately to determine what the patient immediately needs to begin or continue feeling comfortable. The purpose of the initial assessment is not to determine the patient's eligibility for the hospice benefit, which is addressed in 418.22 and 418.24, or to orient the patient to the hospice benefit and obtain the election statement. Additional information regarding physician certification of the terminal illness is available in the FY 2008 Hospice Wage Index, 72 FR 50214, 50223, August 31, 2007. These tasks, which are often part of following-up on referrals from other providers, must already have been completed before the initial assessment is completed. This does not mean, however, that we expect hospices to conduct multiple visits to complete the patient admission and assessment. Once the initial assessment is complete, the hospice develops and implements a plan of care to address the immediate needs identified in the initial assessment.

Next, the hospice must complete a comprehensive assessment within five days of completion of the election statement. The comprehensive assessment is defined as a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and ability to care for the patient. This comprehensive assessment is based on the hospice's policies and procedures as well as the information gathered in the initial assessment. For example, a hospice may have a policy that all patients will receive a psychosocial assessment conducted by an MSW. Therefore, we would expect that a patient's comprehensive assessment in his or her clinical record would include the information gathered by and the conclusions made by an MSW. The comprehensive assessment requirement is flexible to adapt to the needs of individual hospices and patients, and will help hospices gather the information needed to develop accurate and appropriate plans of care.

Then, based on the information gathered in the comprehensive assessment, the hospice IDG, in collaboration with the patient's attending physician (if any), the patient or representative, and the primary caregiver, must develop an individualized plan of care for each patient. The plan of care must reflect patient and family goals, and include all interventions needed to address the problems identified in the initial and comprehensive assessments. The plan of care is where information turns into

actions that will result in patient comfort and dignity, self-determined life closure, and any other goals that the hospice, patient, and family establish for the patient's hospice care.

Once the plan of care is established and all disciplines are aware of their respective roles in caring for the patient, the hospice must implement the plan of care. If the patient's status in one or more areas changes, hospice staff must update the comprehensive assessment to reflect the change(s). We do not expect hospices to complete an entire comprehensive assessment each time a patient's status changes. Rather, we expect that the updated assessment reflects status changes so that other disciplines furnishing services are aware of them. Updating the comprehensive assessment will ensure that all disciplines are providing care based on the most recent information about the patient. We require that these updates occur as frequently as that patient's condition requires, but no less frequently than every 15 days. If a change in the patient's status will affect the kind of care that needs to be furnished, then the plan of care needs to be modified. For example, information from a comprehensive assessment could indicate that a patient has a stage three pressure ulcer and the patient's plan of care indicates that the hospice registered nurse will make three visits a week, in part, for wound care. The wound care provided by the registered nurse results in the pressure ulcer healing. This change in status would be recorded as an update to the comprehensive assessment. Based on this new information in the updated comprehensive assessment, the hospice IDG may decide to reduce registered nursing visits to two times per week because the patient's status and needs no longer indicated that RN visits three times per week were necessary. The hospice IDG would then update the patient's plan of care to reflect that RN visits will be two times per week and that wound care was no longer part of the treatment that the RN would provide. In this way, the patient's assessment and plan of care are both updated to provide accurate and timely information to all disciplines providing services to the patient, and the hospice complies with our requirements to update both the comprehensive assessment and the plan of care.

We believe that the timeline described above will help illuminate the timeframe requirements for both the assessment and plan of care requirements, as well as how these two requirements are related.

Comment: A few commenters explicitly thanked us for not requiring hospices to use a standardized assessment form. Other commenters expressed concern that the proposed assessment requirement would result in CMS requiring hospices to use a specific assessment form. Several of these commenters specifically stated that we should not require hospices to use the OASIS data collection tool that is currently used by home health agencies.

Response: We appreciate the support from commenters who recognized that we are not requiring any type of assessment form, standardized or otherwise. As we stated in the preamble to the proposed rule, and restate here, we are not requiring hospices to use any particular form or tool to document the completion of the initial assessment, comprehensive assessment, or updated assessments at this time. Hospices are permitted to use the written or electronic form or tool that best suits their needs and their patients' needs, provided that the information gathered in the assessments is complete and available in each patient's clinical record. Hospices need to choose a form or tool that gathers thorough information about the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This form or tool must allow hospices to document information in a systematic and retrievable way for each patient. Within the framework of these broad guidelines, it is within each hospice's discretion to choose its own patient assessment documentation form or tool.

Hospices may find it beneficial to examine the CARE (Continuity Assessment Record and Evaluation) tool developed by CMS in choosing their assessment forms/tools. Under the Deficit Reduction Act of 2005, Section 5008, CMS was directed to develop a uniform patient assessment instrument for use in a three year, post acute care-payment reform demonstration, to begin in January 2008. This uniform assessment instrument is now referred to as CARE. The purpose of the CARE tool is to collect standardized data on Medicare beneficiaries' medical conditions, functional and cognitive impairments, and social support factors, affecting treatment and discharge, regardless of site of care. During the demonstration CARE will be administered to Medicare beneficiaries at time of hospital discharge, upon admission and discharge from post acute care (PAC) providers, as well as at interim points, if significant changes occur. CARE is comprised of a set of common assessment items administered to all patients across all settings, and a set of supplemental items only administered for specific conditions or at particular times (*i.e.*, PAC discharge only). A master version of the CARE instrument and item matrix identifying common assessment items and supplemental items is available for viewing at *http://www.cms.hhs.gov/PaperworkReductionActof1995/PRALSep2007/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1205047&intNumPerPage=10.*

If, at some time in the future, we determine that it is necessary to require hospices to use a standardized patient assessment tool, we will follow the provisions of the Administrative Procedure Act, which generally requires us to publish a notice of proposed rule making and solicit public comment on the proposal.

4. Condition of Participation: Interdisciplinary Group Care Planning and Coordination of Services (Proposed § 418.56)

This proposed CoP elaborated on the existing Interdisciplinary group CoP at § 418.68 and combined it with elements of the Plan of care CoP at § 418.58. It contained five standards: ''(a) Approach to service delivery,'' ''(b) Plan of care,'' ''(c) Content of the plan of care,'' ''(d) Review of the plan of care,'' and ''(e) Coordination of services.'' Together, these standards would have required a hospice, through its IDG, to develop, implement, and update a comprehensive plan of care for each patient and family that addresses their needs as identified in the patient assessment.

Standard (a), ''Approach to service delivery,'' would require each hospice to have an IDG that included at least the following: A doctor of medicine or osteopathy who is not the patient's attending physician; a registered nurse; a social worker; and a pastoral, clergy, or other spiritual counselor. This IDG would be required to work together to meet the physical, medical, social, emotional, and spiritual needs of the patient and family. The IDG would also be required to designate a qualified individual to coordinate implementation of the plan of care and assessment of the patient. Paragraph 418.68(d) of the existing rule required the IDG to designate a registered nurse to fulfill this role. In the proposed rule, the IDG would be required to establish policies governing the day-to-day provision of care and services. If a hospice has more than one IDG, one

would be designated in advance to fulfill the policy role.

The next proposed standard, ''(b) Plan of care,'' would require hospices to provide care to patients and families in accordance with a written plan of care established by the IDG and the patient's attending physician. This standard would also require hospices to ensure that patients and families received appropriate education and training that would enhance the implementation of the plan of care. Unlike the existing requirement, this proposed standard would incorporate families into the plan of care, recognizing that hospice care must reach beyond the patient to support those who surround and care for the patient.

In proposed standard (c), ''Content of the plan of care,'' we would require hospices to develop a plan of care based on the problems identified in the patient's assessments. We proposed to require that the plan of care include: Pain and symptom management interventions; a detailed statement of the scope and frequency of services; patient outcomes; any necessary drugs and treatments; any necessary medical supplies and equipment; and documentation of the patient's and family's understanding, involvement, and agreement with the plan of care. The existing plan of care requirement at § 418.58(c) mandated that the hospice describe the scope and frequency of services. The remainder of the elements were new in the proposed rule.

The fourth proposed standard, ''(d) Review of the plan of care,'' would require the hospice medical director or physician designee, along with the IDG and the patient's attending physician, to review, revise, and document the plan of care at intervals specified in the plan of care. The review of the plan of care would be required to occur no less frequently than every 14 calendar days. The revised plan of care would be required to include information from the patient's updated assessment, and the hospice would have to document any progress toward the outcomes specified in the plan of care. This proposed requirement directly linked the results of the updated assessment, including the data elements, to the changes that would be made in the plan of care. This would empower hospices to make care decisions based on evidence of the successes and failures of past care decisions in achieving the desired outcomes.

The final proposed standard, ''(e) Coordination of services,'' was a new addition to the hospice CoPs. Hospice has always been based on an interdisciplinary care model, which requires frequent communication between care disciplines and settings, as well as between the hospice, the patient and the family. This proposed standard would require the hospice to maintain a system of communication and integration to enable the IDG to ensure that care and services are provided in accordance with the plan of care. This system would also be required to ensure the ongoing liaison of all disciplines providing care and services in the home, outpatient, and inpatient settings, notwithstanding the manner in which the care and services are furnished (that is, directly or under arrangement).

Comment: A commenter asked us to clarify the meaning of the following sentence at § 418.56, ''The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment and as it relates to the terminal illness and related conditions.'' The commenter believed that this statement was confusing.

Response: The intent of the sentence is to ensure that there is a direct link between the needs identified in the patient assessment and the plan of care developed by the hospice. The intent is also that hospices are responsible for including those services and treatments in the plan of care that are related to the terminal illness and related conditions, even if the hospice identified other needs in the patient assessment that are not related to the terminal illness and related conditions. We agree that minor grammatical changes to the statement are warranted to clarify our intent. Specifically, we are replacing the singular term ''it'' with the plural phrase ''such needs'' to correspond with the plural ''specific needs'' identified earlier in the sentence. This grammatical change provides a direct link between the needs identified in the comprehensive assessment and those specific needs related to the terminal illness and related conditions that must be addressed in the plan of care. The revised sentence at § 418.56 now states, ''The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.'' We have not attempted to enumerate the conditions in which care outside the hospice would be covered under Medicare because we recognize that there are many illnesses which may occur when an individual is terminally ill which are brought on by the underlying condition of the patient. For example, it is not unusual for a terminally ill patient to develop pneumonia or some other illness as a result of his or her weakend condition. Treatment of such illnesses is considered a hospice service and payment under other Medicare benefits would be waived by the hospice election. We expect that the hospice interdisciplinary group will reasonably determine the services that the individual requires for palliation and management of his or her symptoms.

Comment: A commenter suggested that, when hospices are caring for residents of long term care facilities, the long term care facility medical director should be the individual responsible for designating the members of the IDG to care for the patient.

Response: It is the hospice's responsibility to furnish hospice care. While we agree that designated long term care facility staff should actively participate in a patient's hospice IDG, it is the hospice's responsibility to decide what care is provided, based on the information gathered during the patient assessments. Hospices are not permitted, and certainly should not be compelled, to delegate their responsibilities to the long term care facility medical director and staff.

Comment: Numerous commenters suggested that we include the term ''psychosocial'', rather than ''social'', in § 418.56(a) when detailing the types of patient and family needs that IDGs are required to address during care planning. The commenters stated that the term ''psychosocial'' is more consistent with the terminology used throughout the remainder of the rule.

Response: We agree that the word ''psychosocial'' is more consistent with the terminology in the rest of the rule and we have made this change.

Comment: Numerous commenters made suggestions to refine our proposal at § 418.56(a) that ''The hospice must designate a qualified health care professional that is a member of the IDG to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care.'' A few commenters supported our proposal to permit any qualified health care professional that is a member of the IDG to fulfill the coordinator role, while many other commenters suggested that only nurses and/or social workers should be considered qualified for this role. One commenter suggested that the coordinator should only be responsible for ensuring the assessment of each patient's and family's specific hospice care, rather than being personally responsible for assessing their needs.

Another commenter suggested that the individual responsible for coordinating the plan of care be named the ''interdisciplinary group coordinator.''

Response: We appreciate the many comments that were submitted. We do not believe that the coordinator needs to be given a specific title in this rule. Hospices are free to refer to the coordinator in a manner that meets their needs, as long as there is an individual identified as being responsible for coordinating and implementing each patient's plan of care.

The majority of commenters noted the unique demands of the case coordinator role and the many skills that are necessary to successfully fulfill the role. Commenters described the need for the case coordinator to have solid knowledge of the biological, psychological and spiritual issues of terminally ill patients and their families. They also described the need for the case coordinator to act as an advocate, negotiator, and leader when dealing with the varied members of the IDG, the patient, and the patient's family. We agree that the specific demands of the case coordinator role, as described by the commenters, warrant a more specific requirement regarding who is qualified to fulfill this role. Therefore, we are requiring the coordinator to be a registered nurse. A registered nurse has the necessary medical and interpersonal background to meet the demands of the coordinator position in a way that no other discipline does. Social workers are not educated or trained to identify physical issues, just as physical or occupational therapists are not educated or trained to identify psychosocial issues. The unique skills of registered nurses, who are educated to assess and manage the overall aspects of a patient's physical and psychosocial care, can be used to oversee the coordination and implementation of the care identified by the IDG.

Comment: The majority of commenters asked us to reconsider the specification in proposed § 418.56(a)(1)(i) that the physician member of the IDG may not be the patient's attending physician. The commenters stated that hospice physicians often have their own private practice and may, at times, be in the position of caring for a private practice patient who has chosen to receive hospice care from the hospice the physician works with. Furthermore, the commenters stated that this prohibition could create a barrier to accessing hospice for those patients whose attending physicians also work with hospices. One commenter suggested we should replace the general requirement that a doctor of medicine or osteopathy be a member of the IDG with a requirement that the hospice medical director or physician designee be a member of the IDG.

Response: While it was not our intent, we agree that this prohibition could negatively impact hospice access and treatment. Therefore, we have removed the statement that the physician member of the IDG may not be the patient's attending physician. In its place, we have added a statement that the physician member of the IDG must be an employee of or under contract with the hospice. While the physician member could be the hospice medical director or physician designee, this revised requirement does not mandate this. This new requirement accomplishes our original intent of ensuring that hospice physicians are actively involved in patient care through the IDG without the unintended effect of limiting access that accompanied the original proposal.

Comment: Numerous commenters suggested that we amend the language discussing spiritual counselors in § 418.56(a)(1)(iv). Some commenters noted that the terms ''pastoral'' and ''clergy'' are Judeo-Christian terms that do not encompass other faiths. These commenters suggested that we require hospices to have a board certified chaplain as a member of the IDG because board certified chaplains are routinely educated and trained to work with individuals from various, non-Judeo-Christian faiths. On the other hand, some commenters specifically disagreed with the suggestion that a board certified chaplain be a required member of the IDG. Still other commenters suggested that we should use the language that appears in section 1861(dd)(2)(B)(i) of the Act, which reads that a hospice must have ''at least one pastoral or other counselor'' as a member of the IDG.

Response: Spiritual advisors play an important role in helping many patients and families achieve their end-of-life goals. In the proposed rule we sought to further assure the role of spiritual advisors in hospice care by specifying that the counselor must be capable of addressing a patient's spiritual needs. As some commenters stated, not all patients need or desire the involvement of spiritual counselors in their care. These patients, the commenters contended, should not be compelled to accept the involvement, even if that involvement is only through the spiritual counselor's participation in the IDG meetings. We agree that spiritual counselors, whether they are certified chaplains, clergy, pastoral counselors, or any other discipline, should not be forced upon unwilling patients. Therefore, we have replaced the proposed ''pastoral, clergy, or other spiritual counselor'' requirement with the statutory requirement of ''pastoral or other counselor.'' This revised requirement gives hospices the flexibility to use the counselor that best meets the patient's needs.

Nothing in this requirement prohibits hospices from using certified chaplains as the IDG member to fulfill this role. Indeed, some hospice patients who receive the services of certified chaplains may have better outcomes because certified chaplains are trained to work with individuals from various faiths and backgrounds.

Comment: A few commenters suggested that we should require a bereavement counselor as a member of the IDG. The commenters stated that including the bereavement counselor in the IDG would help ensure that the information gathered in the bereavement assessment, required in final § 418.54(c)(7), is included in the plan of care.

Response: We expect that all disciplines involved in caring for a patient and family will have a voice in the IDG. This voice may be reflected through reports given by the members of the patient's care team who are not part of the official IDG to the individual who is coordinating care plan implementation or through IDG members attending IDG meetings in some manner. Including a bereavement counselor, whether as an individual position or as a function of the counselor or social worker, in the IDG would satisfy our expectations that all disciplines communicate with each other and have a voice in IDG meetings and decisions, and may result in better patient and family satisfaction and outcomes. Nothing in this rule prevents hospices from involving a bereavement counselor in the IDG. The core members of the IDG are identified in section 1861(dd)(2)(B) of the Act. This section permits the use of another type of counselor instead of, or in addition to, the pastoral counselor. Hospices are free to use a bereavement counselor when they believe the needs of the patient and family require it.

Comment: Many commenters took issue with the proposed requirement in § 418.56(a)(2) that, if a hospice has more than one IDG, it must designate one IDG to establish policies governing the day-to-day provision of hospice care and services. Some commenters sought minor changes to the proposed requirement to allow hospices to create a special IDG, culled from all of its

IDGs, for the job of establishing policies. Other commenters suggested that the hospice's administrator, clinical leaders, or governing body should be responsible for developing these policies.

Response: Section 1861(dd)(2)(B)(iii) of the Act requires a hospice IDG to establish policies governing the provision of hospice care and services. Therefore, we believe that it is appropriate to maintain the IDG's responsibility for developing a hospice's policies. At the same time, we agree that the IDG that is responsible for developing those policies does not need to be the same group that works together to care for patients. For example, a hospice may choose to have a policy IDG comprised of the physician from IDG 1, the nurse from IDG 2, and the social worker and pastoral counselor from IDG 3. In order to clarify that an arrangement is acceptable, we have modified the requirement at § 418.56(a)(2) to read, ''[i]f the hospice has more than one interdisciplinary group, it must identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services.''

Comment: A commenter sought clarification of the phrase ''policies governing day-to-day provision of hospice care and services'' as it was used in proposed § 418.56(a)(2).

Response: This phrase, which is also located in the previously existing CoPs at § 418.68(b)(4), refers to the hospice's responsibility to establish its own policies and procedures to govern its practices within the framework of the CoPs. We are not prescribing the exact patient care, documentation, orientation and training, and administration policies and procedures that each hospice will use in its daily operations. Each hospice, through its designated IDG, will establish these policies and procedures. The policies and procedures established by the IDG must be in compliance with the CoPs and other applicable Federal, State, and local laws and regulations.

Comment: In proposed § 418.56(b), many commenters sought clarification on the role of the patient's attending physician in the IDG. Some commenters suggested that all mention of the attending physician's involvement in the IDG should be deleted because not all patients would have attending physicians. Other commenters suggested that the involvement of the attending physician in the IDG should be qualified by statements such as ''at his/her discretion'', or ''only to the extent possible.'' Still other commenters suggested that the patient's attending physician should actively develop the patient's plan of care or even lead the IDG.

Response: The role of the patient's attending physician in the patient's hospice care will vary from hospice to hospice, and from patient to patient. This variability is reflected in the diverse comments that we received on this subject. Some commenters suggested that attending physicians should assume a leadership role in the IDG, while other commenters suggested that the role of the attending physician should be excluded altogether. To accept either of the suggested extremes, that is, attending physician leadership or exclusion, would most certainly not meet the needs of all hospices. To meet these needs, we have chosen to qualify the role of the attending physician in the IDG by adding the phrase ''if any'' to § 418.56(b). This phrase recognizes that not all patients have attending physicians. We expect hospices to document their efforts to involve the attending physician in developing the hospice plan of care, as well as the results of those efforts. Hospices may determine the best method for this documentation in accordance with their own policies and procedures.

Comment: A commenter suggested that hospices be required to make efforts to include the patient and primary caregiver when establishing the plan of care.

Response: We agree that involving the patient and primary caregiver in developing the plan of care is an important step to ensuring that the plan of care reflects the patient's goals. We have achieved this goal by adding a provision to § 418.56(b) that a patient or representative, and primary caregiver should be included in developing the plan of care if they so desire in accordance with the patient's needs. If a patient, his or her representative, and/or primary caregiver decline to participate in actively developing the plan of care, then hospices would need to document this. We also added a provision in the patient rights CoP at § 418.52(c)(2) that patients have the right to be involved in developing their plan of care. In addition, we have added a requirement in § 418.56(c) that the plan of care must reflect the patient's and family's goals. These provisions will, we believe, ensure that the patient's and family's goals are reflected in the plan of care and that patients will have full and open access to the care planning process if they so desire.

Comment: A commenter observed that the proposed rule did not include a requirement that at least two members of the IDG establish the initial plan of care. The commenter appreciated that this requirement was not included in the proposed rule.

Response: The requirement that the commenter referred to is part of the interpretive guidelines that were issued for the current hospice regulations. While we did not include this requirement in the proposed rule, we do not recommend that a single member of the IDG independently develop the initial plan of care without input from other IDG members. This would violate the intent of the hospice interdisciplinary care model. Development of the plan of care is a collaborative effort involving all members of the IDG. We will continue to include this information in the new Interpretive Guidelines.

Comment: A commenter suggested that we should include timeframes for completing the initial plan of care and the comprehensive plan of care.

Response: We do not differentiate between the stages of the plan of care. We expect the first stage of the plan of care to be completed after the initial patient assessment has been completed. This preliminary plan of care must address the immediate care needs identified during the initial assessment. Once the comprehensive assessment is complete, the hospice must then update the plan of care to address the other care needs identified through the comprehensive assessment. We believe that beginning and completing the first iteration of the plan of care should be based on the needs of the patient and family rather than specific timeframes. If a patient is in crisis or is actively dying, then it stands to reason that the plan of care must be developed by the IDG members rather quickly.

Comment: A commenter requested that, in § 418.56(b), hospices only be required to provide education and training to the patient and primary caregiver. In addition, the commenter requested that hospices be permitted to tailor the training and education provided to patients and caregivers based on their responsibilities for care.

Response: We agree that requiring hospices to educate and train the family, as we proposed, is unnecessary because not all family members may participate in furnishing care to the patient. We also agree that hospices should be permitted to tailor the education and training provided to patients and caregivers based on the exact services that patients and caregivers will be providing. For example, if a caregiver is assessed as being competent and willing to care for a patient's catheter, then we would expect the caregiver to be educated and trained on proper catheter

care procedures. The relevant portion of section 418.56(b) now reads, ''The hospice must ensure that each patient and the primary caregiver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.''

Comment: A commenter suggested that § 418.56(b) should explicitly state that only one plan of care is required and that a separate plan of care is not necessary for the family's needs.

Response: One of the most unique and valuable aspects of hospice care is its treatment of the patient and his/her family as a single unit of care. It is current hospice practice to address the needs of the patient's family as part of the patient's plan of care. This standard practice will not change based on the requirements of this rule. We expect that this rule will reinforce this practice by requiring that all services provided to both patients and their families be included in the written plan of care. We note that the term ''plan of care'' is singular and in no way implies that there should be more than one plan.

Comment: A few commenters suggested that we should clarify the scope of the plan of care by stating that the plan of care must address all of a patient's needs, rather than only those services that the hospice is capable of providing. Another commenter suggested that we should specify that the plan of care must be individualized for each patient and that it must reflect the patient's hospice care goals. Still other commenters suggested that the plan of care, including drugs, durable medical equipment and supplies, should be limited to addressing those needs related to the terminal illness and related conditions. The commenters suggested that deleting the phrase ''but is not limited to'' in proposed § 418.56(c) would accomplish this goal.

Response: The plan of care is one of the most important documents in hospice care. It is the essential link between the needs of the patient and the actions of the hospice. Therefore, we agree with the commenters that the plan of care must be individualized to meet all of the needs of the patient and family related to the terminal illness and related conditions. In order to achieve this goal, we have clarified the rule in several places. First, we have added the term ''individualized'' to both § 418.56(b) and § 418.56(c), to require hospices to develop and follow an ''individualized written plan of care.'' Second, we have revised the final sentence of the stem statement in § 418.56(c) from ''The plan of care must include but not be limited to—'' to ''The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including * * *.'' This revised statement more explicitly links the patient's needs, as identified in the assessments, to the services furnished by the hospice. In addition, this revised statement clarifies that hospices are only responsible for furnishing services based on those needs identified in the assessments related to the terminal and related conditions. Needs that are not related to the terminal illness and related conditions are not the responsibility of the hospice, although the hospice may choose to furnish services for those needs regardless of responsibility.

If a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, we would expect the hospice to communicate and coordinate with those health care providers who are caring for the unrelated needs, as described in § 418.56(e). In such situations where a hospice coordinates its care and services for the terminal illness and related conditions with care and services provided by other health care providers for unrelated conditions, we believe that it is essential for the hospice to be aware of their role within the larger comprehensive plan of care for that patient. Furthermore, we believe that it is essential for the hospice to be aware of any gaps in the overall comprehensive plan of care, and the parties responsible for filling those gaps.

Comment: A commenter questioned what was meant by the phrase ''initial comprehensive and updated assessment'' as it was used in proposed § 418.56(c).

Response: Our intent was to require hospices to base the interventions described in the plan of care on information gathered in all of the assessments, that is, the initial, comprehensive, and updated assessments. We have modified the language in § 418.56(c) to reflect this.

Comment: A commenter suggested that we should remove or define the terms ''facilitate'', ''targeted'', and ''anticipated'' in § 418.56(c). Another commenter suggested that we should replace the term ''measurable targeted outcomes'' with ''agreed-upon goals.''

Response: Section 418.56(c) describes the general areas that must be included in each patient's individualized plan of care. We agree that when describing the interventions necessary to manage a patient's pain and symptoms in § 418.56(c)(1), the language should be simplified. We deleted the term ''facilitate'' in this statement and further refined it to require that the plan of care include ''Interventions to manage pain and symptoms.'' We also agree that in § 418.56(c)(3) the language should be simplified. We removed the term ''targeted'' from the statement, which now reads ''Measurable outcomes anticipated from implementing and coordinating the plan of care.'' We did not remove the term ''anticipated'' from this requirement, because the term ''anticipated'' explicitly recognizes that the measurable outcomes are goals and they may or may not be achieved. For example, a hospice may not be able to control pain within 48 hours of admission. The hospice may have anticipated meeting that goal and took all necessary steps. However, 100 percent success is not always guaranteed. The term ''anticipated'' recognizes that fact.

We did not, as the other commenter suggested, replace ''measurable outcomes'' with ''agreed-upon goals.'' Instead, we have added a statement to § 418.56(c) to state that, ''[t]he plan of care must reflect patient and family goals and interventions based on the problems identified.* * * '' We believe that this is an appropriate way to include patient and family goals in the plan of care without excluding measurable outcomes, which are part of the individual patient care planning process and the hospice's overall QAPI program. We expect the hospice plan of care to address all patient goals in some way. If a patient has a goal that is not related to the terminal illness and related conditions, and if the hospice does not intend to address this goal, then the hospice plan of care should identify the party that is responsible for meeting the unrelated goal. Furthermore, final § 418.56(e) requires the hospice to actively communicate with the outside party to ensure that the goal is addressed.

Comment: Some commenters questioned the term ''prescribed'' as it is used in proposed § 418.56(c). The commenters stated that the term ''prescribed'' implied that we were requiring a specific physician's order for each intervention included in the plan of care.

Response: We agree that the term ''prescribed'' implies that all interventions require physician's orders. Requiring physician orders for everything was not our intent. Therefore, we removed the term ''prescribed'' from this standard.

Comment: Some commenters suggested that we should delete the terms ''detailed'', ''scope'', and ''specific'' as related to the services provided (§ 418.56(c)(2)).

Response: We did not delete these terms in this final rule. In § 418.58(c) of the existing hospice regulations, hospices are required to ''state in detail the scope and frequency of services needed to meet the patient's and family's needs.'' We note that the proposed requirement that the plan of care include, ''[a] detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs'' is very similar to the requirement that has existed for the last two decades. We believe that hospices have already determined, and will continue to determine, through their own policies and procedures, how to meet this requirement. The level of detail established by the hospice in the plan of care should be clear enough to provide a complete picture of which disciplines will be furnishing which services, how frequently that care will be furnished, and what needs are being addressed by such care. The plan of care serves as a primary means of communication between all hospice disciplines, the patient, the primary care giver, and the family. It must contain enough information so that all of these individuals know exactly what is supposed to be done, by whom, at what time, and for what purpose.

Comment: A commenter suggested that non-pharmacological interventions should be included, in addition to drugs, in § 418.56(c)(4).

Response: We agree that non-pharmacological interventions should be included in the individualized hospice plan of care; however, we are not specifically referencing them in § 418.56(c)(4). We believe that the provision of required non-pharmacological interventions are already strongly implied in the stem statement of § 418.56, and also in § 418.56(c)(1), which states that the plan of care must include ''interventions to manage pain and symptoms,'' as well as in § 418.56(c)(5), which requires the plan of care to indicate the medical supplies and appliances necessary to meet the needs of the patient.

Comment: Numerous commenters expressed concern regarding our proposal at § 418.56(c)(6) that the hospice document the patient's and family's understanding, involvement, and agreement with the content of the plan of care. The commenters stated that there are times when the patient may agree with the plan of care while members of his or her family do not. Commenters suggested either removing the term ''agreement'' or replacing the term ''family'' with ''representative'' or ''primary caregiver'' to narrow the number of individuals who must agree, and to ensure that the patient's needs and goals take primacy. Commenters also suggested that, rather than requiring hospices to document complete understanding, involvement and agreement on the part of patients and families, which may not be attainable, we should require hospices to document the level of understanding, involvement and agreement attained by the patient and family.

Response: We understand that patients and families may sometimes be in conflict regarding the content of the plan of care, and we agree that it is the patient's understanding, involvement and agreement with the plan of care that takes precedence. Therefore, we have removed the term ''family'' from this requirement and replaced it with the term ''representative.'' As defined in § 418.3, a representative is the individual who makes decisions for a patient when a patient is unable to do so. We believe that limiting this requirement to patients and representatives will help ensure that the patient's needs and goals are primary in the content of the plan of care. We continue to expect a hospice to also address, to the extent possible, the goals of the patient's family in the plan of care. We do not require the entire family to agree to the patient's plan of care.

Furthermore, we agree that, rather than requiring hospices to document complete understanding, involvement and agreement with the plan of care, it is more appropriate to require hospices to document the level of understanding, involvement and agreement attained by the patient or representative. The terminal illness and numerous other factors may affect a patient's or representative's ability to participate in care planning or understand the content of the plan of care. Requiring hospices to document a level of understanding, involvement and agreement with the plan of care recognizes this fact. Hospices will now be required to note whether impediments to understanding are present and the degree to which those impediments impact the patient's or representative's participation in care planning. Documenting this information will help hospices tailor the content of the plan of care and their patient communication process to the needs of the patient, resulting in improved patient outcomes.

Comment: A few commenters questioned the type of documentation that would be necessary in terms of a patient's or representative's understanding, involvement and agreement with the plan of care.

Response: The documentation in the clinical record must be correct and complete, as required by § 418.104, and should provide sufficient detail to fully describe the level of understanding, involvement and agreement with the plan of care. Hospices may choose to include a specific form for this documentation in each patient's medical record, include the documentation in the clinical notes or use any number of other documentation methods as those methods meet the needs and circumstances of individual hospices.

Comment: A commenter suggested that we delete proposed § 418.56(c)(6) because the plan of care is a process, not just a single document.

Response: While we agree that the plan of care is an on-going process with many updates along the way, we are retaining this regulatory element. As the plan of care evolves through updates by the IDG, patients and representatives should continue to be involved, and hospices should continue to seek their understanding of and agreement with the changes. This requirement will help to ensure that patients and representatives are involved in the care planning process and that hospices actively address the needs and goals of patients.

Comment: Some commenters sought clarification on the obligations of the hospice when the family disagrees with the plan of care, even though the patient agrees.

Response: As discussed previously, we have deleted the requirement that hospices must obtain family agreement with the plan of care. Although hospices are no longer required to obtain the family's agreement, the plan of care must still address the family's goals and will still require assistance from the family in its implementation. For these reasons, it remains essential for hospices to actively educate and involve family members to the extent possible.

Comment: A commenter agreed with our proposal in § 418.56(d) that the patient's attending physician should be involved, to the extent possible, in updating the plan of care.

Response: Involving the attending physician to the extent possible in the patient's care, including updating the plan of care, is an important step to help ensure continuity of care. We are setting forth this requirement at § 418.56(d).

Comment: Many commenters requested that the specific reference to the medical director or physician designee's role in updating the plan of care be deleted or rearranged. Commenters stated that the medical director or physician designee is often a member of the IDG and does not need to be mentioned separately.

Response: We agree that it is not necessary to specifically require the involvement of the medical director or physician designee in updating the plan of care because each IDG must have a physician member and that physician member provides adequate medical input in the updates. Therefore, we deleted this proposed requirement.

Comment: We received numerous comments about the proposed timeframes for updating the plan of care (§ 418.56(d)). Some commenters requested that we delete the proposed requirement that the plan of care be updated at least every 14 days. Others suggested that the 14 day requirement be changed to every 14–16 days, every 15 days, every 30 days, or twice per month.

Response: The plan of care is the map that the hospice will follow when delivering care to a patient and family. It is essential that the plan of care accurately reflect the services that must be delivered in order to meet the needs of the patient and family. As the patient's condition changes, the plan of care changes as well. In order to ensure that these updates occur, we proposed timeframes for both updating the comprehensive assessment and the plan of care. As previously discussed, we changed the timeframe for updating the comprehensive assessment from 14 to 15 days. We also believe that it is necessary for the timeframes for updating the plan of care and updating the comprehensive assessment to coincide. This will help to ensure that there is a direct correlation between the two. Therefore, we have also changed the update timeframe for the plan of care from every 14 days to every 15 days.

Comment: Some commenters suggested that we should delete the requirement in proposed § 418.56(d) that hospices must update the plan of care at intervals specified in the plan of care. Commenters stated that the plan of care cannot project future changes in the patient's needs. Commenters suggested that the plan of care should be updated based on the updates to the comprehensive assessment instead.

Response: Our intent in the proposed rule was to tie the updates to the plan of care directly to changes in the patient's condition. Predicting changes in patient status and the related plan of care is too difficult; therefore, we agree that this requirement should be deleted. We have deleted this requirement that hospices must ''review, revise and document the plan as necessary at intervals specified in the plan'', and, in its place, require that hospices must ''review, revise and document the individualized plan as frequently as the patient's condition requires * * * .''

Comment: A commenter suggested that IDGs should be required to meet once every 28 days with all team members and the patient and family. The commenter also suggested that two or three members of the IDG should meet once a week.

Response: We do not believe that mandating an IDG meeting schedule would meet the needs of patients and families or would enhance overall care planning. A large number of patients in hospices die before the 28th day (NHPCO Facts and Figures 2005). In addition, the proposed smaller weekly meetings would lack the essential input of all disciplines involved in the patient's care, potentially resulting in patient and family needs being overlooked or inadequately addressed. Section 418.56(e), Coordination of services, already requires an IDG system of communication that enables frequent information sharing among disciplines and across service locations.

Comment: Several commenters sought clarification regarding the requirement in proposed § 418.56(e) that hospices must have a system of communication and integration. Commenters requested clarification on how the system might be documented, how the system would interact with contract providers, and how the system might be implemented. Other commenters expressed support for the new requirement and stated that the communication system outlined in the requirement is already standard practice in hospice agencies.

Response: We appreciate the support for this standard, as it validates our understanding that hospices have already established robust communication systems. As an interdisciplinary care model, hospice relies on communication between and integration of providers to effectively plan and furnish care to patients and families. Through the years, hospices have developed methods to ensure that all members of a patient's care team receive timely information about patients. This standard expands on the communication and integration systems that hospices have developed for their own uses. This standard requires hospices to communicate, not only with their employees, but also with their contractors. It also requires hospices to integrate those same contractors into the hospice team. Communication and integration with service providers outside of the hospice's direct purview will help hospices ensure that each patient receives appropriate, high quality care in accordance with his or her plan of care, regardless of whether that care is furnished by hospice employees or contractors. As always, the hospice is ultimately responsible for the care furnished on its behalf and must actively ensure that contractors are fulfilling their patient care and communication contractual obligations.

The exact structure of the system of communication and integration will vary depending on the unique needs of each hospice. Telephone, e-mail, instant messaging, the postal service, and any other form of communication may be used in accordance with a hospice's own policies and procedures. Likewise, clinical notes, IDG meeting minutes, and any other form of documentation associated with the patient's plan of care may be used to demonstrate compliance with this requirement, in accordance with a hospice's own policies and procedures. We believe that allowing hospices to determine the structure of the system and the documentation necessary to ensure that the system is used in the best and most flexible method for ensuring that hospices are able to comply with this provision.

Comment: A commenter suggested that we should delete the phrase ''through its designated professionals'' from § 418.56(e)(1) because the members of the IDG are already defined in § 418.56(a)(1).

Response: We agree with the commenter that the above-referenced phrase is not necessary, and we have deleted it.

Comment: A commenter suggested that the language in proposed § 418.56(e)(4) be simplified by substituting the phrase ''all facilities'' for the list of the various settings where hospice care may be provided.

Response: We agree that adopting an all-inclusive term will make it easier for hospices to understand their crosscutting communication responsibilities. Since ''settings'' is a broader term than ''facilities'', as the commenter suggested, we are modifying the text in § 418.56(e)(4) to require that the system of communication provides for and ensures the ongoing sharing of information between all disciplines in all settings.

Comment: A commenter suggested that, in § 418.56(e), hospices should be required to share information with non-hospice providers who are also caring for a patient.

Response: We agree with this suggestion. We believe that it will enhance patient care in the unusual circumstances where patients with multiple illnesses and conditions receive care from multiple providers. This will ensure that hospices actively

coordinate the care that they are providing with the care being furnished by other providers. The coordination will help hospices avoid a duplication of services as well as potentially dangerous drug prescribing and dosage problems. This new requirement is located at § 418.56(e)(5). As stated previously, when coordinating care with other providers, it is essential that hospices are aware of their role within the larger comprehensive plan of care, as well as any gaps in the comprehensive plan of care and the parties responsible for filling those gaps.

5. Condition of Participation: Quality Assessment and Performance Improvement (Proposed § 418.58)

The existing § 418.66, ''Condition of participation-Quality assurance,'' relies on a problem-oriented approach to identify and resolve patient care issues. Failure to meet the quality assurance condition is consistently one of the top 10 deficiencies cited by Medicare surveyors nationwide. During the last decade the health care industry, including the hospice industry, has moved beyond the problem-oriented, after-the-fact corrective approach of quality assurance to an approach that focuses on a preemptive plan that continuously addresses QAPI. Hospice industry associations have indicated that the upgraded QAPI approach used by many hospice providers is incompatible with the existing quality assurance condition. On the other end of the spectrum some providers do not have any quality program.

The proposed QAPI requirement would raise the performance expectations for hospices seeking entrance into the Medicare and Medicaid programs, as well the expectations of those currently participating in Medicare and Medicaid. We proposed that each hospice would develop, implement, and maintain an effective, continuous quality assessment and performance improvement program that stimulates the hospice to constantly monitor and improve its own performance, and to be responsive to the needs, desires, and satisfaction levels of the patients and families it serves. The desired overall outcome of this proposed CoP would be that the hospice would drive its own quality improvement activities and improve its provision of services. With an effective quality assessment and performance improvement program in place and operating properly, a hospice can better identify and reinforce the activities it is doing well, identify its activities that are leading to poor patient outcomes, and take actions to improve performance. A hospice would be free to develop a program that meets its needs. As proposed, a provider's QAPI program would not be judged against a specific model.

The proposed QAPI CoP was divided into five standards. Under standard § 418.58(a), ''Program scope,'' a hospice's quality assessment and performance improvement program would include, but not be limited to, an ongoing program that would be able to show measurable improvement in indicators that were linked to improving palliative outcomes and end-of-life support services. We expect that a hospice would use standards of care and the findings made available in current literature to select indicators to monitor its program. The hospice would measure, analyze, and track these quality indicators, including areas such as adverse patient events and other aspects of performance that assess processes of care, hospice services, and operations. (''Adverse patient events,'' as used in the field, generally refer to occurrences that are harmful or contrary to the targeted patient outcomes.)

The second proposed standard at § 418.58(b), ''Program data,'' would require the hospice program to incorporate quality indicator data, including patient care, administrative, and other relevant data, into its QAPI program. This would include data that were received from or submitted to hospice professional organizations. We did not propose to require that hospices use any particular process or outcome measures. However, a hospice that would choose to use the available quality measures would be able to expect an enhanced degree of insight into the quality of its services and patient satisfaction, compared to beginning the outcome-measure development process anew because currently existing measures have already been tested to some degree for reliability and validity.

Proposed standard (b) also would require that data collected by the hospice, regardless of the source of the data elements, would be collected in accordance with the detail and frequency specifications established by the hospice's governing body. Once collected, hospices would use the data to monitor the effectiveness and safety of services, and to identify opportunities for improvement.

The third standard under the quality assessment and performance improvement program at proposed § 418.58(c), ''Program activities,'' stated that the hospice would set priorities for its performance improvement activities that focused on high risk, high volume and problem-prone areas, considered the prevalence and severity of identified problems' and gave priority to improvement activities that affected palliative care, patient safety, and quality of care outcomes. In § 418.58(c) we also proposed to require the hospice to track adverse patient events, analyze their causes, and implement preventive actions that would include feedback and learning throughout the hospice.

We proposed at § 418.58(d), ''Performance improvement projects,'' that the number and scope of improvement projects conducted annually would reflect the scope, complexity, and past performance of the hospice's services and operations. The hospice would document what improvement projects were being conducted, the reasons for conducting them, and the measurable progress achieved on them.

In the final proposed standard at § 418.58(e), ''Executive responsibilities,'' a hospice's governing body would be responsible and accountable for ensuring that the ongoing quality improvement program was defined, implemented, and maintained. The governing body would ensure that the program addressed priorities for improved quality of care and patient safety. The governing body would also specify the frequency and detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. The governing body's most important role would be to ensure that staff were furnishing, and patients were receiving, safe, effective, quality care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality assessment and performance improvement efforts.

Comment: A few commenters stated that the phrases ''measurable improvement,'' ''palliative outcomes,'' ''end of life support systems,'' and ''quality indicators'' as they were used in the QAPI CoP, were vague.

Response: We agree that the phrase ''end of life support systems'' is vague, and we have removed it in the opening paragraph and standard (a) because it is duplicative of the requirement that a hospice's QAPI program must involve all hospice services, including those services furnished under contract or arrangement. In § 418.58(a)(1) we have replaced the term ''end of life support systems'' with ''hospice services'' to correspond with the ''hospice services'' described in the opening paragraph. We do not agree that the phrase ''palliative outcomes'' is vague. Outcomes are the results of care provided; therefore palliative outcomes are the results of

palliative care provided. Since hospices primarily furnish palliative care to patients and respond to the results of the care furnished, we believe that it is reasonable to expect hospices to include palliative outcomes, gathered as part of the comprehensive and updated comprehensive assessments in accordance with final § 418.54(e), as part of their QAPI programs. We replaced the phrase ''indicators for which there is evidence that improvement in those indicators will improve palliative outcomes'' in § 418.58(a)(1) with the phrase ''indicators related to palliative outcomes.'' We believe that this revised language is clearer and more precise. Therefore, revised § 418.58(a)(1) now reads, ''[t]he program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.'' We do not agree that the phrase ''measurable improvement'' is vague. Hospices are required to have data-driven QAPI programs. Through these data, hospices measure their current performance, implement performance improvement projects, and measure their changes in performance after implementing the performance improvement project. Based on an analysis of the data, we believe that hospices will be able to measure the amount of improvement, stagnation, or decline in their performance and adjust their activities accordingly.

Comment: Numerous commenters asked for more clarification of the term ''adverse event'' as it is used in § 418.58(a) and § 418.58(c) of this Condition of Participation. Other commenters asked for a delay in the proposed requirement that hospices must collect and analyze adverse event data.

Response: We do not define the term ''adverse event'' because we believe that, as part of their QAPI programs, hospices should be free to define and implement the term in the manner that fits their needs. Hospices may choose to develop their own definition or use a definition developed by an accrediting body or industry organization. Once a hospice has identified the definition of an adverse event, it is responsible for adhering to the definition when tracking and analyzing these events and when implementing preventive actions. In general, an adverse event would be any action or inaction by a hospice that caused harm to a hospice patient. However, hospices are not bound to use this generic description.

We believe that it is essential to a hospice's QAPI program to begin tracking and analyzing adverse events at the same time that it begins collecting patient level outcome measure data elements and hospice-wide measures. Since adverse events generally result in harm to a patient, they serve as important indicators of areas for potential improvement. If hospices do not collect adverse event information, they may be missing important data from which to assess their performance. Therefore, we are not delaying the adverse event requirements in this final rule.

Comment: Many commenters submitted suggestions for what hospices may want to consider when selecting the elements of their QAPI program. Commenters suggested that hospices may want to examine such issues as pharmacy services, bar coding, electronic prescribing, clinical decision support programs, adverse event reporting systems, provider education efforts, patient and family education efforts, pain, nausea, shortness of breath, skin integrity, constipation, the appropriateness of emotional and spiritual interventions, and the timeliness of meeting patient needs at the start of care.

Response: We appreciate all of the suggested areas that hospices may choose to examine when developing their QAPI programs. In addition to these suggested domains, hospices may also want to consider issues surrounding patient transitions. Transitions from one care setting/provider to a hospice, or from a hospice to another care setting/provider, are an opportunity for hospices to improve their relationships with their referral sources while improving patient care and safety. Hospices may want to consider the use of shared protocols, agreements to honor advance directives, medication reconciliation processes, caregiver training and support systems, communication arrangements, and feedback systems, all related to patient transitions, as areas to examine in their QAPI programs. We are not requiring hospices to use any of the suggested domains identified above at this time because there is no currently available set of standardized measures.

Comment: A few commenters requested clarification about when and where patient care measures will be documented.

Response: Different patient care measures require different data collection timeframes. While some measures may require data collection only once, other measures may require data collection every few days or weeks. The nature of the patient care measure will determine the timeframe for collecting and updating. We expect hospices to establish their data collection timeframes within the specific context of the measures used, the available literature, any nationwide data collection projects they may participate in, their own data collection needs and goals, as well as the needs of their patients.

We require in § 418.104(a)(4) that the patient care outcome measure data be included in the patient's clinical record because hospices must use such data for individual care planning and coordination of services (§ 418.54(e)(2)). Hospices are free to document the patient care measure data in other locations as well in order to meet their needs. All documentation must be in accordance with the data collection policies and procedures established by the hospice to ensure consistency and retrievability.

Comment: Many commenters requested clarification on the role of national standardized patient outcome measures and their relationship to standardized benchmarks. Specifically, commenters noted that, while some national measures are currently available, there is still work to be done in this area. A commenter suggested that any measures developed should relate to providing physical and emotional support, promoting shared decision-making, individualizing care, and attending to the needs of families. In addition, commenters expressed uncertainty about how national benchmarks may be used to measure patient outcomes. Some commenters suggested that we should work with the hospice industry and quality improvement organizations (QIOs) to establish such benchmarks while other commenters stated that benchmarking is not necessary because the variances between hospices put the validity of the benchmarks into question.

Response: We agree that more work is needed to establish a wide variety of valid patient outcome measures that hospices may choose from. We commissioned a special study, the PEACE project, conducted by the North and South Carolina QIO. This study created a quality-focused self-audit tool for hospices to use, and identified quality measures that focus on the quality of clinical care furnished to hospice patients. Results of the study are available at *http://medqic.org/dcs/ContentServer?pagename=Medqic/MQPage/Homepage*.

In addition, the National Hospice and Palliative Care Organization launched a National Quality Initiative and Quality Collaborative to improve hospice and palliative care outcomes. This initiative is helping hospices develop functional

QAPI programs, including patient outcome measures.

Furthermore, the National Quality Forum has issued voluntary consensus standards for end-of-life care of cancer patients, who comprise approximately 50 percent of the hospice patient population (*National Voluntary Consensus Standards for Symptom Management and End-of-Life Care in Cancer Patients*, December 2006, *www.qualityforum.org/publications/reports/palliative.asp*).

The National Quality Forum also issued the ''National Framework and Preferred Practices for Palliative and Hospice Care Quality'' (2006, *www.qualityforum.org*). This report identified eight domains of quality care as follows: Structures and processes of care; physical aspects of care; psychological and psychiatric aspects of care; social aspects of care; spiritual, religious, and existential aspects of care; cultural aspects of care; care of the imminently dying patient; and ethical and legal aspects of care. Using the structure of these domains, the report identifies 38 preferred practices that have been endorsed as suitable for implementation in hospice programs.

Furthermore, the agency for Healthcare Quality and Research (AHRQ) issued an evidence-based review of end-of-life care and outcomes (*www.ahrq.gov/clinic/epcsums/eolsums.htm*) that may also assist hospices.

We believe that these efforts, combined with the measures already identified by the NHPCO and Brown University (Time Toolkit, *www.chcr.brown.edu/pcoc/toolkit.htm*), are sufficient to provide hospices with patient outcome measure options that suit their needs. Some of the measures that already have been or are being developed relate to comfortable dying, self-determined life closure, and family satisfaction with care.

We do not believe that these efforts are sufficient to establish nationwide benchmarks that are appropriate for inclusion in this rule. More time is needed to test, refine, and collect further data related to any specific measure before we could establish a nationwide benchmark that all hospices should be required to meet. The necessary information is simply not available at this time to establish mandatory benchmarks, although hospices are free to use existing benchmarks to measure their own performance against that of other similar hospices who use the same measures.

In order to further the process of establishing widely-accepted, valid, benchmarked quality measures, CMS is actively pursuing additional research on selected quality measures. This research will help identify and refine measures that are valid, meaningful, and reliable for hospices. It will also help establish benchmarks for hospices to attain.

Following publication of this final rule, CMS will issue further sub-regulatory guidance on QAPI.

Comment: A few commenters questioned the ability or appropriateness of using the same outcome measures for each patient within a hospice. Some commenters noted that not all measures may apply to all patients. Likewise, the commenters noted that certain patients may need individualized measures unique to the patient's needs and goals. Other commenters noted that measures may be different based on the location in which care is provided (that is, in the patient's home or in an in-patient facility). Still other commenters noted that outcome measure data may not be statistically significant when the data are collected from extremely small samples due to a low patient census.

Response: A variety of hospice-specific patient outcome measures are currently available. Many of these measures capture data about universal issues such as patient pain or discomfort. We believe that these universal measures can be successfully applied to all of a hospice's patients, regardless of their diagnosis or care location. At the same time, we agree that hospices may need to add specific outcome measures for specific patients in order to gather data related to the individual's needs and goals. Hospices may add patient-specific measures to the core set of standard measures that they choose to collect data on for all patients. As with the core set of standardized patient data, patient-specific data must be gathered and documented in a consistent, systematic and retrievable manner.

When analyzing data on a patient level, sample size does not matter. To use the patient outcome measure of pain controlled within 48 hours of admission discussed above in the patient assessment section, a hospice would need to document for a patient the presence or absence of uncontrolled pain upon the patient's admission to hospice. If a patient has uncontrolled pain, the hospice would then reassess his or her pain 48 hours after the patient's admission to hospice and document the presence or absence of uncontrolled pain at that time. This does not mean that the hospice does not assess the patient's pain between the initial pain assessment and the 48 hour pain assessment. Indeed, the hospice may need to assess the patient's pain far more frequently in order to adjust the treatments being provided to control the patient's pain. In completing a patient-level analysis of the patient's data, the hospice would be able to judge the effectiveness of the initial care furnished in controlling the patient's pain.

In completing the hospice-wide analysis, this patient's pain control data would be aggregated with the pain control data of the other patients that the hospice cared for. This aggregated data would allow the hospice to look for patterns such as a high level of pain control success for patients with cancer diagnoses and lesser levels of success for congestive heart failure patients. Identifying patterns, areas of strength, and areas of weakness allows the hospice to reaffirm promising practices that lead to positive patient outcomes and re-examine practices that lead to inadequate or negative patient outcomes.

Aggregation of data must be done in accordance with the policies and procedures established by the hospice. If a hospice has an extremely small average monthly census, then it may make sense for that hospice to aggregate several months of data. Likewise, if a hospice has an extremely large average monthly census, then it may make sense for them to aggregate the data more frequently to ensure that the amount of data does not become overwhelming to those analyzing it. The flexible nature of the patient outcome measure standard and the quality assessment and performance improvement CoP allow hospices to adapt data collection and analysis to their needs and goals.

Comment: A few commenters expressed enthusiastic support for the requirement that hospices collect patient outcome measure data, noting that other health care providers have been collecting this data for several years. Other commenters, while expressing support for the overall goals of data collection and QAPI, expressed concern about the potential costs. Commenters cited the potential cost and availability of software to aid in data collection as the single largest concern.

Response: We appreciate the overall support for data collection and QAPI. At the same time, we understand the concerns that some hospices have about implementing these new requirements. We note that the new regulation does not require hospices to use electronic health records or any specific software for data collection. Hospices are free to choose the data collection methods and tools that best suit their needs. We do not believe that this rule is imposing a

burden on hospices by requiring them to obtain sophisticated data collection and analysis computer programs. Analysis of patient outcome measures, as well as administrative data, will allow hospices to determine objectively what care results in the best outcomes for a particular patient or subset of patients. This will help hospices identify best practices and avoid ineffective practices, which may reduce hospice expenditures in the future. We believe these benefits will outweigh any costs associated with the process.

Comment: A commenter suggested that, in § 418.58(b)(2)(ii), hospices should be required to use quality indicator data that they collected to identify priorities, as well as opportunities, for improvement.

Response: We agree that hospices should use data to prioritize their areas for improvement, and we have incorporated this suggestion into the final rule. Section 418.58(b)(2)(ii) now reads, ''[i]dentify opportunities and priorities for improvement.''

Comment: In proposed § 418.58(b)(3), a commenter suggested that the governing body should approve, rather than specify, the frequency and detail of data collection.

Response: We agree that the governing body's general QAPI oversight responsibility would be more appropriately described by the term ''approved'' than the proposed term ''specified,'' and we have made this change.

Comment: Some commenters suggested that the requirement for hospices to conduct performance improvement projects should be phased in.

Response: In accordance with this rule, hospices are required to identify opportunities and priorities for improvement based on the data that they have collected. We agree that it would be appropriate to delay implementation of the performance improvement projects requirement to allow hospices time to develop and implement a data collection program, and actually amass several months of data. For this reason, we have added a 240 day phase-in period. This phase-in period will allow hospices to gather several months of data before being required to develop and implement their data-driven performance improvement projects. Once the 240 day phase-in period is complete, we expect hospices to begin developing and implementing their data-driven performance improvement projects, with evaluation of those performance improvement projects to follow thereafter.

Comment: A commenter asked us to specify, in § 418.58(d)(1), that the number and scope of performance improvement projects that a hospice undertakes should be based on the needs of the hospice's population and its own internal organizational needs. Another commenter asked us to clarify our proposed requirement that performance improvement projects must reflect a hospice's past performance.

Response: While we understand that some hospices may want additional guidance on the number and scope of projects that must be undertaken, we believe that a hospice's performance improvement projects should be required to reflect the needs of its patient population as well as its own needs, and this requirement is included in the final rule. We also believe that hospices must examine their past performance when developing performance improvement projects. If a hospice is aware that it had issues in a particular area in the past, then we believe that it is appropriate to re-examine that issue to assure that it has been remedied. Hospices should conduct these performance improvement projects that focus on previously existing concerns in concert with performance improvement projects that focus on more recently occurring issues, to ensure that they are consistently furnishing quality services to patients. Revised § 418.58(d)(1) reads, ''The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.''

Comment: A commenter suggested that, in § 418.58(d)(2), hospices should be specifically required to document any national quality improvement projects they are participating in. Other commenters questioned whether or not participation in national quality improvement projects would satisfy the QAPI requirement.

Response: Section 418.58(d)(2) requires hospices to document all performance improvement projects they are conducting, including national performance improvement projects. There is no need to single out national performance improvement projects as needing to be documented separately because they are one part of a hospice's larger performance improvement project plan, which must be documented. Hospices are free to participate in such national projects. We would caution however, that participation in such projects does not guarantee that hospices are in compliance with this requirement. As required by § 418.58(b)(2)(ii), hospices must use the quality indicator data that they have gathered to identify and prioritize opportunities for improvement. In addition, § 418.58(a)(1) requires a hospice's QAPI program to be able to show measurable improvement in areas related to improved palliative outcomes and hospice services. Furthermore, § 418.58(d)(1) requires that the scope and number of a hospice's performance improvement projects are to be based on the needs of the hospice and its patient population. Read together, these requirements require hospices to develop, implement, and assess performance improvement projects that reflect their areas of weakness, as identified through the data that they have collected, and the needs of their organizations. If a hospice participates in a national performance improvement project that does not address one or more of its areas of weakness, or if that performance improvement project will not enable the hospices to demonstrate measurable improvement in areas identified as needing to be addressed, then participation in the national performance improvement project would not meet the QAPI requirements of this rule.

Comment: Numerous commenters stated that the proposed QAPI requirement at § 418.58(e) assigned a hospice's governing body too much responsibility for the hospice's QAPI program. Commenters believed that the hospice IDG or a professional advisory committee would better fulfill the executive responsibilities described in this paragraph. One commenter suggested that the role of the governing body should be augmented by requiring it to monitor the QAPI program rather than simply ensuring that is it functioning. Another commenter suggested that the role of the governing body should be further clarified by adapting leadership standards for home care agencies established by the Joint Commission.

Response: Section 418.100(b) of this rule requires the hospice's governing body to assume full legal authority and responsibility for the management of the hospice, including its QAPI program. Section 418.58(e) of the proposed rule specified the QAPI responsibilities of the governing body. It would require the hospice's governing body to ensure that a QAPI program is defined, implemented, and maintained. In addition, the rule proposed that the governing body must ensure that the QAPI program addresses the hospice's quality priorities and that its

effectiveness is evaluated. As the entity that is legally responsible for the hospice, we believe that it is essential that the hospice governing body ensures that the hospice's QAPI program is meeting the requirements of this rule.

We believe that our governing body requirements meet the intent of the Joint Commission leadership standards. Therefore we are setting forth this requirement as final. The governing body may assume hands-on control of the QAPI program to ensure that the program is in compliance with this rule, or it may choose to appoint one or more individuals to handle the structure and administration of the QAPI program while the governing body retains ultimate responsibility for the actions of the designated individual(s).

As many commenters noted, the individuals who compose the governing body may not have significant experience in a hospice QAPI program and would therefore not be the best candidates to actively supervise or direct its activities. For this reason, it may not be appropriate to require the governing body to actively monitor the QAPI program if this function can be managed by others more knowledgeable in clinical and/or related fields of endeavor. A new provision has been added at § 418.58(e)(3) explicitly requiring the governing body to appoint QAPI leaders.

Comment: A commenter asked us to delete the proposed § 418.58(e)(3) which required the governing body to ensure that clear expectations for patient safety are established. The commenter stated that patient safety is already addressed throughout the regulations, and that it is redundant to include this requirement in the QAPI CoP.

Response: We agree that patient safety is already addressed throughout the rule and does not need to be separately included in the QAPI section.

Comment: The majority of commenters that submitted comments on the proposed quality assessment and performance improvement CoP supported its overall goals. The commenters appreciated our recognition of the role that QAPI now plays in the hospice industry as well as its current limitations. The commenters requested assistance from CMS in implementing some aspects of the proposed QAPI requirement. Commenters sought additional CMS involvement in developing measures that hospices may choose to use. Commenters also sought assistance from the QIOs that CMS contracts with to provide quality assistance for other provider types.

Response: In August 2006 CMS contracted with the North and South Carolina QIO to conduct a special study on hospice quality measures. This study created a quality-focused self-audit tool for hospices to use and identified quality measures that focus on the quality of clinical care furnished to hospice patients. Results of the study are available at *http://medqic.org/dcs/ContentServer?pagename=Medqic/MQPage/Homepage.*

In addition to this completed project, CMS plans to sponsor additional research that will examine the validity, reliability, appropriateness, and usefulness of select quality measures. Furthermore, CMS plans to sponsor work that will develop a method for QIOs to actively assist interested hospices in developing and implementing QAPI programs.

Comment: Many commenters made general statements in support of the broad framework adopted by the proposed QAPI requirement. These commenters liked the fact that we did not propose that hospices use any specific quality measures, data elements or benchmarks. Commenters voiced approval that they would be permitted to identify their own quality goals, measures and elements, and that they would be permitted to identify how many performance improvement projects they undertook and what those projects would focus upon. Conversely, other commenters specifically asked for the regulation to detail the quality measures and data elements that must be collected, the number and topics of performance improvement projects that must be undertaken, and the exact benchmarks or results that must be achieved.

Response: The two diametrically opposed viewpoints expressed by commenters are difficult to reconcile. Our intent in developing the QAPI CoP was to ensure that hospices would develop a data-driven program for continuous quality improvement that reflects the needs of patients and hospices alike. We believe that prescribing specific data measures and improvement projects is not appropriate at this time because there is no currently available, valid, reliable, widely applied set of clinical and/or administrative quality measures. As hospice quality measurement and best practices continue to evolve, we believe that a set of measures and practices may be identified, and that such measures and practices may be appropriate for inclusion in the hospice rules.

At the same time, we are sensitive to the concerns of hospice providers who are wary of the new and unknown. As described above, we conducted a special study through the Carolina QIO to identify hospice measures focusing on the quality of clinical care furnished to hospice patients. These measures are publicly available at no cost to hospice providers. In addition, the largest hospice industry group, the National Hospice and Palliative Care Organization, has launched a major quality initiative to provide hospices with the tools they need to begin collecting and analyzing QAPI data and to develop, implement, and analyze performance improvement projects. Furthermore, Brown University has made available the TIME Toolkit, which contains quality measures and related data elements that hospices may use in their QAPI programs. We are confident that these efforts, and others that may arise in the future, will help hospices transition from the quality assurance approach to the QAPI approach. For additional discussion of the former quality assurance requirements and the new QAPI requirements, see pages 30847–30849 of the May 27, 2005 hospice proposed rule (70 FR 30840).

Comment: Many commenters expressed general concern about the cost of implementing a QAPI program. Several of these commenters suggested that implementing a QAPI program will require more staff hours and money than estimated in the impact analysis section of the proposed rule.

Response: We recognize that moving from the basic QA approach to a QAPI approach will require some hospices to reallocate funds to expand and evolve their existing quality programs. However, an effective QAPI program will allow hospices to identify areas for improvement. The analysis of patient care and administrative data for the QAPI program may help hospices identify ineffective therapies, opportunities for staff improvement, low performing contracts for services, etc., and allow hospices the chance to improve services and efficiency. A vigorous QAPI program will benefit hospices and patients, and will help ensure that hospice resources are being used in the most effective and efficient manner possible. While we have adjusted the cost estimate for this CoP in the impact analysis section, we have not factored in the cost savings that hospices may achieve.

Comment: Several commenters stressed the importance of ensuring that all hospice employees are involved in the QAPI program. Of these commenters, a few highlighted the need for board certified chaplain involvement in QAPI.

Response: We agree that it is important to involve employees, both paid and volunteer, as well as

individuals furnishing services under contract, in the hospice's QAPI program. In order to ensure such involvement, we require in § 418.62, that all licensed professionals furnishing services on behalf of the hospice must actively participate in the hospice's QAPI program. Hospices have the flexibility, within the licensed professional requirement, to determine which individuals will lead QAPI efforts based on their own needs and goals. Hospices may choose to use the services of board certified chaplains in developing and implementing their QAPI program.

Comment: A few commenters suggested that we should require hospices to publicly report the results of their data collection, while other commenters expressed concern that we may require hospices to use a data collection tool such as OASIS, which would enable public reporting of hospice data. Similarly, commenters expressed concern that we would expect hospices to use computerized systems in implementing the QAPI requirement.

Response: Quality assessment and performance improvement is a fast growing approach to quality improvement in the hospice industry. However, there is no nationally standardized and accepted set of measures that could be used at this time to develop an OASIS-like tool that would enable public reporting. The intent of this rule is to establish the framework of QAPI in hospice, not to prescribe specific measures or tools. As such, we are not requiring hospices to use specific outcome or process measures, data elements, forms, or computer systems. These decisions are at the discretion of each hospice based on its own needs and goals. We caution that we cannot, at this time, predict with any certainty the future of hospice data collection and its relationship to the public reporting of data.

Comment: Many commenters asked for more information about how State surveyors will survey hospices for compliance with the QAPI requirements. Commenters sought more information about how hospice surveyors will use hospice data and how they will determine a QAPI program's scope, complexity and adequacy of improvement projects.

Response: Hospices are required to collect and analyze patient care and administrative quality data and to use that data to identify, prioritize, implement, and evaluate performance improvement projects to improve the quality of services furnished to hospice patients. In order to assess compliance with the QAPI requirements, hospice surveyors will need to access, upon request, a hospice's aggregated data and its analysis of that data. Surveyors will also need access to the hospice's QAPI plan, any meeting minutes or notes for meetings concerning the development and implementation of the hospice's QAPI program, those individuals responsible for the QAPI program, and any other necessary resources needed to assess a hospice's compliance. This information will allow surveyors to match the data provided by the hospice with the actual experiences of hospice employees and patients to ensure that the QAPI program is prevalent throughout the hospice's operations and services, and that it is positively influencing patient care. Furthermore, this information will enable surveyors to assess the adequacy and appropriateness of a hospice's QAPI program. Surveyors will focus on areas such as how and why a hospice chose its quality measures, how it ensures consistent data collection, how it uses data in patient care planning, how it aggregates and analyzes data, how it uses the data analysis to select performance improvement projects, how it implements such projects, and its use of data to evaluate the effectiveness of those projects. We will include more detailed information about the QAPI survey process and goals in future sub-regulatory guidance such as the State Operations Manual and Interpretive Guidelines.

We note that hospitals are currently required to comply with a very similar performance improvement project regulation and have successfully determined their performance improvement project needs and goals without prescribed minimums. Likewise, hospital surveyors have successfully assessed hospital compliance with the performance improvement project regulation without such minimums. We will use the knowledge gained through the hospital survey process to guide our understanding and implementation of surveys for hospices complying with this performance improvement project regulation.

6. Condition of Participation: Infection Control (§ 418.60)

There are no current requirements for infection control other than the requirements at § 418.100(a) that read in part, ''each patient is to be kept comfortable, clean, well groomed, and protected from accident, injury, and infection,'' and the requirement at § 418.100(e) regarding isolation areas. We proposed a new CoP to help manage the seriousness and hazards of infectious and communicable diseases.

We recognize that a hospice cannot be directly responsible for the maintenance of an infection-free environment in every setting. We proposed in § 418.60(a), ''Prevention,'' that hospices follow accepted infection control standards of practice and ensure that all staff that provide hospice services know and use these current best prevention practices to curb the spread of infection. Periodic training is one way to assure that staff take all appropriate infection prevention and control precautions. Hospices may also consider immunizing their patient care staff for influenza as part of their infection control programs. Hospice staff may transmit influenza to patients, compromising their quality of life at this important time, and to caregivers, compromising their ability to effectively care for the patient. Furthermore, infected staff may create a staffing shortage, compromising the entire hospice's ability to safely and effectively deliver care to all hospice patients and their families.

In § 418.60(b), ''Control,'' we proposed that the hospice be required to engage in an ongoing system-wide program that focuses on the surveillance, identification, prevention, control, and investigation of infections and communicable disease. Where infection and/or communicable disease are identified, we expect that this information would be made part of the hospice's quality assessment and performance improvement program.

As proposed in § 418.60(c), ''Education,'' each hospice would be expected to educate its staff, as well as patients, families, and other caregivers in the ''current best practices'' for controlling the spread of infections within the home during the course of the family/caregiver's interactions. We did not propose any specific approaches that a hospice would be required to adhere to. A hospice would be expected to aggressively seek to minimize the spread of disease and infection through its efforts to help families and caregivers understand what can and should be done to minimize infection.

Comment: Several commenters thanked us and supported the incorporation of this new requirement.

Response: We appreciate the support from the commenters on this proposal. We believe that this requirement is necessary to ensure that patients receive quality care from hospices, regardless of the patient's setting. Due to the potential negative effects on health and safety that are posed by infection and communicable diseases, we believe hospices need to address infection standards of practice and ensure all staff that provide hospice services know and

use the current best prevention practices to curb the spread of infection.

Comment: One commenter requested that we add the word ''visitor'' to the list of those protected by the infection control program.

Response: We agree, and the word ''visitor'' has been added to the opening paragraph. The final language at § 418.60 reads, ''[t]he hospice must maintain and document an effective infection control program that protects, patients, families, visitors and hospice personnel by preventing and controlling infections and communicable diseases.''

Comment: One commenter recommended that the disease prevention plan in § 418.60(b)(2)(ii), should ensure the comfort of the patient.

Response: We strongly agree. The comfort, safety and well-being of the patient must always be the main objective when providing care and services. Section 418.100(a), ''Serving the hospice patient and family,'' already requires hospices to furnish all care, including care related to infection control, in a manner that optimizes patient comfort.

Comment: A few commenters expressed concern about our proposed requirement at § 418.60(c) that hospices must provide infection control education to staff, patients, family and other caregivers. One commenter expressed concern that the tracking of infection in hospice patients, especially in the home setting, is difficult and that in many cases infection is a natural progression of the disease and is not unexpected.

Response: We acknowledge the limitations hospices may encounter regarding infections in patients, and in determining the outcomes for patients that are terminally ill, immune-suppressed and that may have other co-morbidities. However, we believe that this should not affect the need to apprise family and caregivers about infection control. The education standard in § 418.60(c) allows the hospice flexibility in meeting infection control, prevention and education objectives. While we would expect the hospice to adhere to best practices, we are not requiring any specific approaches. Due to the negative effects of infections on the health and safety of patients and staff and the potential financial burden on the hospice, we believe that it is in the best interest of hospices and the patients they serve to focus on controlling the spread of infections in the home.

Comment: A few commenters asked how hospices should handle extremely short lengths of stays, where there may not be an opportunity to educate the caregivers on infection control procedures.

Response: We certainly appreciate that hospices may encounter patients that elect the benefit in the last 24–72 hours of life. We agree that, due to the short timeframe, there may not be time to educate the patient, family and caregiver on myriad infection control procedures, nor given the circumstances, may it be appropriate. Nonetheless, we believe that the demonstration of best practices by the hospice staff while caring for the patient and the ability of the staff to talk to the patient and family regarding basic precautions such as hand washing while providing care would be sufficient. This information will be included in future sub-regulatory guidance.

7. Condition of Participation: Licensed Professional Services (§ 418.62)

Sections of current regulations at § 418.82, ''Nursing services;'' § 418.84, ''Medical social services;'' and § 418.92, ''Physical therapy, occupational therapy and speech-language pathology,'' identify detailed tasks that must be performed by agency staff. We proposed to remove § 418.82, § 418.84, and § 418.92, and replace them with a more simplified condition, ''Licensed professional services.'' Instead of identifying detailed tasks, we broadly described the expected contributions of the licensed professionals who are furnishing hospice services. Licensed professional services, for purposes of this section, would include, but not be limited to, skilled nursing care, physical therapy, speech language pathology, occupational therapy, and medical social services. We proposed that licensed professionals who provide services to hospice patients either directly or under arrangement would participate in coordinating all aspects of care, including updating the interdisciplinary comprehensive assessments, developing and evaluating plans of care, participating in patient and family counseling, participating in the quality assessment and performance improvement plan, and participating in in-service training.

Comment: Several commenters suggested that we amend the language in proposed § 418.62(b) to apply to the coordination of the patient's hospice care. One commenter stated that we should limit the hospice's responsibility to coordination of hospice care, since the hospice cannot control other aspects of patient care that are unrelated to the terminal illness and related conditions.

Response: We appreciate the comments and are accepting the suggested changes. Although we expect that the hospice will actively participate in the coordination of hospice care, it is unrealistic and beyond the scope of the hospice regulations to require hospices to coordinate all aspects of a patient's care. Therefore, we have amended this provision and the final language at § 418.62(b) now reads, ''[l]icensed professionals must actively participate in the coordination of all aspects of the patient's hospice care * * *.'' As previously noted, if a hospice does not coordinate all aspects of a patient's care, it is incumbent upon the hospice to know who is performing this function, and to actively communicate and coordinate with other providers to ensure that the patient's needs and goals are met.

Comment: One commenter asked that we not require contracted staff to participate in the hospice's QAPI program. The commenter suggested that we amend this language so that contracted licensed professionals are encouraged to participate whenever possible.

Response: For QAPI to work effectively for the hospice, all professionals must be involved in the quality process. This would include contracted licensed professionals. We expect all hospices to provide high quality care for all of the patients they serve, and believe that the care should be ''seamless,'' meaning that, whether the individual providing services is an employee or contracted licensed professional, the care provided to patients and their families must be provided at the same high level of quality.

8. Condition of Participation: Core Services (§ 418.64)

The conditions of participation containing the current core services requirements are in § 418.80, ''Furnishing of core services;'' § 418.82, ''Nursing services;'' § 418.84, ''Medical social services;'' § 418.86, ''Physician services;'' and § 418.88, ''Counseling services.'' We proposed to combine these into a single condition. We also proposed to incorporate the requirement at existing § 418.50(b)(3) which required that core services would be provided in a manner consistent with accepted standards of practice. This section was revised to reflect changes to the Act made by section 946 of the MMA. In accordance with section 946 of the MMA, we proposed to allow a hospice (the primary hospice) to enter into arrangements with another Medicare-certified hospice to obtain core hospice services. The Act provided that this could be done under extraordinary or

other nonroutine circumstances. Pursuant to section 1861(dd)(5)(D) of the Act (as amended by section 946(a) of the MMA) those circumstances are: unanticipated periods of high patient loads; staffing shortages due to illness or other short-term temporary situations that interrupt patient care such as natural disasters; and temporary travel of a patient outside the hospice's service area.

In the first proposed standard, ''(a) Physician services,'' we incorporated the existing requirements of § 418.86. The existing and proposed requirement states that hospice physicians, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness, conditions related to the terminal illness, and the general medical needs of the patient. As a result of changes made to the Act by the BBA, we also proposed to add a provision to the CoPs permitting hospices to contract for physician services. This proposed provision would align the CoPs with current CMS policy permitting hospices to contract for physician services.

The second proposed standard, ''(b) Nursing services,'' incorporated the requirements of § 418.82 of the existing CoPs. We also proposed to add specific language to address the role of nurse practitioners in providing hospice care. The services provided by nurse practitioners continue to be guided by Medicare statutory requirements. Within these statutory requirements, we propose to allow nurse practitioners to perform hospice functions that are within the scope of their practice and license, as well as within the laws of the State in which they practice.

We also proposed in § 418.64(b) to allow hospices to provide certain types of nursing services under contract. This proposed change also resulted from section 946 of the MMA, which amended the Act by adding section 1861(dd)(5)(E). As amended, the Act provides that these nursing services must be highly specialized and provided non-routinely and so infrequently that their provision by hospice employees would be impracticable and prohibitively expensive. We recognize that it may be cost-prohibitive for a hospice to employ a nurse that possesses very highly specialized skills when he or she may only care for a few patients a year. By allowing hospices to contract with specialized nursing providers or others to provide these highly specialized nursing services to the few patients who require them, hospices would be able to better implement an efficient staffing plan and ensure proficiency in the skilled services being provided.

In standard ''(c) Medical social services,'' we proposed to maintain the requirements of the current medical social services requirement at § 418.84. This standard would continue to require that medical social services be provided by a qualified social worker under the direction of a physician. This standard would also require that medical social services, when accepted by a patient and family, be based on an assessment of that patient's psychosocial needs. In proposed standard § 418.64(d), we addressed the counseling services that would be available to hospice patients and their families. Those services would be bereavement, nutritional, and spiritual counseling. In the bereavement counseling section, we proposed that a hospice would be required to have an organized program of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling. These services would be required to be made available to individuals identified in the bereavement plan of care up to one year following the death of the patient, and would reflect the needs of those individuals. When appropriate, residents and staff of a SNF/NF, ICF/MR, or other facility would be offered bereavement services.

In the nutritional counseling section, we proposed to allow qualified individuals, such as dietitians and nurses to furnish this service, provided that it was within their scope of practice and expertise according to State law. We believed that allowing other qualified individuals to participate in nutritional counseling would give hospices greater flexibility and would help ensure that all hospice patients had access to this service when needed. This proposal conformed to a recommendation made by the Secretary's Advisory Committee on Regulatory Reform.

In the spiritual counseling section, we proposed that a hospice would be required to assess the patient's and family's spiritual needs and provide spiritual counseling to meet those needs, in accordance with the patient's and family's beliefs and desires. If a patient and family did not desire spiritual counseling, then they would not have to be provided this service. If a patient and family did desire spiritual counseling, then a hospice would be expected to facilitate visits by local clergy, pastoral counselors, or others to the best of its ability.

Comment: Numerous commenters requested that the regulations permit hospices to contract for core services with various entities and for various reasons. Some of these commenters believed that hospices should be permitted to contract with hospice and non-hospice agencies on a routine basis for the provision of core services to hospice patients. Other commenters believed that, in extraordinary circumstances, hospices should be allowed to contract with non-hospice agencies in addition to contracting with other Medicare-certified hospice agencies, as we proposed. Still other commenters stated that hospices should be permitted to use contracted staff when they are providing continuous care to one or more patients, either because continuous care increases the amount of hours of patient care, which results in a period of peak patient loads, or because providing continuous care requires highly specialized nursing skills.

Response: Section 1861(dd) of the Act requires hospices to provide substantially all core services directly (see section 1861(dd)(2)(A)(ii)(I) of the Act). Thus, in accordance with the Act, hospices are prohibited from contracting with other hospices and non-hospice agencies on a routine basis for the provision of core services to hospice patients. The Act specifically states ''substantially all'' in recognition of the fact that there are times when hospices must contract for core services. The Act identifies the circumstances in which hospices are permitted to contract for core services as those that are ''extraordinary'' or otherwise ''non-routine'' such as unanticipated periods of high patient loads, temporary staffing shortages, and travel of a patient outside of the hospice's service area. We agree that hospices should be permitted to contract with non-hospice providers as well as other Medicare certified hospices in order to meet patient needs in extraordinary circumstances, and we have amended the final rule as such.

We also agree that simultaneously providing continuous home care to multiple patients may result in an unanticipated period of high patient load that would warrant contracting for core services through the extraordinary circumstance exception. If a hospice chooses to contract with another Medicare-certified hospice or a non-hospice entity, the contracting hospice must maintain professional management responsibility for the services provided, in accordance with this final rule at § 418.100(e). In addition, all licensed professionals who provide services to hospice patients under contract must actively participate in the coordination of all aspects of the patient's hospice care, including patient assessments; care planning development, delivery, and

evaluation; patient and family counseling and education; in-service training; and the hospice's quality assessment and performance improvement program, to the extent applicable, in accordance with § 418.62.

Comment: A commenter suggested that, in order to ensure the quality of nurses providing care under contract, CMS should survey nurse staffing agencies.

Response: Medicare does not currently have the authority to survey nurse staffing agencies because they are not themselves providers under Medicare. We expect hospices that use the services of a nurse staffing agency to ensure that the nurses provided by such agency are qualified to furnish nursing care to hospice patients. In addition, we expect hospices to exercise full professional management responsibility for the services provided by contractors to ensure that those services are appropriate and are of high quality.

Comment: Many commenters submitted suggestions to refine the proposed ''Physician services'' standard at § 418.64(a). One of these commenters suggested that this standard should be removed, because having a standard for physician services separates physician services from the rest of the IDG. Another commenter suggested that this standard should explicitly state that the hospice medical director would not be required personally to provide direct physician services to every patient. Still another commenter suggested that the role of physician assistants should be included in this standard. Several other commenters suggested that we remove the proposed requirement that hospice physicians be responsible for the general medical needs of the patient, because this responsibility would create a conflict with the role of the attending physician and/or the physicians of a SNF/NF.

Response: We believe that including a standard for physician services under the umbrella of the core services CoP, highlights the fact that physician services are one piece in the larger interdisciplinary services model of hospice care. Physician services are, in this rule, treated as equal to nursing services, medical social services, and counseling services. These four disciplines are required to work together as the core members of the IDG, and we believe that it is appropriate to group them together under a single CoP.

We do not believe that it is appropriate or necessary to state that medical directors are not required to furnish hands-on services to each patient. Elements of the proposed rule, such as the proposed requirement that the hospice medical director communicate with the medical director of a SNF/NF in proposed § 418.112(d), may have incorrectly implied that the hospice medical director would be expected to furnish direct care to every patient. We have removed or revised these elements to reflect the fact that the hospice IDG, including its physician member, is required to fulfill the role originally designated for the hospice medical director. Now that these implications have been removed, it is not necessary to explicitly state that the hospice medical director is not required to furnish care to each patient.

We proposed the provisions governing the role of nurse practitioners in hospice because the use of nurse practitioner services is prevalent in the hospice industry, and we have received numerous requests for this guidance for several years. Conversely, we are not aware of any need to address the role of physician assistants in hospice because, to our knowledge, physician assistant services are rarely used in hospices and are not recognized under the Medicare hospice benefit. We believe that there is no need to regulate services that are not used.

We agree that we need to revise the proposed rule requiring hospice physicians to assume responsibility for the general medical needs of the patient. This responsibility could well be beyond the scope of hospice physician services and could conflict with the responsibilities of other physicians furnishing services for needs unrelated to the patient's terminal illness and related conditions. Therefore, this proposed requirement has been removed. We have retained the requirement that, when the patient's attending physician is not available, a hospice physician is responsible for meeting the patient's medical needs. We do not believe that this requirement creates a conflict because it only applies when the attending physician is not available to perform his or her duties.

Comment: Several commenters suggested that requirements for nurse practitioner services should be included in the same standard as those for physician services. Some of these commenters also suggested that the ''Physician services'' standard should be renamed ''Medical services.'' In addition, some of these commenters suggested that the requirements for nurse practitioner services, as included under the physician services heading, should be expanded to govern the role of all advanced practice nurses.

Response: Section 1861(dd) of the Act clearly delineates those services provided by physicians from those provided by nurses. We believe that the services of nurse practitioners fall squarely into the nursing services category, because they are services provided by nurses. We also believe that, as such, it is not appropriate to relocate the regulation governing the services of nurse practitioners from the nursing services standard to the physician services standard. Since we are not placing nurse practitioner services into the same standard as physician services, it is not necessary to rename the standard. We agree that it is appropriate to replace the term ''nurse practitioner'' as used in proposed § 418.64(b), ''Nursing services,'' and we have replaced it with the broader term ''registered nurse.'' If a registered nurse, including a nurse practitioner, advanced practice nurse, etc., is permitted by State law and regulation to see, treat, and write orders, then they may perform this function while providing nursing services for hospice patients. Hospices are free to use the services of all types of advanced practice nurses within their respective scopes of practice to enhance the nursing care furnished to patients. The Medicare Hospice per diem payment includes nursing costs. A Nurse practitioners cannot bill separately for care provided to Medicare hospice patients, except under very limited circumstances. Please refer to the Hospice chapter of the Medicare Benefit Policy Manual for additional instructions regarding coverage and payment policy.

Comment: A commenter suggested that we remove the proposed requirement that the patient's plan of care describe the role and scope of services provided by nurse practitioners.

Response: We agree that it is not necessary to describe the role and scope of services provided by nurse practitioners separately from the role and scope of general nursing services in the patient's plan of care. Therefore, we have removed this proposed requirement. We continue to expect that the role and scope of nursing services, including those provided by nurse practitioners and other advanced practice nurses, will be specified in each patient's plan of care in accordance with final § 418.56(c)(2).

Comment: A few commenters suggested that we should revise the requirements of proposed § 418.64(b)(3). Some of these commenters suggested that we should delete the requirement that, in order to contract for highly specialized nursing services, those services must be provided infrequently. The commenters believed that the term ''infrequently'' was not specific. Other

commenters suggested that we should clarify that the contract for highly specialized nursing services is not required to be with another Medicare-certified hospice in order to differentiate this contracting requirement from the general core services contracting requirement.

Response: Section 946(a) of the MMA amended 1861(dd)(5) of the Act by adding a new subparagraph (E). That subparagraph states, ''A hospice program may provide services described in paragraph (1)(A) other than directly by the program if services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.'' We believe that this criterion, established by the MMA, is sufficient for hospices to assess whether or not they may contract for a highly specialized nursing service. If providing the nursing service through direct hospice employees is impossible and cost-prohibitive because the service is provided infrequently, and if the service requires highly specialized nursing skills, then the hospice may contract for the service.

We do not believe that it is necessary to state that the contract for highly specialized nursing services need not be with another Medicare-certified hospice because we have revised the requirements for the general core services contract to permit hospices to contract with Medicare-certified hospices and non-hospice providers for core services under certain circumstances. Since hospices may contract with hospice and non-hospice providers for the general core services contract and for the highly specialized nursing skills contract, there is no need to differentiate between the two contracts.

Comment: Several commenters suggested that we should revise proposed § 418.64(c), ''Medical social services.'' Many of these commenters suggested that we should remove the requirement that medical social services be provided under the supervision of a physician. Others suggested that medical social services should be provided under the direction of the hospice medical director or the IDG. Another commenter suggested that this standard should require social workers to have an MSW from an institution of higher learning that is accredited by the Council on Social Work Education. Still another commenter suggested that the scope of medical social services should be broadened.

Response: Effective supervision of medical social services is essential for ensuring high quality care. Section 1861(dd)(1)(C) of the Act requires hospices to provide ''medical social services under the direction of a physician.'' Since the Act specifically requires a physician to supervise medical social services, it is not appropriate to assign supervisory responsibility for medical social services to the IDG. It is also not appropriate to assign supervisory responsibility to the medical director because he or she may not necessarily be the physician member of the IDG assigned to the patient. The medical director, if he or she is not the physician member of the patient's IDG, may not have sufficient knowledge about the patient's care to effectively supervise the medical social services provided to that patient.

In addition to effective supervision, it is essential that the individuals providing medical social services to hospice patients be qualified to provide these services. Section 418.114 addresses the personnel qualifications that social workers must meet in order to provide services to hospice patients. We have addressed the commenter's suggestion of requiring an MSW for social workers in the section addressing § 418.114 in the preamble of this final rule.

Supervision and qualifications both affect the scope of medical social services that are provided to patients. These services are required to be based on the needs of patients and families as those needs are identified through a thorough psychosocial assessment. Since the scope of services provided is directly tied to the needs of the patient and family, it is not possible to generically broaden their scope. Some patients and families may have limited social work needs, and should not be compelled to accept broader social work services that do not meet their needs.

Comment: A commenter suggested that medical social services should be included in the counseling services standard because social workers perform counseling functions in hospices.

Response: While social workers do perform counseling functions in hospices, their duties and responsibilities go beyond counseling. Therefore, it is not appropriate to place the requirements for social workers under the counseling services heading.

Comment: Many commenters requested that we broaden the definition of ''counseling services'' to address the purpose of counseling services rather than naming precisely which types of counseling services are included in hospice.

Response: ''Counseling services'' is a broad category of services that has undergone a change from the traditional physical and psychological interventions and now includes the use of alternative therapies (for example, art therapy, yoga therapy, massage therapy, and light therapy). These therapies are now frequently used to benefit hospice patients and their families. We encourage hospices to continue to explore and employ alternative counseling services. We have adopted the suggestion and have incorporated a broader description into the requirements for counseling services at § 418.64(d). In the proposed rule we stated, ''Counseling services for adjustment to death and dying must be available to both the patient and the family.'' This final rule now states, ''Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process.'' We believe that this revised language reflects the broad nature of counseling services described by the commenters.

Comment: Many commenters suggested that hospices should be permitted to provide certain specialized counseling services under contract, either by inserting a provision to allow such contracting or by relocating the counseling requirements to § 418.70, ''Furnishing of non-core services.'' Commenters suggested that the contract services include dietary counseling provided by dietitians, art therapy and music therapy, to name a few.

Response: Section 1861(dd)(2)(A)(ii)(I) of the Act requires hospices to routinely provide substantially all core services, including counseling services to care for the terminally ill patient and to assist the patient in adjusting to his or her condition. The Act permits hospices to contract for counseling services as well as other core services, only under extraordinary or otherwise non-routine circumstances such as short-term staffing shortages, periods of peak patient loads, and travel of a patient outside of a hospice's service area. Therefore, it is not appropriate to permit hospices to routinely contract for counseling services.

Comment: Numerous commenters suggested changes to the proposed bereavement counseling requirement at § 418.64(d)(1). One of these commenters suggested that hospices should be required to incorporate bereavement services into their daily patient care

services. Another commenter suggested that either education or experience in grief/loss counseling should be an appropriate qualification for the individual supervising the bereavement services program. Other commenters pointed out a distinction between offering and providing bereavement services. They suggested that hospices should only be required to offer bereavement services because they cannot provide such services to individuals who are unwilling to receive them.

Response: We appreciate the general support received for the bereavement services requirement. We agree that bereavement counseling must be a daily hospice activity for each patient and family. To that end, we have revised the definition of the term ''bereavement counseling'' at final § 418.3 to require the services to be provided before and after the death of the patient. We also require hospices to complete an initial bereavement assessment as part of the comprehensive assessment, which must be completed within five days of the completion of the hospice election statement and certification form. Furthermore, as part of the comprehensive assessment, the bereavement assessment must be updated in accordance with § 418.56(d). We believe that these requirements will ensure that bereavement counseling is incorporated into patient care throughout the patient's hospice stay.

We also believe that it is necessary to ensure that the individual supervising this thorough bereavement program is appropriately qualified. We agree that, in addition to experience, education in grief/loss counseling is an appropriate qualification for the program supervisor. We have made this change in § 418.64(d)(1)(i).

We also appreciate the support that we received regarding bereavement services furnished within a SNF/NF or ICF/MR. As we stated in the proposed rule preamble, there are times when facility staff and residents fulfill the role of a patient's family, providing caregiver services, being companions, and generally supporting the patient. We believe it is appropriate for a hospice to consider the bereavement needs of these individuals. However, we agree with commenters that requiring a hospice to offer bereavement services to facility staff may create a conflict between the hospice and the facility, which bears ultimate responsibility for its staff. Therefore, we have separated this requirement into two parts. A hospice may offer bereavement services to facility residents as identified in the patient's plan of care. Additionally, a hospice must include a provision in its contract with a facility that addresses the offering of bereavement counseling to facility staff. Through this contractual provision, hospices and facilities can mutually agree upon a plan that meets the needs of the hospice, the facility, and the staff (see § 418.112(c)(9)).

Additionally, we believe that the offer of bereavement services, as opposed to providing them, is the appropriate requirement for hospices to meet. Hospices cannot force bereavement services upon unwilling recipients; therefore, the bereavement plan of care is only able to state what services will be offered because it cannot predict what services will actually be accepted and provided. As such, we have revised § 418.64(d)(1)(iv) to state that the hospice is to, ''[d]evelop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery * * *.''

Comment: One commenter stated that the reference to ''dietary counseling'' in proposed § 418.74 is confusing because we use the term ''nutritional counseling'' in the proposed ''Core services'' requirement at § 418.64.

Response: We agree with the commenter. Therefore to be consistent, we have amended the language at § 418.64(d)(2) to require hospices to furnish ''dietary counseling.''

Comment: The majority of commenters that submitted comments concerning our proposed requirements for nutritional counseling supported the provision allowing nurses to furnish such counseling if appropriate. However, a small number of commenters suggested that hospices should be required to employ a registered dietitian to furnish this counseling.

Response: In § 418.64(d)(2) hospices are required to assure that the dietary needs of the patient are met. If a nurse is capable of meeting the patient's needs, then we believe that it is appropriate to permit the nurse to fulfill this task. However, if the needs of the patient exceed the knowledge and expertise of a nurse, we expect the hospice to have available an appropriately educated and trained individual, such as a registered dietitian or nutritionist, to meet the needs of the patient. We believe that this needs-based requirement, rather than a prescriptive requirement dictating the individuals that a hospice must employ for this service, will assure that patient needs are met and that hospices have the flexibility to structure their staff in the manner that meets their needs.

Comment: While commenters generally supported the proposed requirement at § 418.64(d)(3) that hospices must assess a patient's and family's spiritual needs, and provide care to meet those needs in accordance with the patient's and family's acceptance of the hospice's service, commenters expressed confusion regarding the statement that hospices are not required to go to extraordinary lengths to facilitate visits by individuals who can support the patient's needs. Some of these commenters noted that spiritual counseling is often extremely important to patients and families and that hospices should try very hard to facilitate outside spiritual support. Other commenters stated that the phrase ''extraordinary lengths'' is unclear and should be removed or replaced. Some of these commenters suggested that the requirement should read, ''[t]he hospice must make all reasonable efforts to facilitate visits by local clergy, pastoral counselors * * *'' or ''[t]he hospice must facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs consistent with the patient's and family's wishes and the willingness of the designated counselors to respond.''

Response: We agree that spiritual counseling is an essential hospice service for many patients and families, and that hospices should strive to facilitate visits and contacts by those spiritual supporters that the patient and family need. However, we realize that there is a limit to what hospices should be expected to do in order to facilitate such visits, as reflected by the proposed requirement that hospices are not required to go to extraordinary lengths. We replaced the proposed ''extraordinary lengths'' requirement with a requirement that reasonable efforts must be made. This change continues to reflect the value of spiritual counseling without burdening hospices with unrealistic expectations.

9. Condition of Participation: Nursing Services Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice (§ 418.66)

The requirements for obtaining a nursing services waiver as provided by section 1861(dd)(5) of the Act is currently set forth in § 418.83, and remained virtually unchanged in the proposed rule. This condition provides hospices the opportunity to obtain a waiver from the requirement that substantially all nursing services be routinely provided directly by the hospice. The Act specifies that to obtain a waiver a hospice must be located in

an area that is not an urbanized area, must have been in operation on or before January 1, 1983, and must demonstrate a good faith effort to hire a sufficient number of nurse employees. Section 1861(dd)(5)(B) of the Act also specifies that if a waiver is requested by an organization that meets the statutory requirements and other provisions required by the Secretary, then the waiver will be deemed granted unless the request is denied within 60 days after the request is received by the Secretary. We proposed to maintain the existing requirement, as well as the regulatory timeframe that provides that waivers are effective for 1 year at a time, and that CMS may approve a maximum of two 1-year extensions for each initial waiver.

Comment: A few commenters asked us to define ''urban area.''

Response: The statute at section 8161(dd)(5)(a)(i) of the Act specifically references urbanized areas as defined by the Bureau of the Census. We refer the commenters to the Web site at HYPERLINK ''*http://www.census.gov*''. In addition, hospices may contact their fiscal intermediary or check the hospice wage index, which is updated and published yearly.

Comment: Several commenters requested that the waiver language requiring a hospice to be in operation on or before 1983 be amended by requiring that hospices to be in operation a specific number of years in order to qualify. Commenters also asked that urban as well as rural hospices be eligible for the nursing waiver.

Response: The nursing waiver language at § 418.66 tracks the statutory language and cannot be significantly changed absent a change in the statute. Therefore, we are unable to promulgate a regulation that would modify the requirements of this statutory provision.

Comment: A few commenters stated that the waiver process described in proposed § 418.66 is complex, cumbersome and time-consuming. Other commenters urged CMS to streamline and simplify the process. One commenter asked that the waiver be deemed granted unless the request is denied within 30 days after it is received. Other commenters asked if it is CMS' intent to limit the waiver for individual hospice programs to only 3 years.

Response: While we understand the waiver process may be at times a lengthy process, CMS is unable to change most of these statutorily based requirements. Changing the current 60-day timeframe to a 30-day timeframe would not allow the CMS Regional Office time to sufficiently review the waiver request. In the proposed rule, we specifically requested information on how frequently this waiver was being used. We heard back from very few hospices or other entities. All of those responding stated that they were not using this waiver. At the request of those commenters that requested clarification on the restriction of only two 1-year extensions, CMS has removed the first sentence in the requirement at § 418.66(d). We are not restricting the number of extensions a hospice can receive on its original waiver request. We believe that this will reduce the burden of requesting a waiver because hospices will no longer be required to submit a new waiver request every three years (original request + two 1-year extensions). Instead, a hospice can submit a single waiver request and an unlimited number of extensions as long as it continues to meet the waiver requirements.

Comment: One commenter requested the waiver not impede a hospice from contracting with non-Medicare-certified hospices. Other commenters requested that CMS allow hospices to contract for continuous nursing care.

Response: The proposed language at § 418.66 does not specify with whom a hospice can contract, nor does it specify the level of nursing care for which contracts can be written. The purpose of the waiver was to allow hospices in rural areas, which were having difficulty hiring nurses, to have the ability to contract for overall nursing services. For a discussion of contracting for continuous nursing care, see the preamble language relating to core services at § 418.64 and existing regulations at 418.204 and 418.302.

Comment: Some commenters confused the proposed § 418.66 with the nursing shortage exemption, which was implemented on October 14, 2004 and renewed on September 14, 2006 by CMS (S&C–05–02, *www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06–28.pdf*). Other commenters stated that the proposed rule fails to recognize the national nursing shortage.

Response: We understand that there may be some confusion about this nursing waiver at § 418.66, which is currently in regulations at § 418.83, and the nursing shortage exemption that has been in effect the past several years. The nursing waiver at § 418.66 is statutory and allows rural hospices in operation before 1983 the opportunity to obtain a waiver from the statutory requirement that substantially all nursing services be routinely provided directly by the hospice, thereby permitting such hospices to contract for nursing services if they meet the statutory requirements. The nursing shortage exemption implemented in 2004, and renewed in 2006, permits all hospices that are having difficulty hiring nurses to apply for an exemption that allows the hospice to contract for nursing services. These two waivers are completely separate from one another. As noted, the nursing waiver is statutory and applicable only to hospices located in a nonurbanized area and in operation since 1983. By contrast, the nursing shortage exemption provides short-term relief to all hospices who qualify during this nursing shortage.

Comment: One commenter requested that this waiver not be available to for-profit hospices, stating that ''for-profit hospices are the fastest growing sector in the hospice industry, and there is no evidence that they need this waiver.''

Response: The statute does not differentiate between for-profit or not-for-profit hospices. Therefore, this waiver applies to any hospice meeting the waiver requirements. We note that hospices must clearly demonstrate that they have made a good-faith effort to hire nurse employees before seeking a waiver.

10. Condition of Participation: Furnishing of Noncore Services (§ 418.70)

The current CoP governing non-core services is contained in § 418.90. We proposed to re-number the CoP and maintain its requirements, with slight language modifications. We also proposed to amend this CoP by adding language contained in § 418.50(b)(3) of the current rule, which states that non-core services must be provided in a manner consistent with current standards of practice.

There were no comments received on this condition of participation. Therefore, we are finalizing it as proposed.

11. Condition of Participation: Physical Therapy, Occupational Therapy, and Speech-Language Pathology (§ 418.72)

Currently, the CoP concerning physical therapy, occupational therapy, and speech-language pathology is found at § 418.92(a). We proposed to recodify this CoP at § 418.72 without changes. This CoP requires hospices to make physical therapy, occupational therapy, and speech-language pathology services available to patients, and to ensure that these services are provided in a manner consistent with current standards of practice.

Comment: Several commenters requested that we add dietary counseling provided by dietitians to the

list of non-core services (that is, physical therapy, occupational therapy, and speech-language pathology) included in proposed § 418.72.

Response: Dietary counseling is seen as a core service, and therefore falls under the regulatory requirements proposed at § 418.64. Within § 418.64 we have proposed that qualified individuals, including dietitians and nurses, may furnish dietary counseling, provided that it is within their scope of practice and expertise according to State law. Also within § 418.64, we allow hospices to contract with other Medicare-certified hospices and contracting agencies for core services under specific circumstances, such as extraordinary or other non-routine circumstances, unanticipated periods of high loads, and staffing shortages due to illness or other short-term temporary situations that interrupt patient care. Additionally, in § 418.74, we allow hospices located in non-urbanized areas to receive a waiver of the requirement that dietary counseling be provided directly pursuant to statutory authorization at 1861(dd)(5)(C). We believe that the staffing flexibility and waivers give hospices the flexibility to provide dietary counseling to all patients who require the service.

12. Condition of Participation: Waiver of Requirement—Physical Therapy, Occupational Therapy, Speech-Language Pathology and Dietary Counseling (§ 418.74)

We proposed a new CoP that would provide for a waiver of certain requirements. This CoP would establish authority to waive the requirement that eligible hospices must provide physical therapy (PT), occupational therapy (OT), and/or speech-language pathology (SLP) services as needed on a 24-hour basis as otherwise required by section 1861(dd)(2)(A)(i). This CoP would also establish authority to waive the requirement that eligible hospices must provide dietary counseling services on a 24-hour basis and/or that eligible hospices must routinely provide dietary counseling services directly through hospice employees.

As in the case for a waiver of nursing services (proposed § 418.66), eligibility for a waiver is based on the primary location of a hospice. For a hospice that operates in multiple locations, its primary location is considered to be the location of its central office. This central office must be located in a non-urbanized area as determined by the Bureau of the Census. The hospice must provide evidence that it made a good faith effort (for example, copies of advertisements in local newspapers, documentation of competitive salaries and benefits, and evidence of recruiting activities) to hire a sufficient number of PTs, SLPs, OTs, and dietary counselors to provide services directly through hospice employees or under arrangement on a 24-hour as needed basis.

Comment: Several commenters supported the optional waiver for PT, OT, SLP and dietary services, but one commenter stated that these services are so critical that it seemed inappropriate to provide a waiver.

Response: We agree that these can be very valuable services for the care of the hospice patient. However, we do not believe that these services need to be offered as needed on a 24-hour basis if the 24-hour requirement places an undue burden on rural hospices. Because of the scarcity of those professionals in non-urbanized areas, we believe the option for a waiver is appropriate. We also note that the waiver conditions are statutory.

Comment: A few commenters requested that we consider allowing hospices located in urban areas the waiver option as well.

Response: As noted above, this waiver language, like the nursing waiver option at proposed § 418.66, is statutory. We are unable to promulgate a regulation that would contravene the statutory provision.

Comment: One commenter asked if it is our intent to limit the waiver for individual hospice programs to only three years.

Response: As proposed, a hospice would have been required to submit an original waiver request. The hospice could then request up to two extensions on the original request. Once those two extensions expired, the hospice would have been required to submit another original waiver request. Thus, while the proposed requirement did not limit a hospice to receiving a waiver for three years in total, it did require a hospice to submit substantially more paperwork once every three years in the form of an original waiver request. We believe that it is not necessary to require an original waiver request every three years. Therefore, we have removed the first sentence in the proposed requirement at § 418.74(d). We are not restricting the amount of extensions a hospice may receive to the original waiver request.

Comment: One commenter requested that this waiver not be available to for-profit hospices, stating that ''for-profit hospices are the fastest growing sector in the hospice industry, and there is no evidence that they need this waiver.''

Response: The statute does not differentiate between for-profit or not-for-profit hospices. Therefore, this waiver applies to any hospice meeting the waiver requirements. We believe that the criteria set out at 1861(dd)(5)(C)(ii) of the Act will ensure that waivers are granted only on an as-needed basis.

13. Condition of Participation: Hospice Aide and Homemaker Services (§ 418.76)

Section 1861(dd)(1)(D) of the Act requires Medicare covered home health aide services to be furnished by an individual who has successfully completed training or a competency evaluation program that meets the requirements established by the Secretary. This section also provides for coverage of homemaker services. Currently, the condition of participation concerning home health aide and homemaker services is set forth at § 418.94, which incorporates by reference the home health aide requirements of the home health agency CoPs at § 484.36. We proposed in § 418.76 to use most of the substance of the requirements of § 484.36. The home health aide CoP establishes that a home health aide must complete a State-established or other training program, and in § 418.76(b) we outline the requirements that this training must meet, which are similar, but not identical to, the provisions of § 484.36. In § 418.76(e) and § 418.76(f) we outline requirements for the individuals and organizations eligible to provide the aide training.

We proposed that three standards be particularly adapted for the hospice conditions of participation. First, § 418.76(h), ''Supervision of home health aides,'' would be revised from the current § 484.36(d), to require that a registered nurse or appropriate qualified therapist conduct an on-site supervisory visit no less frequently than every 28 days while the home health aide is providing care. This in-person supervisory visit would need to be conducted with at least one patient to whom the aide is providing services at the time. Thorough supervision of home health aides is crucial to ensuring that the patient's and family's needs are being met, and conducting supervisory visits when the aide is performing his or her duties is a key way to provide thorough supervision. Onsite supervisory visits will still be required every 14 days, as in the current rule at § 484.36(d)(2), but the aide would not be required to be present for these visits. This supervision schedule would allow hospices to maintain control over the quality and continuity of care being provided, and would help ensure that

all patients receiving home health aide services were having their needs met by these services.

Second, proposed § 418.76(j), ''Homemaker qualifications,'' was adapted from the existing § 418.94. The proposed standard would define a qualified homemaker as a home health aide, as described in § 418.76, or an individual who met the standards in § 418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness. Homemaker services, as noted in § 418.202(g), may include assistance in maintenance of a safe and healthy environment to enable the patient to benefit from care that is furnished.

Finally, § 418.76(k) would require a member of the IDG to coordinate homemaker services, and supply instructions for the homemaker on duties to be performed. The homemaker would be required to report all concerns about the patient or family to the member of the IDG who was coordinating the homemaker services. We have proposed these changes to ensure proper training and supervision, and to protect the quality of the homemaker services provided.

Comment: Numerous commenters suggested that we should change the term that we use to refer to aides who furnish hospice care. Commenters suggested that the phrase ''nursing aide'', ''certified nursing assistant'', or ''hospice aide'' be used instead of the phrase ''home health aide.''

Response: We agree that it is appropriate to re-name aides who furnish hospice care in order to differentiate them from aides who furnish care in other environments. Therefore we have adopted the term ''hospice aide'' as best describing that role.

Comment: A commenter suggested that all of the hospice aide requirements (that is, training, education, and supervision) should be replaced by those for nurse aides, as described in 42 CFR part 483, which sets out standards for long term care facilities.

Response: We agree that nurse aide training and education in accordance with § 483.151 through § 483.154 is an appropriate qualification for hospice aides, and we have incorporated these provisions at new § 418.76(a)(1)(iii). However, we do not believe that the supervision requirements for nurse aides in long term care facilities meet the needs of hospices, whose hospice aides furnish care in the community rather than in a self-contained facility. Therefore, we are not adopting the supervision requirements from part 483.

Comment: Many commenters suggested that, in order to adapt the requirements of the home health aide regulations to the hospice regulations, we should replace all references to home health agencies with references to hospice agencies. Several commenters singled out the reference to home health agencies in proposed § 418.76(f), ''Eligible training organizations,'' which prohibits certain home health agencies from training aides, as a place where a reference to hospice agencies should be substituted.

Response: We agree that, throughout most of this CoP, references to home health agencies should be replaced with references to hospice agencies, and we have made these changes. However, in § 418.76(f), we are unable to substitute hospices for home health agencies. The provisions of standard (f) come directly from Section 1891(a)(3) of the Act. Therefore, certain home health agencies must be prohibited from providing aide training. Hospices, however, are not prohibited from providing aide training, even if they meet the exclusion criteria established for home health agencies. Although hospices are not excluded from providing training, we caution all hospices to ensure that training furnished by other providers meets all of the requirements of this rule and is of the highest quality. It is essential that aides be well trained to perform their patient care duties.

Comment: A commenter suggested that hospice aides should be required to be certified in hospice and palliative nursing assistant care.

Response: Hospices are free to require their hospice aides to be certified in hospice and palliative care. However, this certification goes beyond the standards of aide education and training that are currently in place for other provider types and is uncommon within the hospice industry. Requiring such certification for all hospice aides nationwide would likely result in a shortage of qualified aides, which would negatively impact patient care and outcomes. For these reasons, we are not adding this suggested requirement.

Comment: A commenter suggested that, in the first sentence of § 418.76(c), we should add the word ''aide'' to state that ''an individual may furnish home health aide services on behalf of a hospice * * *.''

Response: We agree that adding the term ''aide'' will clarify our intent, and we have made this change. In this section, the term ''home health aide'' has been replaced by the term ''hospice aide''.

Comment: Many commenters suggested changes to our proposal at § 418.76(e) that would require the registered nurse who provides or supervises hospice aide training to have at least two years of nursing experience, one of which must be in home health care. The commenters suggested that the term ''home health'' be replaced with the term ''hospice''.

Response: We agree that experience in hospice care is an appropriate source of knowledge for a registered nurse to perform or supervise practical training for hospice aides. We replaced the term ''home health'' with the term ''home care,'' which is used broadly in this standard and encompasses both home health care and hospice care. We believe that this fulfills the commenters' request without limiting the opportunity for the registered nurse to gain the necessary experience.

Comment: Numerous commenters made suggestions regarding the proposed requirement at § 418.76(g)(2) that aide services must be ordered by a physician or nurse practitioner and included in the plan of care. Specifically, some commenters suggested that the IDG as a whole, of which the physician is a member, should be allowed to order hospice aide services. Other commenters supported our proposal to allow both nurse practitioners and physicians to order hospice aide services. Still other commenters suggested that the frequency and scope of aide services should not need to be detailed, as is required of all other services contained in the plan of care. A single commenter suggested that the proposed provisions regarding hospice aide assignments and duties should only apply in the absence of State requirements.

Response: While we appreciate the support for our proposal that a nurse practitioner or physician must order hospice aide services, we agree that the IDG as a whole may order hospice aide services because physicians and nurse practitioners are already active members of the IDG. When ordering hospice aide services, we believe that it is necessary to detail the scope and frequency of such services. The purpose of the order, as included in the plan of care, is to provide a comprehensive map of which disciplines are providing which services at which time(s). Without such detailed information there is a lack of clarity that may compromise patient and family care. Therefore, we are keeping the detailed scope and frequency requirements.

Comment: Many commenters requested clarification about what duties hospice aides are permitted to

perform. The commenters were particularly interested in proposed § 418.76(g)(3)(iv), which would permit hospice aides to provide assistance in administering medications that are ordinarily self-administered. Some commenters wanted to know how to determine which medications are ordinarily self-administered, while other commenters noted that the hospice aide training requirement at proposed § 418.76(b) does not require aides to be trained in medication administration. Related to these comments on aide training are commenters who sought clarification on the proposed requirements of § 418.76(g)(2)(iv), which stated that aides may only furnish services that are consistent with their aide training. Still other commenters suggested that medication administration requirements should defer to State laws.

Response: Section 418.106 of this rule requires hospices to evaluate a patient's and family's ability to safely administer medications. This requirement is present because various factors may interfere with a patient's ability to safely adhere to a medication regimen. Allowing hospice aides to help administer those medications that patients are typically allowed to administer to themselves, if they are competent to do so, allows hospices to meet the medication needs of patients and caregivers who are not capable of safely self-administering medications. Assistance in medication administration may consist of helping a patient with hand tremors apply or remove a medication patch or any number of other similar tasks. Allowing aides to fulfill this role may decrease the demand for nursing visits for the purpose of medication maintenance, thus allowing nurses to provided services where needed.

Determining those medications that are appropriate for aides to help administer is the decision of the IDG, based on the needs of the patient and family, the training of the aide, the policies of the hospice, and any applicable State and local laws and regulations. We do not require all hospice aides to be trained in medication administration because not all hospices will choose to have aides perform this task. Section 418.116 of this rule requires hospices to comply with all health and safety related State and local laws and regulations. State or local rules may very well prohibit hospice aides from administering medication. However, if medication administration is within the bounds of State and local rules, and if hospices do choose to have aides perform this task, § 418.76(b)(3)(xiii) requires those hospices to provide aide training for any other task that an aide is expected to perform, which would include medication administration. This, in conjunction with the requirement at § 418.76(g)(2)(iv), that aide services furnished must be consistent with hospice aide training, effectively requires medication administration training for those aides who are charged with assisting patients in administering medications that are ordinarily self-administered.

Comment: Some commenters suggested that we should replace the proposed hospice aide supervision requirements with the supervisory requirements for home health aides found in the home health regulations at § 484.36. Commenters also suggested that we should replace the every-14-day supervisory visit requirement, which was designed to ensure the adequacy and appropriateness of aide services for each hospice patient, with a requirement that the RN should review the patient's plan of care with the aide at least every 60 days, and as needed. These commenters stated that supervising the aide every 14 days, as is currently required in the existing hospice regulations, is overly burdensome. Other commenters explicitly supported the 14 day supervision requirement.

Response: We appreciate the support for this requirement among some commenters. We believe that supervising the aide every 14 days to ensure that aide services are adequate and appropriate for each hospice patient is appropriate, given the length of time that most hospice patients receive hospice services. Many hospice patients die within a few weeks of beginning hospice services. If we were to extend the supervision timeframe, the extension would likely result in no supervisory visits occurring between the time the patient begins receiving hospice care and the time the patient passes away (for example, a hospice patient begins receiving aide services on day three and passes away on day 24, without ever receiving an aide supervisory visit to assess the adequacy and appropriateness of the aide care provided). This lack of supervision would in no way benefit patients and families. In addition, this lack of supervision would likely not help hospices because they would remain completely unaware of the quality and adequacy of the aide services they were providing. This could lead to an over- or under-use of aide services, low quality aide services, patient and family dissatisfaction, and a wide variety of other negative outcomes that hospices wish to avoid. In short, we believe that adequate frequent supervision benefits patient and hospices alike, and the requirement remains in this final rule.

Comment: A commenter suggested that all hospice aide supervision requirements should be removed in favor of outcome and patient satisfaction measures and performance improvement projects when measures indicate inadequate performance in aide services. Another commenter suggested that all hospice aide supervision requirements should be removed because hospices are already required by § 418.76(b) and § 418.76(c) to ensure that hospice aides are trained and that competency evaluations are completed.

Response: We are not deleting these requirements for two reasons. First, while hospice aide training and competency evaluations ensure that aide skills are adequate upon hiring or initial training, they do not ensure that those same skills remain adequate as time passes. We believe that aide skills should be continuously reexamined to ensure competency at all times. Second, hospice quality and outcome measures have not yet reached the point where there is consensus on a single set of measures that have been thoroughly tested and determined to be valid, reliable, and widely applicable. As quality and outcome measures continue to evolve we will consider this suggestion. Nonetheless, hospices may use an outcome measure that targets aide services as part of their QAPI program, however the measure could not replace aide supervision. Outcome measures and supervision can and should work together, rather than replace each other, in order to enhance the quality of the service provided, patient outcomes, and patient satisfaction.

Comment: A few commenters requested clarification about the nursing personnel who may function as hospice aide supervisors. One commenter suggested that licensed vocational nurses (LVNs) and licensed practical nurses (LPNs) should be permitted to supervise hospice aides. Another commenter suggested that any nurse should be permitted to supervise a hospice aide, rather than having a designated nurse supervise a specific hospice aide's care of a patient.

Response: Registered nurses (RNs) have the education and training to adequately supervise hospice aide services. In addition to ensuring that hospice aides furnish the care identified in the plan of care, nurse supervisors must be able to assess the adequacy of the aide services in relationship to the

needs of the patient and family. Registered nurses possess the assessment skills necessary to fulfill this function to a greater degree than LVNs and LPNs, which makes registered nurses uniquely qualified to fulfill the hospice aide supervisory position.

In addition to having the necessary assessment skills, it is important that registered nurses have a relationship both with the aide being supervised and the patient receiving the aide's services. Ideally, the RN responsible for supervising the aide is the RN chiefly responsible for the patient's nursing care. This allows the RN to develop a complete picture of the patient and family and of the aide's services. For this reason, we believe that it is necessary for hospices to identify a specific RN who will serve as the aide's supervisor during the care of a specific patient. We understand that, at times, it is necessary to use other RNs to fill-in and supervise aide services. If a substitute supervising RN is used, this should be noted.

Comment: A large number of commenters expressed concern about our proposal in § 418.76(h) to allow therapists to supervise hospice aides. Some commenters sought clarification regarding the exact meaning of the term ''qualified therapist.'' Other commenters suggested that therapists should only be allowed to supervise hospice aides when aides are furnishing delegated therapy services. Still others suggested that only nurses be allowed to supervise hospice aides.

Response: We proposed to allow hospices to use therapists to supervise home health aides in order to provide more flexibility in meeting the every-28-day in-person supervisory visit requirement discussed later. We have changed the 28-day timeframe, thereby alleviating many of the related supervisory demands. For this reason, we believe that it is no longer necessary to allow therapists, who are not routinely involved in the care of most hospice patients, to supervise hospice aides. Thus, the term ''therapist'' has been deleted from this standard, as well as this CoP.

Comment: A commenter suggested that the every-14-day supervisory visit could be conducted through a telephone contact with the patient or family, rather than through a visit to the patient's home.

Response: In-person visits by the supervising nurse to the patient's home allow the nurse directly to observe the patient and the results of the aide's care. Telephone contacts do not allow the nurse to see if the patient has been bathed, and patients may be hesitant to report these failures of duty to nurses for any number of reasons. In-person home visits simply provide nurse supervisors with more information than telephone contacts do.

Comment: A commenter suggested that we should clarify the purpose of the every-14-day supervisory visit required by § 418.76(h), to state that the visit is designed ''to assess the quality of care and services provided'' by the aide.

Response: We agree that clarifying the intent of the every-14-day supervisory visit will be helpful to hospices. We have added language at § 418.76(h)(1)(i) to reflect the intent of the suggestion. In addition, we have added a statement that the every-14-day supervisory visit is also meant to ensure that the services ordered by the hospice are sufficient to meet the patient's needs.

Comment: Numerous commenters submitted suggestions on the proposed every-28-day timeframe for in-person supervision of hospice aides at § 418.76(h). Although some commenters expressed support for the 28-day supervision requirement, most suggested that the 28-day timeframe be changed to every 60 days, every quarter, every 6 months, every 12 months, or even every 24 months. Some commenters also suggested that the in-person supervision requirement be deleted in its entirety.

Response: We believe that all hospice employees, including hospice aides, must be supervised. To ensure that aides are adequately supervised, we proposed that each aide would be supervised while he or she is furnishing care to a patient for the purpose of observing the aide's skills. In addition, we proposed that this in-person supervision would occur at least every 28 days. After reviewing the comments that we received, we agree that assuring aide skill competency 12 times per year is not necessary. In keeping with our desire to maintain consistency with the aide requirements in the home health regulations, we have changed the in-person supervisory visit timeframe from once every 28 days to once annually per aide.

At the same time, we have added a new requirement at § 418.76(h)(1)(ii) that requires hospices to conduct in-person supervisory visits to observe and assess aide skills if a potential deficiency in care furnished by the aide is noted in the regular 14-day supervisory visit (during which the aide is not required to be present). We believe that linking more frequent in-person supervisory visits to the actual performance of the aides will ensure that aides furnish quality care and that hospices have the flexibility to supervise their staff in a manner that meets their needs.

Comment: A few commenters suggested that the aide in-person supervision visit (proposed as occurring every 28 days and finalized as occurring annually) should be documented in the aide's personnel record, rather than in the patient's clinical record.

Response: We agree that the aide's personnel record is an appropriate place to document the annual in-person supervisory visit. Hospices may determine the appropriate location to document the annual aide evaluation in accordance with their own policies and procedures.

Comment: Many commenters expressed confusion about the in-person supervisory visit to observe the aide furnishing care. Commenters wanted to know whether the observation visit needed to be conducted with each patient that the aide is caring for, or whether the observation visit only needed to be conducted with a single patient that the aide is caring for. The commenters noted that conducting an observation visit with each patient that the aide is caring for would be difficult to schedule and cost-prohibitive.

Response: The intent of the proposed rule was to require an observation once every 28 days with a single patient that the aide was caring for at the time of the visit. In response to public comments, we changed the timeframe for the observation visit from once every 28 days to once annually. In addition, we have changed the phrasing of this requirement to more clearly state our intent for only a visit to a single patient's home. The revised requirement at § 418.76(h)(2) states, ''A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.'' We believe that ''a patient'' is clearer than the language we originally proposed, ''the patient.'' We are not requiring that the aide be supervised with each patient annually to evaluate the aide's proficiency.

Comment: Many commenters addressed the relationship between hospice aide services, hospice homemaker services, and Medicaid personal care benefits. Specifically, commenters suggested that we should state in the regulation text that hospice aide and homemaker services are not 24-hour-a-day primary caregiver services and are not meant to replace personal care aide services covered under Medicaid or other insurers. Commenters also suggested that we should clarify the relationship between the hospice and personal care aides by

stating that hospices may use the personal aides in implementing the plan of care only to the extent that the hospices would routinely use the services of a patient's family in implementing the plan of care. Furthermore, commenters suggested that hospices should be required to coordinate their services with those furnished by personal care aides.

Response: We understand that there may be confusion relative to the interaction between the Medicaid personal care aide benefit and the hospice benefit. The Medicaid personal care benefit is designed to assist eligible Medicaid beneficiaries with daily personal care tasks such as household chores and personal hygiene. The hospice aide and homemaker services covered under the Medicare hospice benefit cover many of the same tasks. However, hospice aide and homemaker services are not necessarily meant to be daily services, and are certainly not meant to be 24-hour daily services. Hospices are neither expected to nor prohibited from fulfilling the caregiver role for a patient. Rather, hospice aide and homemaker services are provided to supplement the primary caregiver(s).

Since there may be occasions where a patient receives services through a personal care aide benefit while receiving hospice services, we agree with the commenters that this rule should address the responsibilities of the hospice for coordinating the care provided by hospice personnel and the Medicaid personal care aide. We have added new elements to address this, § 418.76(i)(2) and § 418.76(i)(3). Section 418.76(i)(2) provides that services furnished by the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care. Section 418.76(i)(3) requires that a hospice coordinate hospice aide and homemaker services with the services furnished by the Medicaid personal care aide benefit to ensure that patients receive all the services that they require.

Comment: Numerous commenters requested clarification of the requirements at proposed § 418.76(j), Homemaker qualifications. The commenters interpreted the proposed standard to mean that only those individuals who have completed hospice aide training are considered qualified to function as homemakers. The commenters disagreed with this policy and stated that orientation to hospice care should be sufficient for homemakers.

Response: In § 418.76(j) we proposed that a homemaker be either an individual who has completed aide training or an individual who has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness. We believe that the commenters misinterpreted this requirement, and that the misinterpretation led to a great deal of confusion. We agree with the commenters that homemakers do not need to complete hospice aide training in order to be qualified, which is why we proposed that hospice orientation is sufficient. We do not agree that hospice aide training should be completely removed from this standard. If an individual has completed hospice aide training, he or she should not be prevented from serving as a homemaker. Indeed, hospice aide training provides an extra level of education and training that would go above and beyond hospice orientation. In order to clarify our intent in this standard, we have reformatted it to place hospice orientation as the first option for homemaker qualifications and hospice aide training as the second option for homemaker qualifications. We believe that this reformatting will make it clearer that either qualification is acceptable.

Comment: A commenter asked whether or not hospices are permitted to contract for homemaker services.

Response: Section 1861(dd)(2)(A)(ii)(I) of the Act requires hospices to provide substantially all nursing, medical social, and counseling services through direct employees. Homemaker services do not fall into any of these categories; therefore hospices may contract for homemaker services. If hospices choose to contract for homemaker services, then the professional management responsibility requirements of § 418.100(e) will apply. We believe that this question may have been prompted by a requirement in proposed § 418.76(h)(4) regarding contracting for hospice aide services. The inclusion of specific requirements for aide contracting, and the omission of requirements for homemaker contracting, seemed to imply that homemaker contracting would not be allowed. We have removed the aide contracting provision at § 418.76(h)(4) in order to remove any implication that homemaker services may not be contracted.

Comment: A commenter suggested that we should explicitly state that homemakers can be volunteers.

Response: Volunteers are permitted to fulfill many roles in hospice care, including providing homemaker services, provided that the volunteers meet all qualifications and personnel requirements established by this rule. We do not believe that it is necessary to explicitly state in this standard that volunteers may function as homemakers. We believe that making this statement may unintentionally imply that volunteers may not function in other capacities within a hospice program. The implication would negatively impact the role of volunteers in hospice and may affect the level of volunteer services that hospices furnish.

Comment: A commenter sought clarification about who is responsible for supervising homemaker services.

Response: We agree that this rule should explicitly require such supervision. We have added a provision at § 418.76(k)(1), stating that the member of the patient's IDG group who is responsible for coordinating homemaker services must also be responsible for supervising those services.

14. Condition of Participation: Volunteers (§ 418.78)

The current CoP for volunteers is located at § 418.70. We proposed to recodify this CoP at § 418.78 with minor changes. We proposed to remove the existing § 418.70(f), regarding the availability of clergy, because the role of the pastoral, clergy, or other spiritual counselor would be described as part of the IDG at proposed § 418.56(a)(1)(iv). This change would not preclude the hospice from continuing to use or starting to use clergy as volunteers. We did not propose any changes to the requirements to document cost savings and to maintain a sufficient level of volunteer activity.

Comment: A few commenters suggested that we should remove the term ''day to day'' from the proposed § 418.78(b). The commenters stated that removing the phrase would permit hospices to use volunteers for special events that occur infrequently.

Response: The phrase ''day-to-day,'' as used, requires hospices to incorporate volunteer services into their daily patient care and operations routine in order to retain the volunteer-based essence of hospice as it originated in the United States. The phrase does not preclude hospices from using volunteer services for special events or non-routine occurrences. Hospices must use volunteers for day-to-day services, and may use volunteers for other services as well.

Comment: Some commenters asked us to clarify that volunteer time spent in training, orientation, travel, direct patient care, and administrative services may be included when documenting the

cost savings that the hospice achieves through the use of volunteers.

Response: Section 1861(dd)(2)(E)(ii) of the Act requires hospices to maintain records on the cost savings achieved through the use of volunteers. That is, hospices must document those hours that volunteers furnished care and services for which a hospice would otherwise have been required to pay its employees to furnish such care and services. If a hospice is training and orienting volunteers, it is most likely using its paid employees to do so. Therefore, no cost savings is achieved. However, if a hospice does pay an employee for time spent traveling for direct patient care and administrative purposes, and does not compensate a volunteer for the time, then it may include the volunteer's travel time, direct patient care and administrative services in its documentation of the cost savings it achieves. Likewise, hospices may document the time that volunteers actually spend providing direct patient care and administrative services, because hospices would compensate paid employees for the time spent performing these duties. We note that travel time is not the same as direct patient care. Following publication of this final rule, we will issue further sub-regulatory guidance addressing the manner in which the cost savings needs to be calculated and documented.

Comment: Several commenters requested clarification about what volunteer hours may be included in calculating the level of volunteer activity within a hospice, as required by proposed § 418.78(e). Commenters specifically suggested that time spent traveling, providing care or services, documenting, and phoning patients should be included in the level of volunteer activity calculation.

Response: We understand that traveling, providing care or services, documenting information, and calling patients all consume volunteer time, and we agree that the time may be used in calculating the level of volunteer activity in a hospice. If a hospice chooses to include any of these areas that are directly related to providing direct patient care or administrative services in its percentage calculation of volunteer hours, it must ensure that the time spent by its paid employees and contractors for the same activity is also included in the calculation. That is, if a hospice chooses to count the hours spent by volunteers traveling to and from patient homes in its calculation of the numerator, it must count the hours spent by its paid employees and contractors in traveling to and from patient homes in its calculation of the denominator. In this way, hospices will be able to accurately assess the proportion of volunteer hours to paid staff and contractor hours. Upon issuance of this final rule, we will issue sub-regulatory guidance to reflect the potential inclusion of certain volunteer hours in the overall calculation.

Comment: Some commenters suggested that hospices should only be required to provide volunteer hours equal to five percent of the routine home care level of care hours furnished to patients. Commenters stated that this would be easier for hospices to comply with because providing direct inpatient, respite, or continuous home care accounts for a substantial number of paid staff hours. Eliminating the hours spent providing direct inpatient, respite, or continuous home care would decrease the number of hours in the denominator, thereby altering the ratio of volunteer hours to paid hours. Other commenters suggested that the five percent goal should be completely eliminated.

Response: Section 1861(dd)(2)(E)(i) of the Act requires the Secretary to ensure a continuing level of effort to use volunteers in providing care and services to hospice patients. In addition to serving as companions, homemakers and administrative staff, volunteers often serve as medical directors, nurses, alternative counselors, and spiritual advisors. All of these services, when provided by volunteers, count toward the five percent goal. Since we permit hospices the flexibility to use volunteers to function in such a wide variety of roles within hospices, we do not believe that it is necessary to artificially lower the standard for achieving continual volunteer use in hospice by eliminating the hours spent by hospices furnishing direct inpatient, respite, or continuous home care. Additionally, we note that hospices have not historically failed to meet the five percent requirement, as this is not a frequently cited deficiency during hospice surveys conducted by the State survey agencies.

Comment: A commenter asked us to define the role of a hospice volunteer.

Response: Hospice volunteers are permitted to fill any role within the hospice, provided that the volunteer filling the role meets the appropriate qualifications of this rule and any other applicable State and local requirements (for example, State licensure). Since volunteers may be used in any role, there is no one volunteer role that can be defined in this rule. Any definition may unintentionally limit a hospice's use of volunteer services, thus compromising its ability to comply with the requirements of this rule.

Comment: Some commenters suggested that board certified chaplains should be required to train and supervise hospice volunteers.

Response: Hospices are responsible for ensuring that volunteers are trained, oriented, and supervised. While a designated employee must supervise volunteers, their training and orientation may be conducted by a person(s) of the hospice's choosing. We believe that it is inappropriate to prescribe the qualifications for the person(s) responsible for training and supervising volunteers because hospices need the flexibility to make the staffing decisions based on their individual needs. If hospices choose to use board certified chaplains to train and/or supervise volunteers, they are free to do so.

15. Condition of Participation: Organization and Administration of services (§ 418.100)

We proposed to combine several conditions of the existing CoPs into a single new CoP. The proposed CoP included the requirements of current § 418.50, ''General provisions,'' § 418.52, ''Governing body,'' § 418.56, ''Professional management,'' § 418.60, ''Continuation of care,'' and § 418.64, ''In-service training.'' We believe that the proposed CoP simplifies the structure of the requirements, making them easier to understand. We also proposed to condense the list of all services that hospices are required to furnish into a single standard. We believe that this single list will emphasize hospice's holistic approach to patient and family care.

We made minor changes to the ''General provisions,'' ''Governing body,'' ''In-service training,'' and ''Continuation of care'' requirements. In § 418.100(e), ''Professional management responsibility,'' we proposed to revise some of the current requirements found at § 418.56(b) and § 418.56(c). This proposed standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management, supervisory, and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that it authorizes all services that it provides, that they are furnished in a safe and effective manner by qualified personnel, and that items and/or services specified in the plan of care are provided.

We proposed to add a new standard to address the issue of multiple service locations. This provision was intended to codify long-standing Medicare survey

and certification policy, which allows for the operation of multiple locations by a single hospice provider with a single Medicare agreement. We expect that any hospice that requests to establish a satellite location (now referred to as a multiple location) will be able to demonstrate how it is able to manage and monitor all of the services provided in its entire service area, including services from a multiple location. Patients who receive care and services from a hospice multiple location must receive the full range of services that are documented in the plan of care.

Before operating a multiple location, also known as a practice location on CMS form 855, a hospice must enroll with the fiscal intermediary and notify the State agency and CMS of all currently approved multiple locations at the time it requests approval for any additional multiple locations. If a hospice provides care and services to Medicare beneficiaries from an unapproved or disapproved multiple location, these services may be determined to be non-covered. At the time of any multiple location closure the hospice is expected to notify the fiscal intermediary, State agency and CMS. Hospice multiple locations are also subject to survey by the State survey agency or CMS regional office. Deficiencies that are identified at any multiple location will apply to the entire hospice issued the provider agreement number. Multiple locations must comply with the hospice conditions of participation at § 418.52 through § 418.116.

Comment: A few commenters suggested that we restate the requirements in proposed § 418.100(a)(1) to clarify that hospices are responsible for providing care that meets the patient's needs for comfort and dignity, but are not responsible for ensuring that patient's actually experience such care because patient perceptions are outside of the hospice's control. A commenter suggested that this requirement should be further qualified by adding a statement that hospices should only be responsible for providing such care to the extent that it is possible within the context in which the patient is living.

Response: We agree that hospices are responsible for providing care rather than ensuring experiences. We also believe that the term ''optimizes'' already reflects the fact that hospices must work within the context of the patient's living situation to address the patient's unique needs and goals. Rather than holding hospices responsible for actually assuring comfort and dignity, we are requiring hospices to optimize, or take all appropriate steps, to provide care that promotes comfort and dignity. The revised requirement reads, ''[t]he hospice must provide hospice care that [optimizes] comfort and dignity.''

Comment: Many commenters suggested that we should reexamine the proposed requirement at § 418.100(a)(2) which would require that the hospice must ensure ''[t]hat each patient experiences hospice care that is consistent with patient and family needs and desires.'' The commenters stated that hospices are not necessarily able to ensure that patients experience care that is consistent with their needs and desires. Rather, hospices are able to, through their actions, promote care that is consistent with patient needs. Furthermore, commenters stated that the term ''desires'' was too broad to be successfully met by hospices. The commenters suggested that it be deleted; qualified by phrases such as ''consistent with hospice practice'' or ''that are reasonable and necessary''; or replaced by ''goals.'' In addition, the commenters expressed concern about the requirement to meet family desires when those desires are in conflict with each other or those of the patient.

Response: We agree with the commenters that hospices should be required to provide care consistent with patient and family needs rather than requiring hospices to ensure that patients and families experience care that is consistent with their needs and desires. Using the term ''provide'' holds hospices responsible for those things that are within their control in contrast to the term ''experience,'' which is subjective and out of a hospice's control. We also agree that the term ''desires'' is too broad and subjective, even when qualified by the suggested phrases. We believe that the term ''goals'' is more objective, and it corresponds with the requirement at § 418.56(c) that the hospice plan of care must reflect patient and family goals. Therefore, we have replaced the term ''desires'' with ''goals'' in this requirement. Furthermore, we have added a statement in § 418.100(a)(2) affirming that the patient's needs and goals are the hospice's primary consideration in care planning and delivery. While hospice treats the patient and family as a single unit of care, this new statement recognizes that not all members of a family may agree about the patient's hospice care. In situations where agreement cannot be reached regarding the goals of hospice care, the patient's needs and goals must take precedence.

Comment: A commenter suggested that the requirement for the governing body to assume full responsibility for management of the hospice may be in conflict with State laws regarding management of entities. The commenter stated that Boards of Directors generally do not perform hands-on management of the entity.

Response: We believe that the commenter may have misunderstood our intent in this section. We are not requiring the governing body to actually perform day-to-day management functions. We clarified in proposed and final § 418.100(b) that the administrator, who is appointed by the governing body, is responsible for the 24-hour operation of the hospice. If the administrator is not available to fulfill his or her assigned duties and responsibilities, the hospice must identify another individual to assume those assigned duties and responsibilities in accordance with the hospice's established policies and procedures. The governing body must assume responsibility for ensuring that the hospice is managed by the administrator and any managers that the administrator appoints.

Comment: A commenter requested that we provide a definition for the term ''administrator'' at § 418.100(b).

Response: At § 418.100(b) we are requiring hospices to have an administrator who reports to the governing body and who is responsible for the day-to-day operations of the hospice. We have added a new requirement that the administrator be appointed by the governing body, to further clarify the relationship between the two parties. We are requiring that the administrator be a hospice employee who possesses the education and experience determined to be necessary by the governing body. We intentionally are not including specific personnel requirements or a job description for the administrator because this leadership position varies from hospice to hospice, based on the unique needs of each hospice. A hospice's governing body, with knowledge of its operations and needs, is far better suited for making administrator personnel and job description decisions.

Comment: A commenter suggested that we should add requirements related to advanced beneficiary notices and expedited determination notices to proposed § 418.100(d), which states that hospices may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

Response: It is not appropriate to add information about advanced beneficiary

notices and expedited determination notices to this rule because these notices are not within the scope of this rulemaking.

Comment: Many commenters expressed concern about our proposed requirement at § 418.100(e) that hospices must retain supervisory responsibility for services furnished under arrangement. The commenters stated that the word ''supervision'' implies that hospices are responsible for providing personnel supervision for those individuals furnishing services. Personnel supervision, the commenters further stated, is the role of the entity with which the hospice has an arrangement. The hospice should be responsible for ensuring that such supervision occurs. Commenters suggested that the word ''supervision'' be deleted and replaced with ''oversight'', ''supervisory responsibility'', or ''continually monitor and manage.''

Response: It was not our intent to imply that hospices must provide personnel supervision for contracted staff. We agree that the term ''supervision,'' as used in the proposed regulatory standard, implies much more than was intended. Therefore, we are deleting the term ''supervision'' and replacing it with the term ''oversight'' to clarify that the hospice must be responsible for the services furnished rather than the individuals furnishing the services.

Comment: Numerous commenters suggested that the proposed requirement at § 418.100(e)(2) regarding the qualifications of contracted personnel be clarified. The commenters suggested that the phrase ''qualified personnel'' replace the phrase ''personnel having at least the same qualifications as hospice employees.'' The commenters stated that for some contracted services, for example, durable medical equipment, there are no equivalent positions between the hospice and the contractor. Therefore, it would not be possible for the contractor's employees to have at least the same qualifications as hospice employees.

Response: Our intent was to ensure that hospice patients receive the same quality service regardless of whether that service is provided by hospice employees or contracted staff. We believe that the commenters' suggestion is appropriate and we revised the requirement found at § 418.100(e)(2). This revised element requires contracted staff to be ''qualified,'' meaning that they must meet the personnel qualifications of whatever profession or job description they are in, as well as any regulatory requirements particular to that profession or job description.

Comment: A large number of commenters expressed support for, or requested clarification regarding, our proposal at 418.100(f), ''Hospice satellite locations.'' Commenters appreciated our inclusion of regulations on this fast growing part of hospice care and our exclusion of mileage restrictions. Some commenters sought specific criteria that hospices must meet in order to open a multiple location, while other commenters requested more detailed information on the Medicare approval process, including what would constitute an ''initial determination'' under § 498.3, regarding such locations. A few commenters suggested that the entire proposed multiple location requirement be deleted.

Response: We appreciate the support from commenters on this proposal. We believe that this proposed requirement is necessary to ensure that patients receive quality care from hospices, regardless of whether those services are being provided by the hospice location originally issued the certification number or by a multiple location of the hospice. (As noted in the discussion of public comments in § 418.3, the term ''multiple location'' is more current and appropriate than the term ''satellite location.'') We also believe that the proposed requirement at § 418.100(f), coupled with the definition of ''multiple locations'' at § 418.3, will provide much-needed guidance for hospices considering operating one or more ''multiple locations.''

As previously stated, we relocated the requirement that hospices must exercise supervision and management over multiple locations from the definition of the term ''multiple location'' at § 418.3 to § 418.100(f)(1)(ii). Furthermore, we reorganized § 418.100(f) to group all requirements related to Medicare approval of multiple locations under a single regulatory element, § 418.100(f)(1), ''Medicare approval.'' We believe that grouping these elements will clarify our expectations for hospices seeking to operate multiple locations. Revised § 418.100(f)(1)(iii) now requires that the lines of authority, and professional and administrative control be clearly delineated in the hospice's organizational structure and in practice. It also requires that the lines of authority be traceable between the hospice location issued the certification number and all multiple locations. This new requirement further clarifies how a hospice must demonstrate supervision and management of the multiple location by the hospice issued the provider number. Revised § 418.100(f)(1)(iv) also includes a provision that a determination of whether or not a location qualifies as a multiple location in accordance with the considerations described above is an ''initial determination'' under § 498.3. An ''initial determination'' is an administrative action made by CMS, and is subject to appeal. Section 498.5 sets out the procedures for appellate review of CMS administrative actions that qualify as initial determinations. Therefore, hospices may appeal an unfavorable multiple location determination in accordance with the procedures of § 498.5.

In the preamble to the proposed rule, we described some of the factors that are currently examined when hospices apply to their CMS regional office for Medicare approval of a multiple location. The factors further explain what evidence must be presented by a hospice to CMS to demonstrate that the requirements of § 418.100(f)(1), such as supervision and management by the hospice issued the certification number, are met by the hospice. The factors, which will be updated in sub-regulatory guidance [(Pub. 100–7, Chapter 2, section 2081)] for this final rule, include, but are not limited to, the following:

The hospice's ability to supervise the multiple location to assure the provision of quality care for the patients and families served by the multiple location;

The hospice's past compliance history;

Relevant state issues and recommendations, such as a reciprocal agreement between states to assure that at least one of the state agencies assumes responsibility for any necessary surveys of multiple locations in situations in which a hospice provides services across State lines, certificate of need requirements, State licensure requirements, etc.; and

The ability of the hospice to ensure that each patient receives care from an assigned IDG that effectively works together to identify and meet the needs of the hospice patient and family.

Once a hospice has received approval from Medicare and the State (where applicable) to operate multiple locations, § 418.100(f)(2) requires that supervision and management of the multiple locations must continually ensure that services delivered through the multiple locations are delivered in a safe and effective manner, and that the care of each patient and family is provided in accordance with the plan of care. All care and services provided by multiple locations must be in accordance with all hospice conditions of participation at all times. Deficiencies

identified at any multiple location will apply to all locations operating under the CMS-issued certification number.

Comment: A few commenters suggested that existing multiple locations should not be required to have individual Medicare approval. Other commenters suggested that multiple locations, whether existing or new, should not be required to have Medicare approval.

Response: Hospices have been required through a CMS policy memorandum from the Director of the Office of Chronic Care and Insurance Policy and the Deputy Director for Survey and Certification to all Regional Administrators on the subject of the Hospice Conditions of Participation (June 27, 1997) to obtain Medicare approval for multiple locations since 1997. Thus, there is no need to exclude existing multiple locations from obtaining Medicare approval because they should have already received such approval. Furthermore, we believe that Medicare approval is essential for ensuring that hospice services furnished from multiple locations are in accordance with all Medicare conditions of participation and that hospice services meet the needs of the patients and families being served.

Comment: Some commenters suggested that we should require hospices to orient each hospice employee to specific job duties that the employee is expected to perform and to the fundamentals of hospice philosophy.

Response: We agree that employees and contracted staff furnishing patient care should be oriented in hospice philosophy, and this requirement has been added to 418.100(g)(1). We do not believe that it is necessary for employees and staff that do not have patient contact to be knowledgeable in hospice philosophy, and requiring them to be oriented as such would be an unwise use of hospice resources. We also agree that hospice employees should be oriented to their specific job duties, and this requirement has been added to § 418.100(g)(2). If hospice employees provide hospice care to patients who reside in regulated facilities (for example, a nursing facility), we believe that it would be beneficial to educate hospice employees regarding the regulatory requirements that the facility and its staff are required to meet. Such education may help improve hospice-facility understanding and cooperation to ensure consistent, high quality care for hospice patients residing in facilities.

Comment: A commenter requested that we add a provision to this standard stating that board-certified chaplains who furnish hospice care must maintain national standards of practice and serve as teachers to other disciplines on the topics of patient rights, advance directives, ethics, and cultural and spiritual needs.

Response: Hospices are permitted to use certified chaplains in the manner that best meets their needs. If a hospice chooses to use the services of certified chaplains, then we would expect the chaplains to maintain national standards of practice just as all other disciplines are expected to do.

16. Condition of Participation: Medical Director (§ 418.102)

We proposed to revise the existing medical director requirements at § 418.54 in several ways. First, we proposed that the medical director could provide services under contract to the hospice. This proposal would have prohibited general contracts with agencies or organizations for medical director services, and reflected existing CMS policy, as permitted by section 4445 of the BBA 1997. Second, we proposed that another physician would be identified by the medical director to assume the role of the medical director in the medical director's absence. We believe that having another physician prepared to assume the medical director role would ensure continuity of care for the hospice's patients, even when the regular medical director was unavailable.

Third, in standard (a) and (b), we proposed to add further guidance on the factors that would need to be considered when certifying and recertifying the terminal illness. We believe that these factors, such as related diagnoses, current medication and treatment orders, and the patient's desire to continue hospice care, are already routinely considered by most medical directors when certifying and recertifying the terminal illness. Fourth, we proposed to further define the role of the medical director. We proposed that the medical director coordinate with other physicians and health care professionals to ensure that patients receive care that is consistent with hospice policy. Additionally, we proposed that the medical director, in tandem with the IDG, be responsible for patient medical care in its entirety. Finally, we proposed that the medical director be responsible for directing the hospice's QAPI program. We believed that these medical director responsibilities would ensure that the medical director was an active leader and participant in all aspects of the hospice's operations and services. We believe active participation would lead to better quality care and patient outcomes.

Comment: While several commenters expressed general support for our proposed medical director requirements, calling them ''appropriate'' and ''much needed,'' many commenters expressed concern that the medical director's role appeared to supersede the role of the IDG. Specifically, commenters stated that the proposed requirement at § 418.102 that, ''[t]he medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy'' seemed to elevate the medical director above the other members of the IDG. In addition, the commenters stated that making the medical director and physician designee responsible for this coordination would be burdensome for volunteer medical directors. Some commenters also stated that a patient's hospice care should reflect the hospice philosophy rather than hospice policy.

Response: Our intent in this proposed standard was to ensure that medical directors are actively involved in patient care. However, after considering commenter concerns, we agree that this level of involvement is not always necessary. Some larger hospices have several physicians who may serve on IDGs, and it is the physician member of the IDG, whether he or she is the medical director or not, who shares the responsibility with the rest of the IDG for communicating with other physicians and health care providers and for ensuring that the care furnished by the hospice reflects hospice policy. Since the medical director may not be the physician member of the IDG, we agree that this requirement should be removed. Hospices will still be required to have a communication system in place to ensure the ongoing sharing of information, both between all disciplines providing care and services in all settings, and with other non-hospice health care providers furnishing services to the patient in accordance with final § 418.56(e). In addition, hospices will still be required to develop and implement an individualized plan of care for each patient that addresses the patient's and family's hospice care needs and goals in accordance with § 418.56(c). The individualized plan of care and the services furnished to execute the plan should be in accordance with hospice policies, which should, in turn, reflect the individual hospice's philosophy of care.

Comment: A few commenters wanted to know if a medical director could be a volunteer.

Response: Medical directors may be volunteers, and we did not intend to imply otherwise. We believe that this question arose from the phrasing in the proposed rule that was used to describe the employment status of the medical director. In § 418.102 of the proposed rule, we stated that the medical director could be ''employed by, or [be] under contract with,'' the hospice. Additionally, in § 418.3 we define the term ''employee'' to include volunteers. Since the proposed phrasing did not explicitly use the term ''employee'', we believe that commenters were confused about our intent. We have clarified in this final rule that the medical director may be an ''employee'' of the hospice, which includes volunteers.

Comment: Many commenters suggested that the hospice, rather than the medical director, should be responsible for identifying the physician designee who fulfills the role of the medical director in the medical director's absence. A few commenters suggested that hospices should be allowed to contract with physician groups, without designating a specific physician, for medical director services, while still other commenters suggested that hospices should not be required to have physician designees at all.

Response: We agree that the hospice is better suited than the medical director exclusively to choose the physician designee, and we have incorporated this suggestion in § 418.102. We are requiring hospices to employ or contract with physician designees because, in many hospices, the medical director may be the only physician employee or contractor in the entire hospice. It is essential that another physician be available to assume the medical director's role when the medical director is absent to ensure continuous quality care for the hospice's patients. Likewise, it is essential that there be a specific individual identified to be the physician designee. Allowing numerous physicians to fulfill the medical director role would likely result in inconsistent care and decreased accountability.

Comment: Numerous commenters requested that hospices be allowed to contract with physicians employed by a professional entity or a physicians'' group. The commenters explained that, for tax and paperwork purposes, it is often easier for the hospice and the physician to arrange the contract for a particular physician's medical director services through the physician's practice or professional organization. In such a case, a specific physician would fulfill the medical director position at the hospice, but the hospice's contract for that particular physician's services would be with the physicians'' group or professional organization.

Response: Our intent in this standard is to ensure that there is a specific physician who fulfills and is held accountable for the medical director's responsibilities. We agree that there may be times when it is beneficial for hospices and physicians to handle contracts through established entities, rather than through direct individual contracts. For this reason, we have added a new standard at § 418.102(a), ''Medical director contract,'' which permits hospices to contract with a self-employed physician or a physician employed by a professional entity or physicians'' group. The new standard at § 418.102(a) establishes that, when contracting for medical director services, the contract must specify the name of the physician who assumes the responsibilities and obligations of the medical director.

Comment: A commenter suggested that we should add attending physicians to proposed § 418.102(a), which requires the medical director or physician designee to review clinical information for each patient and provide written certification of the patient's terminal illness.

Response: The attending physician is a participant in the certification process pursuant to § 418.22(c)(1)(ii). Although regulating the actions of the attending physician is not within the scope to this rule, we agree that attending physicians should consider the same clinical information as the medical director or physician designee to help ensure that all physicians make certification decisions based on the same information.

Comment: Many commenters sought clarification on our proposal at § 418.102(a) that the medical director must consider certain factors when initially certifying that it is anticipated that a patient's life expectancy is 6 months or less if the illness runs its normal course.

Response: We proposed that the medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness. In the proposed rule, we called these areas ''criteria'', and we believe that this term may have been the source of commenter concern. Our intent was to ensure that medical directors carefully examine all relevant information that is gathered about the patient before making this determination in accordance with the requirements for establishing eligibility for the Medicare hospice benefit found at 418.22 and 418.25. The interdisciplinary group may consider the information gathered during the certification in and developing the patient specific plan of care. We have removed the term ''criteria'' in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness.

We believe the requirements in this final rule compliment and encompass the existing Medicare hospice certification requirements and may enhance the health and safety of patients by ensuring that hospices have all relevant information about a patient in the patient's record.

Comment: Several commenters suggested that the IDG as a whole, rather than the medical director or physician designee individually as we proposed, be responsible for reviewing the patient's clinical information in preparation for recertifying the terminal illness. One commenter wanted to know if a review of the patient's clinical information would include a review of the plan of care.

Response: Certifying and recertifying the terminal illness is the function of the medical director or physician member of the IDG, and the patient's attending physician, if any, (in accordance with § 418.22(c)), not the entire IDG. The contributions of the other members of the IDG should be considered when making the recertification decision. Section 418.102(c) of the final rule requires that the patient's clinical information be reviewed before recertification. During this review the physicians would consider all of the patient's clinical information from all disciplines providing services to the patient. The review would, by definition, include the patient's plan of care since we would deem the plan of care to be ''clinical information.'' The plan of care is required to be updated at least every 15 days, and the 90- and 30-day benefit periods that require recertification would coincide with the plan of care updates. We believe that this review will allow the collection of the necessary information from which to make a determination.

Comment: Many commenters asked for clarification of the proposed requirement at § 418.102(b)(2) that provides for review of the patient's and family's expectations and wishes for the continuation of hospice care. Some

commenters suggested that the review should focus on the patient's or representative's expectations and wishes, rather than the family's. Others suggested that a review of the patient's goals would be more appropriate. Some of these commenters contended that, because hospice is an elected benefit and patients are free to revoke their election at any time, this requirement is unnecessary. In addition, commenters expressed concern that reviewing the patient's and family's desire for hospice care may appear to patients and families as though they are being pressured to change their minds about hospice care.

Response: We agree that the proposed requirement is not necessary because patients may choose to leave hospice at any time. Therefore, we are not finalizing this requirement.

Comment: Numerous commenters expressed concern regarding the proposed requirement at § 418.102(c) that the medical director or physician designee and the other members of the IDG have joint responsibility for coordinating the patient's medical care in its entirety. Some of the commenters believed that the proposed standard unnecessarily separated the medical director or physician designee from the rest of the IDG, thereby downplaying the interdisciplinary nature of hospice care. Other commenters believed that the hospice should only be responsible for coordinating the patient's hospice care, because other care being furnished to a hospice patient for unrelated conditions is not within the hospice's control. Still other commenters believe that the patient's attending physician (if any) or the physician of the long term care facility where the patient resides (if applicable) would be the appropriate provider to coordinate the patient's medical care in its entirety.

Response: We agree that it is inappropriate to create an environment which separates the medical director or physician designee from the IDG. We expect that all members of the IDG, including the physician, will actively work together to ensure that a patient's care is coordinated. We believe that this IDG approach to care is already reflected in final § 418.56. Section 418.56(e) of this final rule requires hospices to have a communication system that allows for the sharing of information with health care providers who are furnishing care to hospice patients for unrelated conditions. In addition, § 418.56(a)(1) of this final rule requires hospices to designate a registered nurse who is a member of the IDG to coordinate implementation of the plan of care, which is required to address all of a patient's hospice needs. Since these provisions adequately ensure that each patient's hospice care is coordinated both within the hospice and with other health care providers, we have removed the language in question.

Comment: The majority of commenters expressed support for involving medical directors in a hospice's quality assessment and performance improvement program, but expressed concern about holding medical directors responsible for directing the QAPI program. Commenters stated that medical directors may not be the individuals who are most qualified to direct QAPI programs. Commenters also stated that these medical director responsibilities would be burdensome, particularly for part-time and volunteer medical directors. Some commenters suggested that the IDG designated as being responsible for establishing a hospice's day-to-day policies should have the responsibility for directing the QAPI program, while others suggested that the governing body or a professional advisory committee should have this responsibility.

Response: We agree that the medical director may not be the individual who is most qualified to direct a hospice's QAPI program; therefore, we have removed this requirement. As licensed professionals, § 418.62(c) requires medical directors to actively participate in a hospice's QAPI program. We believe that this requirement is sufficient to ensure that QAPI programs benefit from the expertise of medical directors. We considered commenter suggestions for reassigning responsibility for directing the QAPI program. The final rule at § 418.58(e)(3) requires the governing body to designate individuals to be responsible for directing the hospice's QAPI program.

Comment: A commenter suggested maintaining the existing requirement at § 418.54 that the medical director must be a hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

Response: We do not believe that the medical director requirement in the current regulation is sufficient, because it does not address the issues of contracting for medical director services, physician designees, or the role of the medical director in certifying and recertifying terminal illness status. These are important areas to address, as they impact a hospice's ability to obtain medical director services as well as patient care and patient eligibility. At the same time, we agree that it continues to be appropriate to require the hospice medical director to assume overall responsibility for the medical component of the hospice's patient care program. We have incorporated this requirement into the final rule at new § 418.102(d).

Comment: A commenter suggested that we should incorporate the definition of the term ''medical director'' from the American Academy of Hospice and Palliative Care into the final rule.

Response: No publication or policy of the American Academy of Hospice and Palliative Care defines the term ''medical director''; therefore, we cannot incorporate this suggestion into the final rule.

Comment: One commenter stated that the ''Medical director'' condition of participation should be deleted because the requirements can be incorporated into the physician services requirement at § 418.64(a).

Response: The hospice medical director's role is above and beyond that of general physician services because, in addition to furnishing physician services and being a member of the IDG, the medical director also is responsible for providing overall medical leadership in the hospice. We believe that this additional level of responsibility, coupled with the medical director's supervisory role of other hospice physicians, warrants a separate condition of participation.

Comment: Some commenters suggested that we should require hospice medical directors to have additional education, experience, and/or training in palliative and end-of-life care.

Response: We agree that hospices should choose a medical director with an appropriate set of knowledge and skills to meet the needs of patients and the hospice. We do not believe that a single set of personnel requirements for medical directors would achieve this goal. Hospices need the flexibility to determine the qualifications of the medical director based on the role of the medical director in that particular hospice. That is, a medical director who is the only physician in the hospice, and who is thus expected to provide direct patient care to each patient needs a very different set of skills and knowledge than the medical director of a large hospice whose job it is to manage numerous hospice physicians and perform various other administrative-type tasks.

17. Condition of Participation: Clinical Records (§ 418.104)

The proposed condition of participation, ''Clinical records,'' would

incorporate several of the existing requirements in § 418.74 of the current regulation, ''Central clinical records'' (for example, that clinical records contain past and current findings, be maintained for each patient who is admitted by the hospice, be protected from loss or unauthorized use, and be readily accessible). We proposed to add a new requirement that the clinical record contain accurate clinical information that would be available to the physician and hospice staff.

At § 418.104(a), ''Content,'' we proposed to retain the requirement that the clinical record include all assessments (including the initial assessment and all updated assessments), plans of care, consent and election forms, and clinical and progress notes. We proposed the following additional requirements for the content of the clinical record—

- Advance directive information as described in proposed § 418.52(a)(3);
- Authorization forms;
- Responses to medications, symptom management, treatments and services;
- Patient process and outcome measures as they relate to the plan of care; and
- Physician certification of terminal illness as required in § 418.22(c) and described in proposed § 418.102(a) and (b) (now (b) and (c) in the final rule).

We proposed to add a new standard at § 418.104(b), ''Authentication,'' to require authentication of clinical records. This proposed standard was similar to a requirement in the conditions of participation for hospitals. We proposed that all entries be legible, clear, complete, and appropriately authenticated and dated. Authentication would include verification of handwritten and/or electronic signatures by signature logs or a computer secure entry of a unique identifier for a primary author who has reviewed and approved the entry. This new standard would address technological changes in information management, such as the computerization of records and electronic signatures.

Under § 418.104(d), ''Retention of records,'' we proposed to ensure protection of patient information by adding a new requirement that patient records be retained for five years after the death or discharge of the patient, unless State law stipulated a longer period of time.

Under § 418.104(e), ''Discharge or transfer of care,'' we proposed a new requirement that Medicare/Medicaid-approved hospice facilities forward a copy of the patient's clinical record and hospice discharge summary to the facility or provider to which the patient was being transferred. We believe that this would help to ensure that the information flow between the hospice and the transfer facility/provider would be smooth, and that appropriate care would continue without being compromised. Furthermore, we proposed that the hospice discharge summary would include information that accurately described the patient's stay; current plan of care; recent treatment, symptom, and pain management information; most recent physician orders; and any other documentation that would assist in post-discharge continuity of care.

Comment: One commenter requested that we clarify the term ''accurate'' as it pertained to the information contained in the clinical record.

Response: CMS expects that the hospice will ensure that information placed into the clinical record is correct and we have replaced the term ''accurate'' with the term ''correct'' to reflect this expectation. This would include providing correct information in appropriate sections of the clinical record in accordance with accepted hospice documentation policies.

Comment: One commenter suggested that updated plans of care as well as assessments should be included in the clinical record requirement because updated plans of care are better to use than progress notes.

Response: We agree with the commenter's suggestion and have amended the language at § 418.104(a)(1) to indicate that the patient's clinical record must include, ''the initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.''

Comment: Several commenters asked CMS to clarify what is meant by the term ''authorization'' in proposed 418.104(a)(2). Another commenter asked that we amend the language to read ''election statement, which is required to include consent to start hospice services as well as patient rights.''

Response: We agree that the word ''authorization'' was confusing in this context. We also agree that ''election statement'' should be added to this section. Therefore we have removed ''authorization'' and have added ''election statement'' to the regulatory text. The election statement must be completed in accordance with the requirements of § 418.24, which is not a part of these conditions of participation. The new § 418.104(a)(2) now requires the patient's clinical record to include signed copies of the notice of patient rights and election statement.

Comment: The majority of commenters believed that proposed § 418.104(b) was too broad and held hospices to a higher standard than home health agencies. They recommended that we consider using the language in the home health CoPs regarding authentication issues. Another commenter recommended that we mirror the home health requirements by not having a signature requirement. The commenter stated that making a home health agency and a hospice conform to the same requirements would offer entities that have both a hospice and a home health agency an administrative advantage. For example clinical record software could be utilized by both entities. One commenter believed that the proposed language looked too much like the hospital conditions of participation. The majority of commenters strongly recommended that this section be excluded from the hospice conditions of participation.

Response: We do not believe it is the best interest of the hospice to exclude this requirement, nor do we believe the clinical record requirement of the home health agency conditions of participation meets the needs of hospices. We agree that the proposed language could be difficult for the hospice to comply with; therefore we have amended the language to allow greater flexibility. We believe that a hospice should have the authority to create its own policy on authentication of clinical records. We have modified the proposed rule to reflect this change. Hospices will follow State laws regarding authentication of clinical records, and, within this context, alter their policies as often as necessary to adapt to changing technologies and practices.

Comment: One commenter asked if a unique user name and password that would allow access to, and creation of, an electronic health record would constitute authentication. One commenter stated that electronic medical records already have multiple protections in place, such as frequently changed passwords, making the proposed signature requirement duplicative and unnecessary. Some commenters stated that hospices have no mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by the registered nurse. Another commenter suggested that we require authentication of documents, not signatures. One commenter asked if authentication requirements apply to consulting physicians and covering physicians. Another asked whether they would be required to maintain a sample

signature on file as proof of the legitimacy of an authentication. An additional commenter suggested that hospices should only be required to authenticate handwritten and electronic signatures made by hospice employees.

Response: It will be up to the individual hospice to decide how it will handle authentication of entries made by employees, contracted staff, attending physicians, and any other individuals who input information in a patient's clinical record. Hospices must first decide on who is permitted to enter information into a clinical record. If the hospice is using electronic medical records, electronic authentication must have a user ID and frequently changed passwords. Every entry, both written and electronic must be signed and dated. Hospices must continue to comply with any applicable State laws regarding record authentication.

Comment: Many commenters asked what we meant by ''primary author'' in proposed 418.104(b). Commenters asked whether faxed signatures would meet the authentication requirement, and who (if anyone) would be required to authenticate a faxed signature. Commenters also asked if we were requiring hospices to be held accountable for signature logs for attending physicians not employed by the hospice, or whether we were requiring a signature log for everyone. Finally, they asked whether this standard would apply to contracted entities.

Response: ''Primary author,'' a term that has been removed from this final rule, referred to the person who wrote the entry. For information that is transcribed, we would require both the physician's and transcriber's signatures. Faxed signatures supporting orders and documentation, or care and services delivered would be acceptable, and we will provide sub-regulatory guidance to that effect. The hospice would need to make its own decision as to how it wanted to approach authentication; it will be up to the hospice to make decisions regarding signature logs.

Comment: Several commenters noted that there were differences between the hospice proposed record retention standard and Health Insurance Portability and Accountability Act (HIPAA) requirements as set out at 45 CFR 164.530(j)(2).

Response: We thank the commenters for pointing out the different timeframe requirements under HIPAA. It was an oversight by us. To ensure consistency between these two regulations, we have changed the language at § 418.104 (d) to read: ''Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time.''

Comment: Several commenters requested that we amend the discharge summary language by stating that we prefer the use of electronic methods for sending discharge summaries and/or clinical records when a patient is discharged.

Response: We believe that when electronic clinical records are available, sharing of discharge summaries and/or clinical record information through an electronic format would be acceptable if agreed upon by both the sender and the receiver. Electronic sharing of information may include access to a record through a secure internet access portal. We understand that many hospices may not have this capability. We are not mandating this as a requirement. Paper copies of the discharge summary and clinical record are acceptable.

Comment: One commenter requested that we amend the language at § 418.104(e) so that it does not apply to patients discharged as a result of their death.

Response: We have amended the regulatory text to indicate that a discharge summary is only necessary for patients discharged under § 418.26. We agree with the commenter that a discharge summary need not be completed for deceased patients; we do not deem a patient's death to be a discharge within the meaning of § 418.26.

Comment: Several commenters requested language changes under § 418.104(e); for example, commenters requested that ''Medicare/Medicaid approved'' be changed to ''Medicare/Medicaid certified''; that we add the phrase ''as requested'' to the end of proposed § 418.104(e)(3)(iv); and that we add the phrase ''patient's written consent'' to the same element. Others commented on the unnecessary requirement that both the clinical record and discharge summary be sent. Many commenters believed that the discharge summary contains enough information to maintain continuity of care, and believed that a copy of the clinical record should only be sent upon request of the receiving entity. One commenter questioned whether sending the discharge summary would violate the HIPAA ''minimum necessary'' standards.

Response: In response to these suggestions we have decided to amend the language under § 418.104(e). We have changed ''Medicare/Medicaid approved'' to ''Medicare/Medicaid certified,'' and have added the term ''if requested'' when forwarding the clinical record. Pursuant to the HHS privacy rule at 45 CFR 164.502(a)(1)(i), 164.502(b)(2), and 164.506 the ''minimum necessary'' standard does not apply to disclosures to or requests by a health care provider for treatment. The transfer of patient information is permitted when the patient transfers from one provider to another.

In the reorganization of § 418.104(e) we believe we captured the commenters' concerns in the area of discharge summary. We recognize that the discharge summary and clinical record are very important, and have amended the language to specify that the discharge summary will be sent automatically, but that a copy of the patient's entire clinical record will only be sent if requested. When patients transition from a hospice to another provider, it is important for hospices to establish communication channels with receiving providers. The communication channels give hospices to opportunity to receive feedback from receiving providers regarding the adequacy and appropriateness of the hospice's discharge process. This feedback, which can be incorporated into a hospice's QAPI program, gives hospices the opportunity to improve patient transitions to ensure that patients receive safe and effective care at all times during the transfer process.

Comment: A commenter asked us to elaborate on the proposed requirement at § 418.104(f), ''Retrieval of clinical records.''

Response: Clinical records, either in electronic or hard copy form, must be made available to the appropriate requestor, such as the State survey agency or and accrediting body, within a reasonable amount of time. Access needs to be granted to any and all patient related documentation that the hospice maintains. If the hospice maintains electronic clinical records, equipment must be available to allow access to the clinical record information.

Comment: Many commenters responded to our request for information and input on the use of electronic health records. The overwhelming consensus at this time was that electronic health records (EHR) would be burdensome and cost prohibitive, especially for smaller hospices. A few commenters stated that financial assistance may be necessary to achieve EHR standards, and one commenter suggested that at the very least, EHR standards would need to be phased in.

Response: Given the potential financial constraints, we are not amending the final rule to mandate

EHRs. Hospices may use EHRs if they choose, and would need to ensure trouble-free record retrieval.

Comment: A few commenters requested that Federal regulations as a whole need to address the development of EHRs that can be accessed and used in multiple care sites, including the patient's home. One commenter included the specific pieces of information that should be in the EHR. Some commenters commented on the advantages of the EHR, such as: improved coordination of care, increased communication, increased accuracy, accessibility from any computer, easy portability and legibility, with documentation available to others much more rapidly.

Response: We acknowledge and appreciate the comments. The overall goal of the EHR is to achieve and improve collaborative practice among all care providers and to ensure continuity of care as patients move across the care continuum.

Promoting the use of health information technology (HIT) is a major health initiative of the President and the Secretary of the Department of Health and Human Services (HHS). The President has made implementation of interoperable HIT a national priority and has expressed a goal that most Americans have an electronic health record (EHR) by 2014. While this rule does not require hospice providers to use specific health information technology solutions, including EHRs, we encourage hospice providers to become knowledgeable about ongoing HHS activities and actively participate in efforts to develop and implement cost-effective HIT. For example, one activity recently undertaken by the Secretary has been the formation of the American Health Information Community (AHIC), a public-private sector federal advisory body charged with providing advice on accelerating the adoption of interoperable EHRs. In another effort, the Health Information Technology Standards Panel (HITSP) has identified widely accepted, consensus-based HIT standards to enable and support the development and use of interoperable HIT products in several healthcare domains. While HITSP did not focus on the quality measures that are typically important to hospice providers, several of the identified standards could be used to support the development of interoperable quality measurement and reporting HIT products needed by hospice providers.

Comment: Some commenters noted the disadvantages of EHRs. For example, software requirements to meet regulatory requirements and quality initiatives have not been finalized, EHRs may be less flexible that paper records, EHRs can be time consuming to computer challenged staff, and EHR systems may be more prone to failures. Commenters believed that one of the biggest barriers to the EHR was the potential to allow personal health records to automatically be left available to the patient/caregiver. The commenters stated that clear safeguards need to be in place to ensure the security and appropriate use of personal health records in the home. A commenter believed that caregivers might be less likely to record certain procedures or observations because of open access in the EHR.

Response: We acknowledge the disadvantages the commenters listed. Because of these and other issues, we are not abandoning the traditional clinical record keeping process in favor of the EHR at this time.

18. Condition of Participation: Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106)

This proposed condition of participation would revise the current general requirement, found at § 418.96, that durable medical equipment, supplies, appliances, and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

Section 418.106(a)(1), ''Administration of drugs and biologicals,'' would have required that all drugs and biologicals be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient's plan of care. In § 418.106(a)(2) we proposed to add a new requirement that the IDG be responsible for reviewing the plan of care to determine whether the patient and/or family has and continues to have the ability to safely administer drugs and biologicals.

In § 418.106(b), we proposed that the hospice would have a written policy for tracking, collecting and disposing of controlled drugs that are maintained in a patient's home. We proposed that this policy would be discussed with patients and their families during the initial assessment to ensure that patients and families were educated about the uses and potential dangers of controlled drugs. We believe that the hospice's policy, coupled with patient and family education, would result in shared responsibility for these beneficial, but potentially dangerous, drugs.

Standard 418.106(c) proposed that hospices assume responsibility for the use and maintenance of durable medical equipment and supplies. This standard proposed that hospices, either directly or under contract, would be responsible for ensuring the maintenance and repair of durable medical equipment in a manner that conformed to manufacturer recommendations. If no manufacturer recommendations existed for a piece of equipment, then repair and routine maintenance policies and procedures would have to be established. This standard also proposed that the hospice ensure that the patient, family, and all other caregivers receive instruction in the safe use of equipment and supplies. Likewise, the hospice would have to ensure that the patient, family, and other caregivers could demonstrate the safe use of such equipment and supplies to the satisfaction of hospice staff. We believe that proper maintenance and education are essential to ensuring the patients benefit from fully functional equipment and supplies that they are able to use in a safe and effective manner.

Comment: A commenter asked us to define the term ''controlled drugs.''

Response: In this regulation we intend controlled drugs to mean those substances identified under schedules II, III, IV, and V of the Federal Controlled Substances Act (Pub. L. 91–513) and FDA regulations (see 21 CFR part 290) issued thereunder.

Comment: A few commenters suggested that we should require hospices to use pharmacists to participate in the drug review. Other commenters suggested that we should require a pharmacist as a member of the IDG to help identify and prevent drug-related complications such as duplication, improper dosing, and drug interactions. Still other commenters suggested that the requirements for pharmacist and pharmaceutical services at proposed § 418.110(m) and § 418.110(n) should apply to the entire hospice, rather than only to the hospice inpatient facility. The commenters stated that, since drugs are prescribed to virtually all hospice patients, these patients should benefit from the expertise of a pharmacist and the additional level of drug oversight required by these regulatory standards. One commenter suggested that we should retain the existing requirements for drugs found at § 418.96(b), which requires the hospice to have a policy for the disposal of controlled drugs maintained in the patient's home when

those drugs are no longer needed by the patient.

Response: Many hospices, particularly those with hospice inpatient facilities, have already realized the benefits of actively involving pharmacists in patient care planning. Hospices are seeking to use drugs more effectively and efficiently to improve patient outcomes and reduce costs. In the last years of life, patients typically use five drugs or more at any one time, increasing the risk of duplicative drug therapy, drug interactions, or drug side effects, as well as the risk of dispensing or dosing errors. (Steinman, M., Landefeld, C.S., Rosenthal, G., Berthenthal, D., Sen, S., *et al.*, ''Polypharmacy and prescribing quality in older people,'' Journal of the American Geriatrics Society, 2006; Koh, N.Y., Koo, W.H., ''Polypharmacy in palliative care: Can it be reduced,'' Singapore Medical Journal, 2002; Meredith, S., Feldman, P., Frey, D., Hall, K., Arnold, K., *et al.*, ''Possible medication errors in home healthcare patients,'' Journal of the American Geriatrics Society, 2001; Twycross, R., Bergl, S., John, S., and Lewis, K., ''Monitoring drug use in palliative care,'' Palliative Medicine, 1994.) The need for the use of drugs in caring for hospice patients, coupled with the risk of negative patient outcomes, warrants an additional focus on drug management for all hospice patients, regardless or whether they receive care in their place of residence or in an inpatient facility. Therefore, we have moved and modified the requirements of proposed § 418.110(m) and § 418.110(n) to § 418.106 and have reorganized the requirements in standards (a) through (e).

In new standard (a), ''Managing drugs and biologicals,'' we combined some of the requirements of proposed § 418.110(m) and § 418.110(n), such as the proposed requirement that a qualified licensed pharmacist direct the inpatient hospice's pharmaceutical services, including evaluation of a patient's response to drug therapy, and identification of adverse drug reactions. New standard (a) requires the hospice to ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

Hospices may choose to use a licensed pharmacist, an individual who has an extensive and up-to-date knowledge of drugs, to fulfill this role. Approximately 1,600 hospices already contract with pharmacy benefit management companies to provide drugs and pharmacist services to each of their patients. Hospices may also choose to use other individuals with specialized education and training in drug management, including evaluating the effectiveness of drug therapies, identifying drug side effects, identifying actual or potential drug interactions, identifying redundant drugs, and taking appropriate corrective actions. All hospices must be able to demonstrate an individual's knowledge, skills, and abilities in managing the use of drugs in accordance with accepted standards of practice and all applicable State and local requirements, including State licensure requirements.

Standard (a)(2) also incorporates the proposed requirements of § 418.110(m) and § 418.110(n) that a pharmacist must oversee an inpatient hospice's pharmacy program. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action. New standard (b), ''Ordering of drugs,'' relocates the requirements of proposed § 418.110(n)(1). This new standard indicates who may order drugs for a hospice patient and how verbal or electronic drug orders should be documented. New standard (c), ''Dispensing of drugs and biologicals,'' combines some of the requirements of proposed § 418.110(m), with proposed § 418.110(n)(4)(ii). This new standard requires a hospice to have a written policy that promotes dispensing accuracy, to maintain current and accurate records of the receipt and disposition of all controlled drugs, and to obtain drugs and biologicals from community or institutional pharmacists or from its own stock. New standard (d), ''Administration of drugs and biologicals,'' combines the requirements of proposed § 418.106(a)(2) and § 418.110(n)(2). The new standard addresses drug administration in both the home and hospice inpatient facility environments to ensure that drugs and biologicals are administered to a patient by an individual who is competent to do so, regardless of the patient's current environment.

New standard (e), ''Labeling, disposing, and storing of drugs and biologicals,'' combines and revises the requirements of proposed § 418.106(b) and § 418.110(n)(3), (n)(4)(i), (n)(4)(iii), and (n)(5). This new standard ensures that drugs are safely labeled, stored, and disposed of in accordance with accepted standards of practice and applicable Federal and State laws and regulations. It also ensures that patients and families are properly educated about drug disposal.

We understand that the revised drug requirements may have some financial impact on hospices. However the cost saving achieved through a more efficient and effective use of drugs in the hospice, as well as improved patient outcomes and satisfaction, will, we believe, offset a portion of this financial impact. Additionally, we believe that the new standards (for example, development of hospice-wide policies and procedures, patient and family education) will help hospices create partnerships with patients and families to ensure that controlled drugs are used and disposed of in a safe manner.

Comment: Numerous commenters suggested that we should address the issue of hospice patients bringing their own drugs from their homes into a hospice inpatient facility.

Response: This rule does not prohibit patients from bringing their own drugs into a hospice inpatient facility. If patients do so, the transportation and use of these drugs must be in accordance with any applicable Federal, State, and local laws and regulations, as well as with the hospice's own policies and procedures.

Comment: A commenter suggested that we should delete the requirement that drugs and biologicals must be obtained from a community or institutional pharmacist or stocked by the hospice.

Response: We assume that the commenter seeks to obtain drugs and biologicals from sources outside of the United States. Due to concerns about the safety of drugs and biologicals obtained from sources that are outside of the purview of the Food and Drug Administration, we believe it it necessary to continue to require hospices to obtain drugs and biologicals from a community or institutional pharmacist or from its own stocks.

Comment: A commenter requested that the following statement be added to proposed § 418.106(a) (now located at § 418.106(d)(1)):

''If the patient and/or family are determined to be unable to safely administer drugs and biologicals, the patient and family will be encouraged to relocate the patient to a setting where administration assistance can be routinely offered. However, it is recognized that the patient, if competent, and the patient's surrogate if the patient is not competent, can refuse to relocate. Given patient rights and the home setting, [the] hospice will be expected to provide reasonable

assistance. [The] hospice will not be expected to restrict the provision of medications unless there is a blatant safety issue for non-competent adults or children in the home.''

Response: If a patient and all family members are unable to safely administer drugs themselves, then it is incumbent upon the hospice to identify alternatives to ensure safe administration. Depending on the circumstances, alternatives may include friends and neighbors of the patient and family who are competent to administer medications with appropriate training from the hospice, the hospice's own paid employees and volunteers, paid caregivers, and, lastly, patient relocation. We do not believe that it is necessary to include the suggested language because the options mentioned above are already available to hospices. Furthermore, we do not believe that it is necessary to establish in this regulation criteria for restricting the placement of drugs in a patient's home. We believe that hospices should be able to assume the responsibility to determine when it is or is not appropriate to place drugs in a patient's home.

Comment: A few commenters suggested changes regarding who is permitted to administer medications to patients in a hospice inpatient facility. One commenter suggested that licensed practical nurses (LPN) and licensed vocational nurses (LVN) should be allowed to administer medications, while other commenters suggested that the patient's family or caregiver should be allowed to administer medications.

Response: In accordance with § 418.106(d)(2) of this final rule, licensed nurses are permitted to administer medications in accordance with their scope of practice. If an LPN's or LVN's scope of practice permits him or her to administer medications, then it is appropriate to allow them to administer medications in accordance with this rule. However, it is not appropriate to allow the family or primary care giver of a patient to administer medications in an inpatient facility. Patients enter hospice inpatient facilities for two primary reasons, respite and general inpatient care. If a patient is in an inpatient facility for respite care, it is because the family/care giver needs a temporary break from care giving duties. It would not be appropriate to expect the family/caregiver to administer medications to the patient in the inpatient facility. If a patient is in an inpatient facility for general inpatient care, it is because the patient is experiencing pain or symptoms which cannot be managed in the patient's home by the patient's caregivers in conjunction with the hospice staff, in which case it is not appropriate to expect the family/caregiver to handle the complex medication regimen the patient likely requires. This is the job of the hospice inpatient staff.

Comment: Numerous commenters expressed concern regarding our proposal in § 418.52(a)(3) that hospices inform patients and families about their drug policies before hospice care is furnished. Commenters believed that providing the drug policy information at that time would overwhelm patients and families with information that was not urgent. Some commenters suggested that a hospice should be required to provide information about its drug policy in the admission package of information that is left with the patient. The content of the admission package, including the drug policy, could be discussed with the patient and family at some time during the comprehensive assessment period. Other commenters suggested that hospices be required to discuss their drug policies when patients are prescribed drugs to which the hospice's policy applies. Other commenters requested clarification regarding the form of the drug policy notice, noting the difficulties involved in furnishing the notice in obscure or otherwise uncommon languages. As with the general notice of patient rights in § 418.52, many commenters requested that we explicitly allow the use of translators when providing the drug policy notice. Additionally, as with the general notice of patient rights, a few commenters requested that we clarify how hospices should document the fact that patients and families were informed of the hospice's drug policies.

Response: We agree that providing controlled drug policy information before the start of care may not be appropriate in all cases because not all patients are taking controlled drugs at the start of care. We also agree that providing such information may unnecessarily overwhelm patients and families. Therefore, we have replaced the proposed requirement at § 418.52(a)(3), with a requirement set out at § 418.106(e)(2) that, at the initial time that controlled drugs are ordered by the hospice for the patient's use at home, the hospice must provide a copy of its written policies and procedures on the management and disposal of controlled drugs to the patient or representative, and the family.

While we are requiring hospices to provide drug policy and procedure information to patients and families, we are not prescribing the manner in which they must document this information sharing. The drug policy and procedure information, unlike the notice of patient rights in § 418.52, is more of an educational effort. The hospice's drug policies and procedures will help patients learn how to safely use controlled substances and avoid negative outcomes. The drug policies and procedures will also help the hospice explain its own role in controlled drug management. We do not believe that it is necessary to dictate the method for educating patients and families about the hospice's drug policies and procedures, nor is it necessary to prescribe how hospices should document that patients and families have received such education. Hospices should decide for themselves, in their own policies and procedures, how staff will document the discussion of the hospice's drug policies and procedures. Obtaining a patient or family member signature would be appropriate, as would any number of other documentation methods.

As previously discussed in the notice of patient rights section, it is acceptable to use translators, either professional or family members, to ensure that patients and families fully understand the hospice's controlled drugs policies and procedures.

Comment: In § 418.106(b) we proposed that hospices have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. The majority of commenters who submitted comments on this CoP asked us to remove this requirement. The commenters were concerned that the tracking requirement would require hospice staff to conduct pill counts. They were also concerned that these proposed requirements would compel hospice employees to remove drugs from the patient's home, which employees are prohibited from doing because the drugs are the patient's property.

Response: While it was not our intent to imply that hospices would be required to conduct pill counts or remove drugs from patient homes, we understand that the terms ''tracking'', ''collecting'' and ''disposing'' implied precisely that. Therefore, we have removed these terms and replaced them with a requirement at new § 418.106(e)(2) that hospices have written policies and procedures for management and disposal of controlled drugs maintained in the patient's home. The intent of this revised requirement is to ensure that hospices have a clear picture of what drugs have been prescribed and delivered to the patient,

and are therefore present in the patient's home, at any time. Through the written policies and procedures, hospices will have a plan detailing how they can assist a family in safely disposing of controlled drugs after a patient's death.

Comment: The majority of commenters who submitted comments on this CoP asked us to replace the proposed requirement that hospices must discuss the potential dangers of controlled drugs with a requirement that hospices must discuss the ''safe use,'' ''appropriate use,'' or ''risks/benefits'' of controlled drugs.

Response: Our intent in the proposed standard was to ensure that hospices educate patients and families on how controlled drugs are used and the risks associated with abusing and/or improperly disposing of them. We agree that requiring hospices to discuss the ''safe use'' of controlled drugs accomplishes this intent without the negative connotations that may be associated with the language of the proposed rule. The safe disposal of controlled drugs should also be part of the patient and family education effort. Therefore, we revised § 418.106(e)(2)(B) to require that, when controlled drugs are first ordered for use in the patient's home, the hospice must, ''[d]iscuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs.''

Comment: A commenter suggested that we should require hospices to educate patients and families about drug policies in a language and manner that the patient and family understand.

Response: HHS guidance on Title VI, ''Guidance to Federal Financial Assistance Recipients Regarding Title VI, Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' August 8, 2003 (68 FR 47311), related to limited English proficiency persons, presents guidelines for developing and implementing communication strategies in a variety of settings, including hospice. Since hospices are already expected to meet these guidelines, we agree that it is appropriate to re-enforce the existing guidance by requiring the discussion of drug policies to occur in a language and manner that the patient and family understand.

Comment: A few commenters wanted to know where drug discrepancy investigation reports should be sent to. One of these commenters suggested that sending drug discrepancy investigation reports to State and Federal officials should be done only when required by law.

Response: We agree that such reports should only be sent to the appropriate agencies when required by a specific Federal or State law or regulation. These State specific laws and regulations may vary, and describe the appropriate reporting mechanism, timeframe, and recipient. We have added the phrase ''if required by law or regulation'' to the end of the reporting requirement, which is now located at § 418.106(e)(3)(ii).

Comment: A commenter asked us to clarify the relationship between the requirement that hospices must provide drugs for patients and the Medicare Part D benefit.

Response: Hospices are required by section 1861(dd)(1)(E) of the Act to furnish all drugs and supplies related to the terminal illness and related conditions. Hospices may not expect patients to obtain drugs related to the terminal illness and related conditions through the Medicare Part D benefit. If a patient requires drugs that are not related to the terminal illness and related conditions, then it may be possible for the patient to obtain those unrelated drugs through the Medicare Part D benefit.

Comment: A commenter suggested that hospices should note in the patient's clinical record any drugs that are prescribed for the patient that are not standard treatment for that patient's symptoms. The commenter further suggested that the patient's clinical record should include an explanation for such unconventional use.

Response: Hospices are free to determine the type, dose and administration methods for any drugs that they choose to prescribe. We would expect hospices to confer with an individual with education and training in drug management and use current practices to select the most appropriate drugs for a particular patient, and to be able to explain drug choices to those providing patient care, the patient or representative, the family, and any authorities having jurisdiction, as necessary. Hospices may find it appropriate to document those drugs that are prescribed for uncommon or unconventional reasons, and the rationale behind such decisions; however, we do not believe that it is necessary to require such additional documentation.

Comment: Numerous commenters stated that, when durable medical equipment (DME) is provided under contract, the contracted DME provider is responsible for DME maintenance. As such, the commenters stated that hospices should not be held responsible for DME maintenance when it is provided under contract.

Response: We understand that the majority of hospices contract with outside entities for DME equipment. We also understand that, as part of that contract, most hospices require the DME company to provide maintenance services. This is an acceptable arrangement. However, requiring a DME company to maintain the equipment that it provides does not absolve the hospice of its ultimate responsibility to ensure that all services provided on its behalf, whether by its employees or through a contract, are safe and effective. An improperly or inadequately maintained piece of DME is neither safe nor effective. Thus, it is the hospice's ultimate responsibility (as it is with respect to all of its contracted services) to ensure that maintenance is performed on DME equipment, regardless of the source of such equipment. A written statement from the DME supplier and signed by a person of authority stating that equipment has been serviced according to manufacturer recommendations or other comparable standards would be one way that the hospice could assure that the equipment is safe and performs as required. If a hospice does not ensure that such maintenance is performed, it is not in compliance with the requirement that it must maintain professional management responsibility for all services provided or this requirement at new § 418.106(f)(1).

At the same time, we understand that the proposed requirements should be clarified to ensure that hospices may provide DME maintenance services under contract. We have revised new § 418.106(f)(1) to state that hospices must ensure that manufacturer maintenance recommendations are followed. If there are no manufacturer recommendations, hospices must ensure that maintenance policies are developed. We believe that adding the term ''ensure'' will clarify that hospices must make sure that such maintenance is complete, but that hospices are not necessarily required to handle maintenance through their employees.

Comment: Numerous commenters stated that the contracted entity that supplies the DME is best suited to instruct the patient and family in the safe use of the DME provided.

Response: In the proposed rule at § 418.106(c)(2), we stated that hospices must ensure that patients and families receive DME instruction. Our intent was to allow hospices to provide such instruction through a contracted DME supplier. We agree that this intent

should be further clarified. We have added a provision to the final rule at § 418.106(f)(2) to clarify that, ''[t]he hospice may use persons under contract to ensure patient and family instruction.''

Comment: A few commenters asked for clarification about the role of the Medicare Supplier Standards and accreditation in contracting for DME services. Some of these commenters suggested that any DME supplier who furnished DME equipment as part of the Medicare hospice benefit be required to meet the Medicare Supplier Standards and be accredited by a national accrediting body. Another commenter suggested that by contracting with a DME supplier that met the Medicare Supplier Standards, hospices would have more assurance that the DME provider would safely and effectively perform its maintenance and instruction duties.

Response: We believe that Medicare beneficiaries should receive the same high quality DME service whether they receive such DME through Medicare Part B or through the Medicare hospice benefit. In order to ensure continuous DME service quality, we agree that hospices should contract with those DME suppliers who meet the Medicare Supplier Quality and Accreditation Standards. A provision to this effect has been added at new § 418.106(f)(3).

Comment: A commenter suggested that the National Safety Council should be involved in conducting site inspections of DME suppliers to determine compliance with the Medicare Supplier Standards.

Response: As part of the effort to ensure quality DME services for Medicare beneficiaries, the Medicare Supplier Quality and Accreditation Standards require DME suppliers to be accredited by national accrediting organizations. (See 42 CFR 424.58.) Accreditation requires regular surveys by CMS-approved accrediting bodies. The existing DME accreditation regulations, we believe, respond to the commenter's concern.

Other Issues

We are aware that the appearance of a conflict of interest or an actual conflict of interest could exist when a pharmacist or pharmacist service under contract to the hospice recommends one brand name drug over another, favors one drug in a therapeutic class over another, or recommends an increase in the utilization of a specific drug. For example, a conflict of interest exists when a pharmacist under contract to the hospice is employed by the pharmacy that supplies drugs to the hospice and that pharmacy accepts access/performance rebates or other price concessions designed to or likely to influence or impact utilization of drugs in the hospice. The term ''access/performance rebates'' refers to rebates manufacturers provide to pharmacies that are designed to prefer, protect, or maintain that manufacturer's product selection by the pharmacy or to increase the volume of that manufacturer's products that are dispensed by the pharmacy under its formulary (referred to as ''moving market share''). If a conflict of interest exists, it has the potential to compromise the judgment of the pharmacist which could affect the care of a patient. The hospice IDG retains responsibility for all patient care decisions independent of others, and it is inappropriate for a pharmacist or any other member or consultant of the IDG to drive patient care decisions based on financial or business incentives. It is incumbent upon a hospice to obtain assurance that a contracted pharmacist or pharmacist service is free of any potential or real conflicts of interest or financial incentives.

19. Condition of Participation: Short-Term Inpatient Care (§ 418.108)

Under § 418.108, we proposed to retain the requirement that hospices make inpatient care available for pain control, symptom management, and respite purposes, and that care be provided either in the hospice or in a participating Medicare or Medicaid facility. We proposed to recodify the current standard found at § 418.98(a), ''Inpatient care for symptom control,'' as § 418.108(a), ''Inpatient care for symptom management and pain control.'' We proposed to recodify the current standard found at § 418.98(b), ''Inpatient care for respite purpose'', as § 418.108(b), with the same title and only minor terminology changes.

We proposed to eliminate the existing requirement found at § 418.100(a)(2), requiring that a registered nurse provide direct patient care on each shift. In its place, we proposed that the patient's plan of care and the patient's condition should determine the amount and skill level of nursing care required, as well as the skill level and State licensing requirements of the staff required to provide requisite care.

Under proposed § 418.108(c), ''Inpatient care provided under arrangement,'' we proposed to incorporate the requirements of existing standard 418.56(e), ''Inpatient care.'' In particular, we proposed to require that, if a hospice chose to contract with another type of facility to provide inpatient care, the hospice would have to include in its contract a provision that it would train the personnel who would be providing hospice patient care in the inpatient facility (currently at § 418.56(e)(5)). We believe the training is necessary because the hospice palliative model of patient care is very different from the curative model of patient care in which medical personnel are routinely trained. We also proposed that, as part of the contract, a copy of the inpatient clinical record and discharge summary would have to be available to the hospice at the time of discharge from the inpatient facility.

Under proposed § 418.108(d), ''Inpatient care limitation,'' and § 418.108(e), ''Exemption from limitation,'' we proposed to re-codify the existing parallel requirements at § 418.98(c) and (d) respectively, without changes, because these requirements are derived directly from section 1861(dd) of the Act.

Comment: Many commenters believe that a reference to the psychosocial/family crisis situations should be added to the opening paragraph of the CoP as an additional reason to admit a patient to inpatient care. Adding psychosocial and family crisis situations would, according to the commenters, conform to the requirements of Chapter 9, section 40.1.5 of the Medicare benefit policy manual. Another commenter asked that we allow inpatient care to be used for acute caregiver breakdown. One commenter stated that the hospice should have the option of placing the patient in a general inpatient level of care for a short period of time while developing a more appropriate plan of care.

Response: We believe that caregiver and family status should be considered in the comprehensive assessment process. This allows families and hospices time to develop back-up plans for any family or caregiver breakdowns that may occur in the future. As this issue primarily relates to Medicare payment rules, we refer readers to the FY 2008 hospice wage index (72 FR 50214, August 31, 2007) for additional discussion of the appropriate use of the respite and general inpatient levels of care in situations where a caregiver breakdown has occurred.

Comments: One commenter requested that we change the language in proposed § 418.108(b)(2) from ''Medicare/Medicaid approved'' to ''Medicare/Medicaid participating.'' Two commenters requested that we use the phrase ''Medicare certified.''

Response: We have amended the language to read ''Medicare or Medicaid-certified.''

Comment: One commenter asked for clarification of whether or not a freestanding hospice inpatient facility operated by a Medicare-certified hospice would qualify as a participating Medicare or Medicaid facility.

Response: Yes, the facility would qualify if it met all applicable requirements of the hospice regulations at 42 CFR part 418.

Comment: One commenter stated that a hospice should not be able to send its own nursing staff to supplement contracted facility staff to meet inpatient care staffing requirements.

Response: We understand the commenter's view; however, this issue is related to a hospice's contractual agreement with its providers. A hospice must set up its own polices and guidelines, as well as its own written contract with an inpatient provider. We would not prohibit a hospice from sending in its own staff to care for the hospice patient, if it is permitted within the provisions of its contractual arrangement and the statutory and regulatory requirements applicable to the contracted inpatient provider.

Comment: One commenter requested that we allow up to four patients per room for inpatient respite purposes.

Response: We do not agree with the commenter. The level of care provided to the patient should not determine the level of patient and family privacy. Therefore, we believe that no more than two patients per room should be permitted.

Comment: Many commenters thanked us for proposing to remove the 24 hour nursing requirement for respite care. The commenters felt it was not always necessary to have an RN on duty 24 hours a day for respite care and that the proposed nurse staffing requirement allowed for greater staffing flexibility and improved coordination of care between hospices and nursing homes where respite care may be provided.

Response: We agree that it is not automatically necessary to have a registered nurse on every shift to provide direct patient care if the only hospice patients in a facility are receiving the respite level of care. We believe that respite care is meant to give the family time to rest and re-energize before the patient returns to the home. The care needs of a respite patient are equivalent to those of the patient in his or her home and therefore may not necessitate registered nursing care on a 24-hour basis. Rather, staffing for a facility solely providing the respite level of care to hospice patients should be based on each patient's care needs. The requirements for nursing services for respite care are now at § 418.108(b)(2).

Comment: A few commenters requested that that we define nursing services in inpatient facilities as care provided by an RN or LPN.

Response: Because Congress was not specific about what level of nursing services were required, we believe that the intent of section 1861(dd) of the Act has always been for hospices to furnish nursing services from a variety of different categories of nurses, ranging from nurse practitioners to licensed vocational nurses to registered nurses. Since hospices have not, to our knowledge, had any difficulty in determining what constitutes nursing services, we see no reason to establish a definition for the term at this time.

Comment: One commenter stated that the respite level of care should be able to be provided in any facility that meets the general nursing requirements that apply to all hospice care; that is, that the nursing services provided must meet patient needs without CMS issuing specific regulations prescribing the exact level of nursing services that must be available at all times (such as 24-hour RN services). A few commenters requested that assisted living facilities and licensed group homes providing 24-hour care (but not necessarily nursing care) that meet the needs of the patient should be authorized for inpatient respite purposes.

Response: To meet each patient's nursing needs the facility would need to be a Medicare/Medicaid certified nursing facility, a Medicare-certified hospice or a Medicare-certified hospital or skilled nursing facility because these facilities already maintain the requisite staff to meet hospice patient's needs at the respite level of care.

While we understand that care of the respite patient is much different than care of the general inpatient, we do not have regulatory authority over assisted living facilities or group homes. Therefore, to maintain continuity and safe care of the respite patient, we require that all respite care be provided in Medicare or Medicaid certified inpatient facilities. This in no way prohibits a hospice patient from residing in an assisted living facility or licensed group home.

Comment: One commenter requested that we add language that states that general inpatient care and respite care are coordinated by the hospice in a Medicare or Medicaid facility.

Response: We agree with the commenter in that care of the general inpatient and respite patient must be coordinated by the hospice. The standard at § 418.108(c), ''Inpatient care provided under arrangements'' has been modified to read: ''If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement, coordinated by the hospice * * *.''

Comment: A few commenters suggested that the inpatient clinical record should be provided by the inpatient facility only if requested by the hospice, and that a discharge summary would be routinely provided to the hospice at the time of discharge.

Response: We agree with the commenters, and the amended language at § 418.108(c)(3) requires the written agreement to specify, ''[t]hat the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge.''

Comment: One commenter requested that we replace the word ''individual'' with ''position'' in proposed § 418.108(c)(4). This would have the effect of permitting more than individual holding that position to implement the provisions of the agreement.

Response: Identifying a single individual, rather than a position that may be shared by more than one individual, in the inpatient facility that is responsible for implementing the contract, ensures that accountability is clearly assigned. Therefore, we are not accepting the commenter's suggestion and are finalizing this requirement as proposed.

Comment: A few commenters stated that, since inpatient facilities provide services to more than one hospice, the hospice should retain responsibility for ensuring the training of all personnel who will be providing care to the patients in facilities for which it has responsibility, rather than the hospice actually arranging such training. In addition, a description of the training and the names of those giving the training would be documented. Another commenter noted that hospices have no control over the staff of facilities, and therefore, requiring hospice responsibility for training will pose problems for hospices.

Response: The training of personnel who will be furnishing care must be specified in the contractual agreement. The hospice must ensure that facility personnel are trained. Through the contractual agreement, the hospice is responsible for ensuring that the facility makes its staff available for these trainings. We agree with the

commenters that hospices are responsible for ensuring that training occurs, but not necessarily arranging for or providing such training; therefore, we are amending the language at § 418.108(c)(5) and § 418.108(c)(6) to require the agreement between the hospice and the inpatient facility to state: ''that the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training is documented; and (6) A method for verifying that the requirements in paragraphs (c)(1) through (c)(5) of this section are met.''

Comment: A few comments were submitted regarding the proposed requirement in § 418.108(d), ''Inpatient care limitation.'' The commenters stated that the 20 percent limitation is problematic because patients who reside a great distance from the hospice must be admitted to the hospice, making their entire hospice stay an inpatient stay.

Response: We believe that there may be some confusion about the proposal in this section. Hospices are permitted to admit patients to their own facilities if the patient lives a long distance from the hospice, cannot stay at home, or for any number of other reasons. However, if the patient is admitted for a reason other than the need for short-term respite care, or for symptom management or pain ---control, then the patient is not receiving an inpatient level of care that counts toward the 20 percent inpatient cap. atients admitted for reasons other than short-term respite care, symptom management, or pain control receive the routine home care level of payment.

20. Condition of Participation: Hospices That Provide Inpatient Care Directly (§ 418.110)

We proposed to recodify most of the requirements of existing § 418.100 at § 418.110, with some revisions. We proposed to recodify, without change, the requirements of § 418.100(d), ''Fire protection,'' at § 418.110(d); § 418.100(e), ''Patient areas,'' at § 418.110(e); § 418.100(f), ''Patient rooms and toilet facilities,'' at 418.110(f) and (g); § 418.100(g), ''Bathroom facilities,'' at § 418.110(h); § 418.100(h), ''Linen,'' at § 418.110(k); and § 418.100(k), ''Pharmaceutical services,'' at § 418.110(m) and (n).

We proposed to replace existing § 418.100(a) with § 418.110(a), ''Staffing,'' and § 418.110(b), ''24-hour nursing services.'' The existing regulation requires that a registered nurse must provide direct patient care on each shift. The two proposed standards provide some flexibility and would require hospices that provide inpatient care in their own inpatient facilities to ensure that staffing for all services, including nursing services, is adequate, based on the volume of patients, their acuity, and the level of services they need. These standards further proposed that staffing must meet the needs of patients to ensure that each patient's plan of care is adhered to and that the outcomes described in each patient's plan of care are achieved. Finally, these standards proposed that nursing services must be adequate to ensure that each patient is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection. We believe that this outcome-based approach meets the needs of patients and hospices without using prescriptive requirements.

At § 418.110(c), ''Physical environment,'' we proposed that the hospice maintain a safe physical environment that was free of hazards for patients, staff, and visitors. In § 418.110(c)(1), ''Safety management,'' we proposed that the hospice prevent situations that posed a real or potential threat to the health and safety of the patients, others, and property. The hospice would be required to promptly investigate, correct, and report to appropriate State and local bodies with jurisdiction all breaches of safety. The hospice would be required to take steps to prevent equipment failures, and correct and report any equipment failures promptly.

In addition, § 418.110(c)(1)(iii) proposed to retain the existing requirement at § 418.100(b) that the hospice periodically rehearse with staff a disaster preparedness plan for managing the consequences of natural disasters and other emergencies that affect the hospice's ability to provide care. In developing and rehearsing their disaster preparedness plans, we believe that it is important for hospices to be engaged with their local and state disaster preparedness planning counterparts. Although this disaster preparedness requirement applies only to hospice inpatient facilities, we encourage all hospices to be aware of the need for disaster planning at the hospice, local, and State levels, and to actively engage in the planning process. We also proposed, at § 418.110(c)(2), that the hospice develop procedures for managing trash and medical waste disposal; light, temperature and ventilation; emergency gas and water supplies; and equipment maintenance and repairs. We believe that these basic precautions and actions will help the hospice ensure that buildings, as well as the equipment inside of them, are fully and safely functioning at all times to ensure patient and family comfort and satisfaction.

Proposed § 418.110(f), ''Patient rooms,'' would recodify and revise the requirements of existing 418.100(f). We proposed in § 418.110(f)(3)(iv) that each room accommodate no more than two patients because we believe that hospice patients and families need the additional privacy that a two-patient room affords them in order to help preserve the patient's comfort and dignity during the dying process. We believe this is the standard accommodation in most facilities. We proposed to allow existing hospice facilities with more than two patients in each room to receive a waiver of this requirement. This waiver would be based on whether the hospice was already providing direct inpatient care in a non-compliant facility when this regulation became effective. That is, if a hospice was providing direct inpatient care in a non-compliant building on the day before the effective date of the final rule and could demonstrate that the imposition of a two-patient-per-room requirement would result in unreasonable hardship or jeopardize its ability to continue to participate in Medicare or Medicaid, then the hospice operating in the non-compliant building could qualify for a waiver of the proposed requirement. A hospice would have to demonstrate to CMS that the waiver served the needs of its patients and did not adversely affect their health and safety. If that same hospice moved into a non-compliant building after the effective date of this final rule, then the hospice would be deemed out of compliance with our rules. If a hospice chose to begin operating its own inpatient unit after the effective date of this final rule, then it would not qualify for the proposed waiver, and would be required to have no more than two patients per room. The remaining paragraphs in this standard would be virtually the same as in the current requirement, with only minor revisions to the language that would not change the substantive requirements of the regulation.

In § 418.110(i), ''Infection control,'' we proposed to revise the infection control standards to conform to those required of other provider types, such as home health agencies and hospitals. We proposed to require a hospice to establish an infection control program that would protect patients, families, and staff against communicable diseases and would prevent and control the

spread of infections. The infection control program would be required to follow professionally established infection control standards and be part of the hospice's overall quality assurance and performance improvement and education program. We did not propose any specific approaches to meeting the infection control requirement.

In § 418.110(l), ''Meal service and menu planning,'' we proposed to revise the existing § 418.100(j). We proposed to make this standard less restrictive by eliminating several structural requirements, such as serving at least three meals at regular times, with no more than 14 hours between substantial evening and breakfast meals, and having a staff member trained in food management or nutrition. In place of these prescriptive requirements, we proposed that a hospice should focus on meeting the individual patient's nutritional and plan of care needs.

We proposed a new standard at § 418.110(o) to address the use of seclusion and restraints in hospice inpatient facilities. Anecdotal evidence indicates that seclusion and restraints are occasionally used in hospice inpatient facilities ostensibly to protect patients, visitors, and/or staff. The proposed requirements, modeled on those for hospitals issued by CMS in 1999, and on the requirements of section 3207 of the Children's Health Act (Pub. L. 106–310), would ensure that, when seclusion or restraints are used, they are used in a safe manner for the shortest time necessary to ensure patient and staff safety.

The proposed standard, divided into seven elements, focused on the proper use of seclusion and restraints, and on the need for hospice personnel to receive training and education both in the proper use of seclusion and restraint application and techniques, and in the use of alternative methods for handling situations that arise. The standard proposed specific requirements for physician orders for seclusion or restraint (for example, consultation with the hospice medical director, 1 hour face-to-face evaluation of the patient, and time limits on the length of orders). The proposed standard also included a requirement that a hospice would have to report to its CMS regional office any death that occurs while a patient is restrained or in seclusion, or that occurred within 24 hours of a patient being removed from seclusion or restraint.

Comment: A commenter asked us to clarify that the requirements in § 418.110 would apply only to facilities operated by the hospice and not to nursing facilities or hospitals with which the hospice has a contract for inpatient care.

Response: The commenter is correct that, with the exception of § 418.110(b) and § 418.110(f), the requirements of this CoP only apply to hospice operated inpatient facilities. These facilities may be in a building owned wholly by the hospice, or may be in space leased from a company or health care provider, such as a designated hospice inpatient facility leasing and occupying a floor in a hospital. In order to clarify our longstanding intent that this CoP only applies to inpatient facilities operated by a hospice, we have added the term ''in its own facility'' to the stem statement, which now reads, ''[a] hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards.'' We believe that restricting the majority of the requirements of § 418.110 to hospice-operated inpatient facilities, and permitting contracted facilities to comply with their own applicable regulations, will help avoid and potential regulatory conflicts between the hospice regulations and the regulations pertaining to a contracted facility (for example, a hospital or skilled nursing facility). A contracted facility would nonetheless be required to comply with (b) and (f), because these requirements are necessary to ensure appropriate staffing levels to care for seriously ill patients receiving the general inpatient level of hospice care and to ensure that hospice patients and families receive the care in a comfortable environment.

Comment: A commenter suggested that we should define the term ''nursing services'' as it is used in proposed § 418.110(b) to include the services of licensed practical nurses within their scope of practice.

Response: The nursing services, as well as all other services, furnished by a hospice inpatient facility must meet the needs of the patients in the facility. Hospices may choose to use registered nurses, licensed practical nurses, licensed vocational nurses, and any other level of nurse to meet the needs of their patients. We expect all nurses, as well as other professionals, to always act within the scope of their training and licensure. We do not believe that a statement to this effect needs to be in regulation because we require in § 418.114 that all professionals must obtain the license offered by their State. In order to obtain and maintain the license, these providers are required by their State to practice only within the scope of their license.

Comment: The majority of commenters who submitted comments on this CoP made suggestions regarding the 24-hour nursing services requirement at proposed § 418.110(b). An overwhelming number of commenters suggested that, if a hospice is providing general inpatient care, the hospice should be required to have a registered nurse (RN) on duty at all times. These same commenters stated that it is not necessary to have a registered nurse on duty at all times if the hospice is only providing respite care. Other commenters agreed with our proposal to require that the nursing services provided by the hospice must meet patient needs rather than requiring hospices to have a registered nurse on duty at all times. Still other commenters suggested that, if a registered nurse is not present in the facility, one must be available for on-call consultation and direct care, if needed.

Response: We proposed to eliminate the 24-hour registered nurse requirement in order to make it easier for providers to care for respite patients. We continue to believe that it is not necessary to require a registered nurse on duty for all shifts if patients in the facility are receiving respite care only, and we therefore did not include a 24-hour RN requirement in § 418.108(b)(2), which pertains to nurse staffing levels in facilities that are only providing respite level care to hospice patients. At the same time, we agree that the needs of patients receiving general inpatient care, who are in distress to such a degree that their pain and symptoms cannot be managed in their homes, necessarily require care from a registered nurse on all shifts. Therefore, we have incorporated a requirement for 24-hour RN services at § 418.110(b)(2), and have cross-referenced this requirement at § 418.108(a)(2). All facilities providing the general inpatient level of care, whether operated by the hospice or under arrangement with the hospice, must provide 24-hour RN care if at least one hospice patient is receiving general inpatient care.

Comment: Numerous commenters asked us to define and provide examples of the terms ''breach of safety'' and ''equipment failures'' as they are used in proposed § 418.110(c)(1) (i) and (ii), respectively. Commenters asked us to clarify the relationship between the requirements for equipment failures and the requirements of the Safe Medical Devices Act of 1990 (Pub. L. 101–629). Furthermore, commenters asked us to clarify which State and local bodies should receive reports of safety breaches and equipment failures.

Response: The intent of these proposed requirements was to ensure that the proper authorities were alerted by hospices regarding situations that may jeopardize patient health and safety. We agree that this goal has already been accomplished both through the requirements of the Safe Medical Devices Act, with which health care providers are required to comply (21 U.S.C. § 360L), and the requirements of final § 418.110(c)(2)(iv), which requires hospices to have procedures for controlling the reliability and quality of their emergency maintenance and repair program for their equipment. Therefore, we have deleted the proposed requirements.

Comment: A commenter was confused about the requirements for chapter 9 of the Life Safety Code, as included in proposed § 418.110(d)(4).

Response: In January 2003 we published a final rule adopting the 2000 edition of the Life Safety Code. The 2000 edition of the Life Safety Code requires health care facilities, including hospices, to have emergency lighting systems meeting certain specifications. We allowed hospices a 3-year phase-in period after the effective date of the Life Safety Code rule to purchase and install their emergency lighting systems. That phase-in period expired March 13, 2006. Therefore all hospices must now have emergency lighting systems that comply with the specifications of chapter 9 of the 2000 edition of the Life Safety Code. Since the phase-in date has now passed, we have removed the phase-in language in this final hospice rule. We believe that removing the phase-in language will make it clearer that hospices must comply with all of the requirements of the 2000 edition of the Life Safety Code.

Comment: Some commenters suggested that we should define the terms ''home-like'' and ''equipped for nursing care'' as they are used in proposed § 418.110(e) and (f).

Response: Hospice inpatient facilities have been required, since the inception of the Medicare hospice benefit, to have a home-like environment for patients and families to enjoy. Hospices should take all appropriate steps to minimize a cold, clinically sterile environment by incorporating materials and items typically found in private residences where appropriate. We understand that certain standards of hygiene may preclude the use of certain materials or objects. We also understand that certain machines and devices needed to provide medical care to patients may need to be present and that such machines and equipment may not appear ''home-like.'' We expect hospices to take appropriate steps, where feasible, to create a soothing, inviting atmosphere within the context of creating an environment where nurses and other hospice staff are able to effectively provide care and services.

Comment: Many commenters submitted comments regarding our proposal at § 418.110(f), ''Patient rooms.'' Some suggested that hospices should be allowed to have more than two patients in a room during community disasters or evacuations. Others suggested that patient rooms should be required to accommodate families as well as patients. Still others supported our proposal to waive the maximum two patients per room requirement for existing hospice facilities.

Response: We appreciate the support and thoughtful comments that we received in this area. We agree that the two-patient rooms should accommodate patients and family members, and we have specified this in revised § 418.110(f)(3)(iv). We also agree that hospices should be allowed to place more than two patients in a room during community disasters or evacuations. This situation is already addressed through separate waiver authority in section 1135 of the Act. Furthermore, we agree that the two-patient-per-room waiver for existing facilities should remain. Requiring a hospice to reduce the number of beds per room without the opportunity for a waiver may reduce the number of overall beds available and could create a hardship for affected facilities and problems for patients requiring access to inpatient care.

Comment: All commenters who submitted comments on proposed § 418.110(l), ''Meal service and menu planning,'' supported our proposal to replace prescriptive food planning and service requirements with requirements based on patient needs and goals.

Response: We thank the commenters for their support of this change. The final rule will require that food service in a hospice inpatient facility be based on the needs and wants of the patient in the facility, rather than on prescriptive regulatory requirements.

Comment: Numerous commenters who submitted comments on our proposed seclusion and restraint requirements at § 418.110(o) were confused about the applicability of the proposed standard. Commenters seemed to believe that the proposed standard would apply to patients in their homes or to hospice patients who reside in long term care facilities.

Response: This standard is located in the CoP that governs hospice inpatient facilities operated by the hospice. It only applies to care furnished to hospice patients in the hospice's inpatient facility. This requirement does not apply to care furnished to hospice patients outside of the hospice's inpatient facility. If a hospice contracts with another facility (for example, hospital, or SNF) for inpatient care, we believe that it is preferable for the seclusion and restraint requirements for that provider to apply to the hospice patient.

Comment: A single commenter suggested that we should convene an expert task force to examine the use of drug restraints in hospice care.

Response: Under the revised definition of ''drug restraints'' previously described, we believe that it will be a rare situation for a hospice to use a drug restraint on a patient. Since the situation is likely to be very rare, we do not believe that it is necessary to convene an expert panel to examine the issue. Moreover, we are following the statutory definition, which applies to hospices through the Children's Health Act (42 U.S.C. 290ii(d)(1)(B)).

Comment: Many commenters made suggestions to modify proposed § 418.110(o)(3)(ii) regarding orders for seclusion and restraint. One commenter sought clarification about the prohibition on standing or as needed orders for seclusion and restraint. Other commenters stated that it would be difficult for a hospice physician to get to the inpatient facility in time to complete the one-hour visit and evaluation of a patient in seclusion or restraint. A commenter questioned the role and responsibility of the attending physician ordering restraints or seclusion. Other commenters suggested that orders be allowed to be written for eight or even 24-hour periods, rather than only for four hours as proposed. One commenter suggested that there should be no maximum length of time for a seclusion or restraint order.

Response: An order for seclusion or restraint must be specific to the patient, time, and place where the intervention will be used. A physician may not order restraint for a patient unless the patient requires such intervention at that very moment. In other words, orders based on future contingencies are not acceptable.

Hospices may authorize their medical director, physician designee, other hospice physician employees, and/or attending physicians to issue restraint or seclusion orders. If an order for seclusion or restraint is not ordered by the attending physician, medical director, or physician designee, then the medical director or physician designee must be consulted as soon as possible after the order is issued.

Once an order for seclusion or restraint is issued and implemented, the patient must be seen within one hour to evaluate the need for continuing the intervention. We agree that it may be difficult for a hospice physician to arrive at the inpatient facility and actually see the patient within this one-hour window. Therefore, we have added a provision permitting a registered nurse trained in the proper use of seclusion and restraint to conduct the one-hour face-to-face evaluation of the patient.

In addition to the one-hour evaluation, we believe that it is necessary to regularly re-evaluate the patient's status and need for the ordered intervention. To ensure a thorough re-evaluation, we are requiring orders for seclusion or restraint to last no more than four hours each for a total of up to 24 hours. We believe that frequently re-ordering the intervention will ensure that patients remain in seclusion or restraint for the shortest time possible to control their distress.

Comment: A commenter asked us to clarify the meaning of the term ''continually'' as it is used in proposed § 418.110(o)(4)(i). The commenter specifically asked if this term meant that patients would need to be constantly monitored when restraint and seclusion are used simultaneously.

Response: If restraint and seclusion are used simultaneously, the patient must be continually monitored, face-to-face, by an assigned, trained staff member or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. For the purposes of this provision, ''continually'' means ongoing without interruption.

Comment: Some commenters expressed concern that the presence of seclusion and restraint requirements would seem to discourage their use, even when medically necessary and appropriate. Other commenters suggested that the requirement proposed at § 418.110(o)(7), regarding the reporting of seclusion and/or restraint-related deaths, would discourage the use of seclusion and/or restraint because hospices would fear that the reports would result in State surveys. They therefore suggested deleting the seclusion and restraint requirements in their entirety, while other comments suggested that hospices should only be required to report unexpected deaths or deaths that occur by hanging due to physical restraints.

Response: Seclusion and restraint requirements are needed to protect a patient from harm by ensuring that professionals will be able to appropriately use seclusion and restraint methods. These regulations also implement sections 591–593 of the Public Health Service Act, as added by section 3207 of the Children's Health Act. In order to further the goal of safe and appropriate implementation of seclusion and restraint techniques, we clarified the training requirements for hospice inpatient staff. Staff must be trained in techniques to identify behaviors, events, and environmental factors that may trigger the need for seclusion and restraint techniques. Staff must also be trained in the following: using nonphysical intervention skills, choosing the least restrictive intervention, safely implementing all types of restraint and seclusion, recognizing and responding to distress signs, identifying behavioral changes that indicate that seclusion and restraint are no longer necessary, monitoring patient well-being, and using first aid and cardiopulmonary resuscitation techniques. We believe that this staff training will minimize the likelihood of a patient death related to the use of seclusion or restraint for a patient, and will thus minimize the number of deaths that hospices must report. These regulations are similar to those that we plan for other facility types, as required by section 593(b) of the PHS Act.

Should a seclusion or restraint-related death occur, our intent is to ensure that hospices fully investigate the death and notify CMS of the death and the investigation findings. We have clarified that the seclusion and restraint investigation and reporting requirements in final standard § 418.110(o), ''Death reporting requirements,'' only apply to those patients who die unexpectedly.

Section 592 of the PHS Act requires facilities to report all deaths within 24 hours after a patient is removed from restraint or seclusion, or where it is reasonable to assume that a patient's death is a result of such seclusion or restraint. Therefore, we have also clarified that unexpected deaths occurring within 24 hours of a patient being removed from seclusion and/or restraints would need to be investigated. We believe that unexpected deaths require a full investigation by the hospice to determine the presence or lack of a relationship between the seclusion and/or restraint and the patient's death. We also believe that CMS must be apprised of such situations because a patient death related to seclusion and/or restraint use may indicate the presence of patient safety issues within the hospice that require additional guidance from the State or CMS. It is important to remember that we are in no way seeking to discourage the use of seclusion and restraint if, within these regulatory boundaries, their use will benefit a patient. Our goal is to ensure that seclusion and restraint, when used, are used in a safe manner for the shortest amount of time necessary, as required by the PHS Act.

21. Condition of Participation: Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/MR (§ 418.112)

We currently do not separately address the provision of hospice care to a hospice-eligible resident of a facility. This includes hospice care provided to residents who choose to live in skilled nursing facilities, nursing facilities, intermediate care facilities, and many other types of facilities. The provision of, and questions related to, hospice care for residents of those facilities has come under scrutiny as a result of a variety of report findings, including Operation Restore Trust (ORT) activities, Inspector General (OIG) reports from 1996, 1997, and 1998, and a 2000 report from the Department's Assistant Secretary for Planning and Evaluation (ASPE) Office of Disability, Aging and Long-Term Care Policy and the Urban Institute. (U.S. D.H.H.S. OIG, ''Hospice and Nursing Home Contractual Relationships,'' Nov. 1997, OEI–05–95–00251; OIG Special Fraud Alert, ''*Fraud and Abuse, Nursing Home Arrangements with Hospices*,'' Mar. 1998; ''Synthesis and Analysis of Medicare Hospice Benefit Executive Summary and Recommendations.'' (Harvell, J.; Jackson, B.; Gage, B.; Miller, S.; and Mor, V., Mar. 2000)). The relationship between hospices and nursing facilities was also addressed by the Secretary's Advisory Committee on Regulatory Reform. The committee focused on clarifying the responsibilities of each provider and on patient access to the hospice benefit while residing in a facility.

Based on the recommendations of the committee, as well as the reports from Operation Restore Trust, the Office of the Inspector General, and ASPE, we proposed to add a new condition at § 418.112, ''Hospices that provide care to residents of a SNF/NF, ICF/MR, or other facilities.'' We are also preparing a separate regulatory document to address long-term care facility obligations regarding residents receiving hospice services.

Under § 418.112(a), ''Resident eligibility, election and duration of benefits,'' we proposed that the hospice ensure that the resident met all the same Medicare eligibility requirements for hospice care (found at § 418.20 to

§ 418.30), as a patient who resides in his or her home in the community.

At § 418.112(b), ''Professional management,'' we proposed that the hospice assume full responsibility for all of the hospice care provided to the patient. This would include making arrangements for any inpatient care that the patient would require in accordance with § 418.100. This standard would reinforce the necessity of continuity of care for patients who reside in a SNF/NF, ICF/MR, or other facility. In § 418.112(c), ''Core services,'' (and in accordance with sections 1861(dd)(1) and (2)(A) of the Act), we proposed that the hospice be required to provide all necessary core services to its patients residing in a SNF/NF, ICF/MR, or other facility in the same manner that it would provide such core services to a patient residing in a home in the community. It is not reasonable for the hospice to delegate any of its standard hospice core services to the nursing or residential facility staff.

In § 418.112(d), ''Medical director,'' we proposed that a hospice medical director would be expected to communicate with all facility physicians, including the facility's medical director, and the attending physician and other professionals involved in developing and/or implementing the patient's plan of care. This standard was designed to ensure that all physicians, including those in leadership positions, were in agreement regarding the patient's care to ensure that duplicative and/or conflicting physician orders are not issued for patient care.

Under § 418.112(e), ''Written agreement,'' we proposed that a comprehensive written agreement be developed between the hospice and facility, and that it be in effect before any hospice care was provided to a facility resident. The purpose of the written agreement would be to ensure that the duties and responsibilities of the hospice and facility were clearly articulated and executed in a manner that ensured that the patient would receive quality hospice care. The written agreement would be required to include the following:

(1) Written consent and documentation of the patient or the representative's desire for hospice services.

(2) Identification of the services that the hospice and the facility would provide.

(3) The manner in which the facility and the hospice would communicate to ensure that the needs of the patient were addressed and met 24 hours a day.

(4) A requirement that the facility immediately notify the hospice when:

(A) A significant change in the patient's physical, mental, social or emotional status occurred;

(B) Clinical complications appeared that suggested a need to alter the plan of care;

(C) A life threatening condition(s) appeared;

(D) A need to transfer the patient from the facility arose; or

(E) The patient died.

(5) A provision stating that the hospice assumed responsibility for determining the appropriate course of care, including the determination to change the level of services provided. (An agreement that it was the facility's primary responsibility to furnish room and board.)

(6) A delineation of the hospice's responsibilities, which would include, but not be limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling, provision of medical supplies and durable medical equipment, provision of drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions, as well as all other hospice services that might be necessary for the care of the resident's terminal illness and related conditions.

(7) A provision that the hospice could use the facility's nursing personnel where permitted by law and as specified by the facility to assist in the administration of prescribed therapies included in the plan of care, but only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.

These would be mandatory agreement provisions, but would not otherwise limit the scope or content of the relationship between the hospice and the facility. Additional provisions could be added subject to mutual agreement.

Under § 418.112(f), ''Hospice plan of care,'' we proposed that the content of the plan of care for a patient residing in a SNF/NF, ICF/MR, or other residential facility would be similar to the content of the plan of care for a patient residing in a home in the community. The plan would have to reflect the hospice philosophy in all aspects, be based on an assessment of the patient's needs and unique living situation in the facility, and be updated at least every 14 calendar days. In addition to the standard plan of care requirements, the plan of care for a patient residing in a SNF/NF, ICF/MR, or other facility would be required to be coordinated with and developed by the hospice IDG and SNF/NF, ICF/MR, or other facility in collaboration with the attending physician. Furthermore, the plan of care would have to specify which provider would be responsible for providing a particular form of care. The performance of the functions would reflect the participation of the hospice, SNF/NF, ICF/MR, or other facility, and the patient and family to the extent possible.

At § 418.112(g), ''Coordination of services,'' we proposed that the hospice designate a member of the IDG to coordinate the implementation of the plan. The hospice would provide the residential facility with the plan of care, hospice consent form, contact information for hospice personnel involved in the care of the resident, instructions on accessing the hospice 24-hour on-call system, medication information specific to the patient, physician orders, and any advance directives. We believe that these requirements would ensure effective communication between the hospice and the facility.

Under § 418.112(h), ''Transfer, revocation, or discharge from hospice care,'' we proposed to cross-reference the proposed requirement for discharge or revocation at § 418.104(e). In addition, we proposed that discharge or revocation of the hospice care would not impact the eligibility to continue to reside in a SNF/NF, ICF/MR, or other facility.

At § 418.112(i), ''Orientation and training of staff,'' we proposed that the hospice staff would be required to train facility staff who provided care to hospice patients on aspects of the hospice philosophy and unique program features, including policies and procedures, methods of comfort, pain control and symptom management, general principles about death and dying and individual responses, patient rights, appropriate forms, and record keeping requirements.

Comment: Many commenters suggested that the phrase ''other facilities'' be removed from the title and text of this CoP. The commenters stated that this phrase was too broad and imprecise to enable hospices to effectively determine when they would have to comply with the additional requirements of this CoP. Some commenters suggested that ''other facilities'' should only apply to those that were Medicare-or Medicaid-approved, while others suggested that assisted living facilities could be included as well.

Response: We agree that the phrase ''other facilities'' is ambiguous and difficult to objectively determine. We also agree that this requirement should be limited to those facilities that can be Medicare-certified so as not to impose a de facto burden upon facilities that do not receive Medicare funds. Therefore, this final requirement applies only to those types of residential facilities that are eligible to be Medicare-certified, that is SNFs, NFs, and ICFs/MR. Hospices are permitted to use the structure and content of this section when establishing and managing their relationships with other facility types such as assisted living facilities.

Comment: A commenter asked us to clarify that the requirement of proposed § 418.112(a) regarding eligibility criteria would apply to residents of ICFs/MR in addition to residents of SNFs and NFs.

Response: We agree that this clarification would be helpful, and we have made the suggested change.

Comment: Many commenters asked us to specify in § 418.112(b) that hospices would only be responsible for making the necessary arrangements for inpatient care related to a patient's hospice care (that is, the terminal illness and related conditions).

Response: We agree that is it helpful to clarify that the hospice is responsible for hospice-related inpatient care for the patient, and we have made this change. In addition, we have clarified that the arrangements for hospice inpatient care must be in accordance with the requirements of § 418.108, ''Short term inpatient care,'' as well as the requirements of § 418.100(e), ''Professional management responsibility.'' We believe that the new reference to the requirements of § 418.108 will ensure that hospices make arrangements with the appropriate facilities and ensure proper staffing to meet the needs of the patient.

Comment: Numerous commenters sought clarification on proposed § 418.112(b), ''Professional management.'' Commenters were confused by the proposed requirement that the hospice must assume full responsibility for professional management of the resident's hospice care. They believed that this requirement could create conflicts with long term care facility responsibilities. One commenter suggested that, in order to further clarify the hospice's responsibility, we should add a statement that the hospice is responsible for those services that are included in the hospice plan of care. Another commenter suggested that deleting the word ''full'' would clarify the scope of the hospice's responsibility.

Response: We agree that further clarification is warranted in this standard. Hospices are only responsible for furnishing and managing a patient's hospice care related to the terminal illness and related conditions. They are not responsible for managing all of a patient's care. We believe that requiring hospices to take responsibility for the care they furnish is not in conflict with the long term care facility regulations at 42 CFR part 483. To ensure that our intent is clear in the requirement, we have removed the word ''full'' and have added a provision that the hospice is responsible for services provided in accordance with the plan of care. Revised standard (b) now reads, ''[t]he hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to § 418.100 and § 418.108.''

Comment: A commenter sought additional clarification on the distinction between coordination of care and responsibility for the provision of care as the latter appears in the proposed rule at § 418.112(b).

Response: Hospices are responsible for furnishing all care and services related to the terminal illness and related conditions as those services are identified in the plan of care, regardless of where the patient resides. Hospices are required by section 1861(dd) of the Act to provide some of these services directly, while other services may be provided under arrangement. Regardless of whether the hospice services are provided directly or under arrangement, hospices are required to assume full professional management responsibility for those services. In addition, hospices are required to designate a registered nurse who is a member of the hospice's IDG to coordinate the implementation of the patient's hospice care and services. Furthermore, hospices are required to have a system of communication to ensure that all disciplines furnishing hospice care to patients communicate with each other about patient needs. This system of communication must also include a sharing of information with health care providers that are simultaneously caring for the same patients that the hospice is caring for to ensure that the hospice is able to coordinate its care with that being provided by others.

Through these mechanisms, the hospice maintains responsibility for all of its care and services for all of its patients and ensures that the care it is providing complements the care being provided by others. In addition to these mechanisms used for all patients, hospices are required to establish written agreements and communication systems with SNFs, NFs, and ICFs/MR when hospices are furnishing hospice care to residents of those facilities. Clear communication between the hospice and the SNF/NF or ICF/MR will help hospices ensure that they are meeting their responsibility to furnish the care necessary to meet the needs of its patients.

Comment: Many commenters suggested that we should revise or remove the proposed requirement at § 418.112(e)(4)(iii) that the written agreement between a hospice and a SNF/NF or ICF/MR must contain a provision that the facility notifies the hospice if a life-threatening condition appears in a hospice patient. Some commenters stated that this should be clarified to state that the life-threatening condition is only required to be reported if it is unrelated to the terminal illness and related conditions. Other commenters stated that this should be removed because the requirement at proposed § 418.112(e)(4)(i), stating that the facility must notify the hospice if a significant change in a patient's status occurs, would apply to life-threatening conditions as well.

Response: We agree that proposed § 418.112(e)(4)(i), now located at 418.112(c)(2)(i), applies to life threatening conditions, and, as a result, we have deleted the proposed requirement at § 418.112(e)(4)(iii).

Comment: Many commenters asked us to clarify or remove the proposed requirements of § 418.112(e)(6), which would require the agreement between the hospice and the residential facility to state that it would be the residential facility's primary responsibility to furnish room and board. Commenters stated that, although SNFs/NFs and ICFs/MR do provide room and board, describing these functions as their primary responsibility ignores the other functions that the facilities perform. Commenters also stated that the services provided by the SNF/NF or ICF/MR should not be assumed by the hospice. Rather, the commenters stated, the SNF/NF or ICF/MR should furnish services in the role of the primary caregiver at the same level that would have been provided if the resident had not elected to receive hospice care.

Response: We agree that the term ''primary'' unnecessarily excludes the other functions that SNFs/NFs and ICFs/MR perform for their residents, and it has been deleted. Nonetheless,

the responsibility of room and board will be deemed to be that of the residential facility. In addition, we have expanded this requirement to clarify that hospices should not be expected to assume the functions of the SNF/NF or ICF/MR. The revised requirement, located at new § 418.112(c)(4), requires the agreement to state that ''it is the SNF/NF or ICF/MR's responsibility to continue to furnish 24-hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.'' This expanded requirement clarifies that hospices are not required to assume the functions that the SNF/NF or ICF/MR performed for the patient before the patient elected to receive hospice care. This requirement is not, however, meant to imply that the SNF/NF or ICF/MR is required to automatically increase its level of services simply because the resident has elected to receive hospice care. All Medicare and Medicaid approved facilities, be they SNFs/NFs or ICFs/MR are responsible for providing services to their residents in accordance with their respective laws and regulations.

Comment: Numerous commenters suggested that the written agreement between the hospice and the SNF/NF or ICF/MR should contain a provision that the SNF/NF or ICF/MR will continue to provide services at the same level as those services would have been provided before the patient elected the hospice benefit.

Response: We agree that it is beneficial for hospice patients to continue to receive the same level of services provided by the SNF/NF or ICF/MR upon entry into the hospice program. These facilities often function as a patient's family, and, just as hospices are not expected to replace the role of the family in caring for hospice patients, we do not expect hospices to replace the role of the SNF/NF or ICF/MR staff in caring for hospice patients who reside in those facilities. We have clarified proposed § 418.112(e)(6) to this effect, and have relocated the requirement to new § 418.112(c)(4). To further clarify this issue, we have also added a new requirement for the written agreement, located at § 418.112(c)(5), that it is the hospice's responsibility to provide services to residents of a SNF/NF or ICF/MR at the same level and to the same extent as those services would be provided to patients residing in their own private homes. Regardless of where a patient resides, a hospice is continually responsible for furnishing core services, and may not delegate these services to the staff of a SNF/NF or ICF/MR. We believe that this new requirement will help to ensure consistent, high quality hospice care for all hospice patients, regardless of their place of residence.

Comment: Numerous commenters sought clarification on our proposal at § 418.112(e)(8) that a hospice may use the nursing personnel of the SNF/NF or ICF/MR, where permitted by law and as specified by the facility, to assist in administering hospice care, to the extent that the hospice would routinely use a patient's family to implement the plan of care. Some commenters suggested that hospices should be allowed to use the nursing personnel of SNFs/NFs or ICFs/MR to a greater extent than family members would be used, because the nursing personnel have more training and education in furnishing medical care than family caregivers typically do. Other commenters wanted to know how this provision would affect the long term care facility requirement that long term care facility staff must provide care to residents as needed to maintain resident well-being. Other commenters were concerned that utilizing facility nursing personnel could be a ''slippery slope'' whereby hospices would delegate essential tasks to the facility's personnel. Still other commenters sought clarification regarding which laws would apply to hospices utilizing facility personnel to implement the plan of care. These commenters suggested that State laws would most appropriately apply. A single commenter suggested that the personnel of the SNF/NF or ICF/MR should be expected to provide all nursing care unless the facility specifically asks the hospice to perform a nursing function.

Response: The utilization of SNF/NF or ICF/MR personnel in implementing the hospice plan of care for a patient is difficult to address because both hospices and these facilities provide varying levels of care based on the needs of the patient/resident. We agree that State laws are best suited to governing the use of facility personnel by hospice staff, and we have specified this in the final rule. This provision is not intended to preempt any State laws that may apportion duties between hospice and residential facility staff.

We proposed that hospices may only use the staff of the SNF/NF or ICF/MR as specified in the written agreement signed by the SNF/NF or ICF/MR. This is being retained in the final rule at § 418.112(c)(7). It recognizes that facilities must give consent for their staff to be used in caring for the hospice patient and must determine the extent of staff involvement. This consent allows facilities and hospices to match their corresponding levels of available personnel service to the needs of the patients being served. As stated above, hospices are not responsible for assuming the functions that the SNF/NF or ICF/MR performed for the patient before the patient elected to receive hospice care. Likewise, SNFs/NFs and ICFs/MR are not responsible for assuming the functions that the hospice would provide for a patient residing in his or her own home.

The hospice benefit is not designed so that hospice personnel routinely provide 24-hour care or serve as the patient's primary caregiver. Hospice patients in their private homes have private caregivers, be they family members, friends, hospice volunteers, paid assistants, or any of a number of other combinations. These caregivers are trained by the hospice to administer care in accordance with the patient's plan of care. Caregivers may help patients with a variety of duties, such as medication administration, bathing, and housekeeping.

Hospice patients in SNFs/NFs and ICFs/MR depend, at least in part, on facility staff to provide caregiver services. As such, we believe that it is reasonable to allow hospices to use facility staff who act as caregivers in the same manner and to the same extent that hospices would use family members, friends or other caregivers who care for patients in their private residences. For example, hospices typically instruct home caregivers in how and when to administer medications to hospice patients. Therefore, it would be appropriate to instruct facility staff caregivers in how and when to administer medications. Hospices typically do not instruct home caregivers in how to draw blood to monitor medication levels; thus it would not be appropriate to expect facility staff to draw blood, even though some members of the facility's staff may be competent to do so. Hospices are to use facility staff in the same way that they would use home caregivers to implement the patient's plan of care. While facility staff presumably possess more sophisticated health care skills than home caregivers, they may not be used to perform functions more frequently, or with a greater degree of complexity, than the hospice would utilize home caregivers under similar circumstances.

We understand that, in times of crisis, it may be necessary for a hospice to direct staff of the SNF/NF or ICF/MR to perform more sophisticated functions than caregivers would typically perform in order to ensure patient comfort while

the hospice staff are in route to the patient. A hospice should, in the contract between it and the facility, address potential crisis situations, and how they would be handled, with facility staff. Potential crisis situations specific to the circumstances of individual patients should also be included in individual plans of care. The temporary emergency measures should be undertaken at the direction of the hospice, which maintains responsibility for ensuring that all hospice care is provided in accordance with the patient's plan of care.

We understand that this does not provide the exact specificity of what functions may or may not be performed by facility caregivers that some commenters sought. We cannot provide an absolute list because such a list is subject to many variables (for example, patient needs, provisions of the written agreement, staff skill levels, etc.).

Comment: Some commenters supported, while others demurred, on our proposal, originally at § 418.64(d), to require hospices to provide bereavement services to facility personnel when appropriate and identified in the patient's plan of care.

Response: We appreciate the support that we received regarding bereavement services furnished to facility personnel. There are times when facility employees fulfill the role of a patient's family, providing caregiver services, being companions, and generally supporting the patient. In order to ensure that the needs of these individuals are met in a manner that accommodates the needs and responsibilities of the hospice and the SNF/NF or ICF/MR, we moved the requirements concerning bereavement care for staff from 418.64, ''Core services,'' to 418.112(c), which governs the written agreement between a hospice and a facility. The relocated requirement at 418.112(c)(9) requires the written agreement to include a provision delineating the responsibilities of the hospice and the facility with regard to providing bereavement services to facility staff that fulfill the role of a hospice patient's family.

Comment: Numerous commenters suggested that the proposed written agreement requirements at § 418.112(e) should be clarified. A primary concern of the commenters was the proposed requirement that the written agreement must include the written consent of the patient or the patient's representative that hospice services are desired. Commenters stated that this proposed requirement implies that a new written agreement must be developed for each resident who receives hospice services. Commenters then noted that, if a written agreement is necessary per patient, it may be difficult to secure the agreement before furnishing care to the patient.

Response: We agree that the proposed requirement implied that a new written agreement must be developed for each resident who receives hospice services. We also agree that such a requirement would be difficult to fulfill before any hospice services are furnished to a specific patient. As a proxy for the written consent of the patient or representative, we will use the requirement at new § 418.112(e)(3)(ii), which requires hospices to provide SNFs/NFs, ICFs/MR, and assisted living facilities with each patient's hospice election form, to ensure that each provider is aware of the patient's choice to receive hospice care. In this way, the election form is not linked to the content of the written agreement. We believe that this will help to clarify that the written agreement does not need to be completed for each and every patient who is a resident of an SNF/NF or ICF/MR. In addition, we believe that this will make it easier for hospices to secure agreements before furnishing care to the patient because they will be required to secure the agreements less often than was implied.

We would like to clarify that the written agreement requirements only apply to hospice patients who are residents of SNFs/NFs and ICFs/MR. The written agreement, and the remaining requirements of § 418.112, do not apply to hospice patients who are placed in SNFs/NFs for general inpatient or respite care by the hospice itself. Rather, the requirements for the written agreement between a hospice and a facility that furnishes general inpatient or respite care are described in § 418.108(c).

Comment: Several commenters suggested that we should add a provision requiring the written agreement to contain information about the services to be provided by the SNF/NF or ICF/MR.

Response: The services provided by the SNF/NF or ICF/MR will vary based on the plan of care which will identify the resident's needs. The written agreement established between the hospice and the SNF/NF or ICF/MR is not the appropriate place for a list of the services to be provided by the SNF/NF or ICF/MR. The services provided by the facility are included in the plan of care and coordinated by the hospice and the facility in accordance with new § 418.112(d).

Comment: Some commenters expressed confusion about the proposed hospice plan of care requirements at proposed § 418.112(f). Commenters questioned if the standard required hospices and SNFs/NFs and ICFs/MR to have a single plan of care that applied to both providers. If so, commenters stated that updating the plan of care every 14 days would be burdensome to long term care facilities that otherwise would be required to update the resident's plan of care only every three months.

Response: Hospices and SNFs/NFs and ICFs/MR must have a single plan for each patient. We would expect the hospice and the facility to develop and update this plan in full consultation with each other. The hospice portion of the plan of care governs the actions of the hospice and describes the services that are needed to care for the patient. The patient's single, coordinated plan of care must identify which provider (hospice or facility) is responsible for performing a specific service. The plan of care may be divided into two portions, one of which is maintained by the long term care facility and the other of which is maintained by the hospice. These two sections must work together to ensure that the needs of the patient for both hospice care and long term care facility care are met at all times. The facility is required to update its portion of the plan of care in accordance with any Federal, State or local laws and regulations governing the particular facility just as hospices would need to update their plans of care according to § 418.56(d) of these CoPs.

Comment: As with the proposed update of the plan of care requirements in § 418.56, many commenters suggested changes to the update timeframe for the hospice plan of care for residents of SNFs/NFs and ICFs/MR. Commenters suggested that the update timeframe be changed from ''at least every 14 days'' to ''at least every 15 days'' or ''at least twice a month.''

Response: We agree that the update timeframe should be lengthened to at least every 15 days to correspond with the lengths of the Medicare hospice benefit periods. This change has been made by referencing the requirements of § 418.56, which includes an every-15-day update timeframe.

Comment: A commenter suggested that we should clarify that the hospice plan of care must be based on a comprehensive assessment of the patient's needs.

Response: We agree that the plan of care must address those needs identified in the comprehensive assessment of the patient. This requirement is included in § 418.56, and the revised hospice plan of care standard at new § 418.112(d) references the requirements of § 418.56.

Comment: Numerous commenters suggested that the proposed requirement at § 418.112(f)(4) should be clarified. Specifically, these commenters expressed concern about the proposed requirement that changes in the plan of care must be discussed ''among all caregivers.'' These commenters stated that the phrase ''among all caregivers'' was very broad, considering that multiple facility staff may act as caregivers for a resident on any given day. Some commenters suggested that ''between both providers'' or ''discussed by the IDG, facility representatives and the patient/family'' should replace the phrase ''among all caregivers.''

Response: We agree that discussing plan of care changes with ''all caregivers'' should be replaced by a more definite requirement. Therefore, the final rule at § 418.112(d)(3) requires changes in the hospice portion of the plan of care to be ''discussed with the patient or representative, and SNF/NF or ICF/MR representatives* * *'' This revised requirement allows the facility to identify those with whom plan of care discussions must occur and provides hospices with a defined list of those individuals who must be consulted before a change in the hospice portion of the plan of care is implemented. The revised requirement still states that the hospice must approve any changes to the hospice portion of the plan of care before those changes are implemented. We believe that this enables hospices to maintain control over the hospice portion of the plan of care while allowing facilities to have their voices heard before final decisions are made about hospice care.

Comment: A commenter wanted to know what forms of communication are acceptable between the hospice and the residential facility concerning care planning.

Response: Hospices are free to use any form of communication that best suits their needs in accordance with their established system of communication as required by § 418.56(e). In accordance with 418.112(c)(1) of this final rule, hospices must document that this communication has occurred to ensure that the hospice has made all necessary efforts to consult facility representatives in hospice care planning activities.

Comment: A large number of commenters requested clarification of the proposed medical director requirement at proposed § 418.112(d). The overall response of commenters was that the proposed requirements were overly burdensome. Many of these commenters suggested that the medical director requirement should be entirely deleted. Others suggested that the communication responsibilities assigned to the hospice medical director would be more appropriately handled by all physicians in the hospice, the hospice IDG, or the RN member of the IDG who is assigned the care plan coordinator role. Still others expressed concern that the proposed medical director communication requirement would overwhelm SNF/NF and ICF/MR medical directors with information about the care of patients that they are not actively involved with.

Response: Our intent in proposing the medical director requirement was to ensure that there was communication and agreement among the clinical leadership of both providers. The purpose of this communication was to ensure that these senior physicians did not issue incompatible care orders for the same patient or otherwise disagree on the approach to patient care. However, as some commenters noted, hospice and facility medical directors are not necessarily involved in actively caring for all patients and facility residents. Some hospices and facilities have multiple physicians, and one of these physicians, rather than the medical director, could potentially be the most knowledgeable with respect to the care of a particular patient or resident. For this reason, we agree that it is appropriate to remove the medical director requirement. We also agree that it is appropriate to reassign communication responsibilities to the IDG responsible for caring for the resident of a SNF/NF or ICF/MR. New § 418.112(e) requires the hospice IDG to designate one of its members to coordinate the patient's hospice care with representatives of the SNF/NF or ICF/MR. The designated IDG member must also communicate with representatives of the SNF/NF or ICF/MR and any other health care providers to ensure quality care for the patient.

Additionally, the designated IDG member must ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and any other physicians caring for the patient as needed to coordinate the patient's hospice care with the care provided by other entities. We believe that this new requirement will alleviate the demand on the hospice and facility medical directors while actively involving all members of the patient's care team, both within the hospice and the facility, in care planning and delivery.

Comment: Commenters expressed general support for the coordination of services requirement at proposed § 418.112(g), stating that it would have the greatest potential for strengthening the partnerships between hospices and SNFs/NFs and ICFs/MR. Several commenters suggested that we specify that the hospice provide the SNF/NF or ICF/MR with a copy of the hospice plan of care.

The commenters believe that requiring this would reinforce the fact that the hospice and the facility have separate, but coordinated plans of care for each patient. Other commenters suggested that, in addition to the original hospice plan of care, facilities should also be provided with updated plans of care. Still other commenters suggested that hospices should provide SNFs/NFs and ICFs/MR copies of each patient's initial certification and recertification of terminal illness forms.

Response: We appreciate the general support of this requirement. We agree that this standard, now at § 418.112(e), should specify that hospices provide facilities with the most recent hospice plan of care. This will ensure that facilities have the most current plan for what services the hospice is providing as well as what services they are committed to providing. We also agree that it is helpful for the hospice to provide the facility with a patient's certification and recertification forms. Having these forms on file will serve as a reminder to the facility that the patient is terminally ill and that he or she is a Medicare hospice beneficiary.

Comment: A few commenters sought clarification about what kind of physician orders hospices would provide to facilities. Other commenters suggested that we should take action to require SNFs/NFs and ICFs/MR to accept hospice physician orders.

Response: Although a large amount of the care decided upon by the hospice IDG does not require specific physician orders, certain elements of the plan of care, such as medications and laboratory work, do require physician orders. Whenever physician orders are issued, whether by the hospice physician or the attending physician in coordination with the hospice, a copy of those orders must be provided to the SNF/NF or ICF/MR in a timely manner. Providing a copy of physician orders to the SNF/NF or ICF/MR allows the staff of the facility to implement any portions of the order for which they may be responsible. Providing a copy of orders is simply another way in which the hospice keeps the SNF/NF or ICF/MR abreast of its hospice care activities. In the final rule at § 418.112(e)(3)(vii) we clarified that the ''physician orders'' supplied by the hospice are those issued by the hospice physician(s) and the patient's attending physician (if any). The acceptance of hospice physician orders by residential

facility staff is not within the purview of this rule. In its contract with the residential facility, the hospice is responsible for ensuring that the management of the residential facility communicates with its staff regarding the acceptability of hospice physician orders.

Comment: A majority of commenters who submitted recommendations on this CoP recommended that we revise the proposed requirement at § 418.112(i) regarding the training of staff of a SNF/NF or ICF/MR in hospice philosophy. Most of these commenters noted that a SNF/NF or ICF/MR may work with several different hospices and that facility staff should not be required to be oriented to hospice philosophy by every hospice. The commenters suggested that hospices be required to assure that the staff of the SNF/NF or ICF/MR has received the required training, rather than requiring each hospice to provide the training. One commenter suggested that the responsibility for orienting facility staff in hospice philosophy should fall to the facility, rather than the hospice.

Response: The intent of this proposed standard was to ensure that facility staff who furnish care to patients are provided information on the hospice philosophy and approach to care, much in the same way that home caregivers are routinely provided information on the hospice philosophy and approach to care. We agree that facility staff should not be oriented multiple times using the same basic information. Therefore, we have amended this requirement at new § 418.112(f) of the final rule to state that hospices must assure the orientation of facility staff.

At the same time, we note that the entire purpose for using outside hospices to furnish hospice care to facility residents is to fulfill a need that the facility is not able to fulfill on its own. If a facility is unable to provide hospice care because it lacks the capability to do so, then the facility is certainly not qualified to orient its staff in hospice philosophy. Furthermore, the facility would not be qualified to orient its staff in a particular hospice's policies and procedures, patient rights, forms, and record keeping requirements. In that case, the hospice working with the facility needs to provide information, guidance and/or staff to assure orientation of the facility staff.

Comment: Several commenters asked how frequently hospices are to be involved in offering training to facility staff, considering the high staff turnover rates of some facilities. Commenters also questioned who might be in the best position to coordinate the training sessions.

Response: It is the hospice's responsibility to coordinate the trainings with representatives of the facility. It is also the hospice's responsibility to determine how frequently training needs to be offered in order to ensure that the staff furnishing care to hospice patients are oriented to the philosophy of hospice care. Facility staff turnover rates should certainly be a consideration in determining training frequency.

Comment: A commenter disagreed with our proposed requirement that facility staff should be trained by hospices in hospice philosophy and care. The commenter stated that there is a ''spillover effect,'' whereby the training received by staff affects the care furnished to non-hospice patients as well as hospice patients. The commenter further stated that this ''spillover effect'' may not be desirable for those patients who do not choose to receive hospice care.

Response: While there may be a ''spillover effect'' when facility staff are oriented to hospice philosophy, we do not believe that the effect is inherently negative. The hospice philosophy focuses on using multiple treatment modes to make patients physically, emotionally, and spiritually comfortable. Providing comfort to residents, regardless of whether those residents receive hospice care or not, would positively impact their well-being. Therefore, we do not view a ''spillover effect'' as a problem that would warrant removal of the proposed facility staff orientation requirements.

Comment: A commenter suggested that hospices be required to educate the facility staff regarding the individualized plan of care for each hospice patient who resides in the facility.

Response: We agree with this suggestion. Section 418.56(b) of this rule, ''Plan of care,'' requires hospices to ensure that each patient and his or her primary caregiver(s) receives education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care. Facility staff members acting as the patient's primary caregivers are expected to receive education specific to each patient's hospice plan of care and the caregiver's role in implementing the content of the hospice portion of the plan of care.

Comment: A commenter suggested that hospices should be required to orient facility administrative staff as well as the staff who furnish care to hospice patients that reside in the facility.

Response: With the facility's consent, hospices may orient facility administrative staff as well as hands-on care staff. However, we do not believe that this orientation should be required because it is unlikely to improve patient care or outcomes.

Comment: A commenter asked for a definition of the term ''nursing facility.''

Response: Our use of the abbreviation ''SNF/NF'' refers to the long term care facilities referenced at 42 CFR part 483, where skilled nursing facilities (SNF) and nursing facilities (NF) are described.

Comment: Many commenters stated that this section of the rule should require SNFs/NFs and ICFs/MR to contract with any hospice that a resident chooses. Many other commenters stated that hospices should be prohibited from contracting with SNFs/NFs and ICFs/MR that do not contract with all interested hospices.

Response: As noted above, these CoPs regulate hospices, not SNFs/NFs and ICFs/MR. We are not proposing mirroring requirements for Medicare/Medicaid facilities at this time. We also note that we do not have jurisdiction or authority to regulate facilities that do not participate in Medicare or Medicaid. In addition, even though these CoPs do regulate hospices, we do not believe that it is appropriate to preclude hospices from contracting with certain SNFs/NFs or ICFs/MR because the facility chooses to be selective in its contracting decisions. Indeed prohibiting hospices from contracting with selective SNFs/NFs and ICFs/MR could deny residents of those facilities any access to hospice care furnished by Medicare-approved hospices. We believe that this would be a disservice to those residents.

Comment: Some commenters took issue with the requirement that, when hospice services are furnished to Medicaid eligible SNF/NF residents, the hospice receives payment from Medicaid for room and board care and is responsible for paying the SNF/NF for this service.

Response: Payment and billing procedures are not within the scope of these CoPs. We have shared this comment with the appropriate officials within CMS, and it will be taken under advisement.

Comment: A commenter suggested that hospices should be required to notify hospice patients who reside in a SNF/NF or ICF/MR that Medicare does not pay for room and board for a patient who is receiving the routine home care level of hospice care.

Response: The commenter is correct that Medicare does not pay for room and board. We believe that Medicare coverage of services under the hospice benefit is already addressed by § 418.52(c)(7), stating that patients have the right to ''[r]eceive information about the services covered under the hospice benefit.'' We do not believe that it is necessary to require hospices to provide a separate notice in writing regarding Medicare non-coverage of a patient's room and board in a SNF/NF or ICF/MR.

Comment: Many commenters had questions about the proposed core services requirement at § 418.112(c), which would have required hospices to routinely provide all core services to hospice patients who are residents of SNFs/NFs or ICFs/MR. Some commenters wanted to know if this requirement was the same as proposed § 418.64, ''Core Services.'' If so, the commenters suggested that it should be deleted because it is duplicative and unnecessary. Other commenters asked if it would be permissible to use staff of the SNFs/NFs or ICFs/MR to furnish core services to hospice patients. A single commenter suggested that, for clarity, we should add the word ''work'' to the term ''medical social'' to clarify that hospices must provide medical social work services to patients who reside in SNFs, NFs, or ICFs/MR.

Response: Hospices that furnish hospice services to residents of a SNF/NF or ICF/MR are required to furnish core services to those residents under the same requirements and in the same manner as those services are furnished to patients residing in their own homes. The core services requirement at § 418.64 applies equally to both facility and community residents. We agree that it is not necessary to state the same requirements in both § 418.64 and § 418.112. Therefore, the core services standard in § 418.112 has been removed.

Since the core services requirement at § 418.64 applies, regardless of where services are provided, hospices are not permitted to routinely delegate hospice services to the staff of a SNF/NF or ICF/MR. Hospices are required to routinely provide substantially all core services directly. Hospices may only provide core services under arrangement if they meet the conditions for an extraordinary circumstance exemption described in § 418.64, the nursing services waiver described in § 418.66, or the nursing shortage waiver described in CMS S&C letter 05–02.

Comment: Numerous commenters asked us to clarify or delete the proposed requirement at § 418.112(h), ''Transfer, revocation, or discharge from hospice care.'' Most of these commenters stated that this requirement should be deleted because hospices have no authority to govern the discharge actions of SNFs/NFs and ICFs/MR, thereby making it very difficult for hospices to comply with the requirement. Some commenters suggested that the intent of the standard should be clarified. One commenter suggested that we should add the following statement to the end of the requirement: ''It is believed that patients should not experience the trauma of an external move because they perhaps have stabilized and may not continue to be eligible for hospice.''

Response: We agree that resident eligibility is not within the control of the hospice, and this requirement has been removed. Absent this requirement, the discharge requirement set forth in § 418.104(e) continues to apply to any hospice patients who reside in a SNF/NF or ICF/MR. The requirements of § 418.104(e) do not place any requirements on residential facilities serving as a patient's home.

Comment: A large number of commenters stated that it would be difficult for hospices to implement the requirements of this CoP without the inclusion of complementary requirements in the long term care CoPs at 42 CFR part 483. Some commenters suggested that we should not issue this CoP until the complementary requirements are included in the long term care CoPs, while other commenters suggested that we should add a phase-in period for this CoP to allow the long term care CoPs to ''catch-up'' to this hospice CoP. Still other commenters suggested that this CoP should be issued as planned, but that survey enforcement of its requirements should understand that not all provisions can be adequately implemented until the long term care CoPs agree with those for hospices.

Response: Upon issuance of this final rule we intend to issue a proposed rule to add a new requirement to the long term care CoPs at § 483.75(r). This proposed rule would describe:

- The manner in which long term care facilities may furnish hospice services to their residents;
- The minimum content of the written agreement between the long term care facility and the hospice;
- The conditions under which the long term care facility must contact the hospice;
- The participation and coordination of the long term care facility in care planning and delivery; and
- The information that the long term care facility must obtain from the hospice.

We agree that, without this requirement in the long term care facility regulations, it will be challenging for hospices to comply with the requirements of this CoP. We will work with the hospice and long term care industries to address any situations that may occur during the intervening time period.

Comment: Several commenters sought clarification about how surveyors would determine accountability for negative patient outcomes when patients were both hospice patients and residents of a SNF/NF or ICF/MR.

Response: Hospices are responsible for all hospice care and services provided to a patient, regardless of where that patient resides. Hospices are also responsible for coordinating the plan of care for a particular patient with representatives of the facility where the patient resides to ensure that both the hospice and facility are aware of their respective patient care responsibilities. Furthermore, hospices are responsible for ensuring that the terms of the arrangement established between the hospice and the facility are met to ensure patient care and safety at all times. We expect hospices to fulfill their responsibilities at all times and for all patients. If a hospice does not fulfill its responsibility and take all appropriate actions to ensure the health and safety of its patient in accordance with the requirements of this final rule, then that hospice will be held accountable for its actions. We note that these final provisions do not propose to judge hospices on ''negative patient outcomes'' except to the extent that those outcomes are connected with regulatory non-compliance.

Comment: Several commenters noted that the interpretive guidelines that surveyors will use to ensure compliance with this CoP needs to provide further detail regarding provider responsibilities for individual aspects of hospice care.

Response: We agree that additional detail is needed and we will take this suggestion under advisement as we develop interpretive guidelines for this regulation.

Comment: A commenter suggested that frequent onsite verification of hospice agency compliance with this proposed CoP is the best way to ensure that hospices are fulfilling their regulatory obligations.

Response: State surveyors are required to survey long term care facilities annually. These surveyors have already been directed to report issues involving long term care facility residents who are hospice patients to their hospice surveyor counterparts for

follow-up with the hospice. We believe that using hospice survey resources to focus on potential problems is preferable to randomly surveying hospices where issues involving long term care facility residents have not appeared.

Comment: Several commenters suggested that we address the responsibilities of the attending physician in caring for residents of a SNF/NF or ICF/MR who receive hospice services. The commenters suggested that the attending physician be responsible for coordinating the patient's care and communicating with hospice and facility physicians.

Response: We do not have the authority to regulate the actions of a patient's attending physician who is not an employee of or under contract with the hospice through this hospice rule. If a patient has an attending physician who is actively involved in his or her care, then the hospice is required to consult the attending physician in developing and updating the patient's hospice plan of care. The hospice may use this consultation with the attending physician to gather information about other care and services the patient is receiving from the facility where the patient resides and from any other health care providers. The hospice may not delegate its responsibility to coordinate the patient's hospice care to the attending physician.

Comment: A commenter asked if the medical director of a SNF/NF or ICF/MR may also be the medical director of a hospice.

Response: These regulations do not prohibit this arrangement.

Comment: A commenter suggested that the interpretive guidelines should allow the medical director of the SNF/NF to relinquish or assume secondary professional responsibility for coordinating the medical care for residents who elect the hospice benefit.

Response: As discussed above, we have deleted the proposed medical director requirement at proposed § 418.112(d), including the requirement that the hospice medical director must provide overall coordination of the medical care of the hospice patient residing in a SNF/NF or ICF/MR. We have replaced it with the requirement of the final rule at § 418.112(e)(1) that a member of the IDG coordinate the patient care and services with the facility.

22. Condition of Participation: Personnel Qualifications (§ 418.114)

We proposed significant revisions to the personnel qualifications for hospice employees. Specifically, we proposed to provide that in cases where personnel requirements are not statutory, or do not relate to a specific payment provision, personnel would only be required to meet State certification or licensure requirements.

In § 418.114(a), ''General qualifications,'' we proposed that licensed professionals who provide hospice services directly, either as employees or under individual contract, or under arrangement with a hospice must be licensed, certified, or registered to practice by the State in which they perform the functions, as applicable. All personnel who fall into this category must act exclusively within the scope of the State license, certification or registration. In proposed § 418.114(b), ''Personnel qualifications for physicians, speech-language pathologists, and home health aides,'' we proposed to include those personnel requirements that are included in the Act.

When a State does not have a licensure, certification, or registration requirement, the hospice would apply the qualifications in proposed § 418.114(c), ''Personnel qualifications when no State licensing laws or State certification or registration requirements exist.'' This category would consist of all personnel qualifications specified in existing § 418.3, ''Definitions,'' including a requirement that a social worker have a baccalaureate degree from a school of social work accredited by the Council on Social Work Education (proposed § 418.114(c)(7)).

In § 418.114(d), we proposed a new requirement that a hospice obtain a criminal background check for all hospice and contract employees before employment at the hospice. We believe that this is an important safety measure to protect both patients and the hospice. We did not propose any specific type, scope, or frequency requirements for completing the background check.

Comment: A commenter noted that the proposed title of this CoP is ''Personnel qualifications for licensed professionals,'' and that this title could be interpreted as to apply only to those individuals for whom licensure is available. As such, the commenter reasoned, the criminal background check requirement would not apply to unlicensed individuals.

Response: Our intent, as stated in the proposed rule, is for all appropriate individuals to have background checks. We have removed the phrase ''for licensed professionals'' from the title of this CoP to avoid any confusion in this area.

Comment: Several commenters supported the proposed requirement that, if a State offers licensure for any discipline, including social workers, the individuals practicing within that discipline must obtain State licensure. One commenter even suggested that social workers should be required to obtain the highest level of State licensure available to them. However, a few commenters disagreed, stating that social workers should not be required to obtain State licensure.

Response: The existing hospice requirements at § 418.72 require employees who provide services to be licensed, certified, or registered in accordance with applicable Federal and State laws. We believe that it is necessary to maintain this requirement in this final rule to ensure that the individuals furnishing services to hospice patients are legally authorized to furnish care in their respective disciplines. We believe that State licensure, certification and/or registration, where required by State law or regulation, help to ensure that individuals are qualified to furnish safe and effective care to patients and families. As professionals and equals among the IDG members, we believe that it is necessary to require social workers to meet the same licensure qualifications that all other hospice professionals are required to meet.

Comment: The majority of commenters who submitted comments on our proposed personnel qualifications section made suggestions to revise the requirements for social workers. While some of these commenters agreed with our proposal to defer to State requirements for social workers, the majority of commenters believed that all hospice social workers should be required to meet the same basic qualifications. Of these commenters, many suggested that hospice social workers should be required to have a baccalaureate degree in social work from an accredited higher education institution. Other commenters suggested that a baccalaureate or higher degree in a field related to social work, such as psychology, would be an appropriate qualification for hospice social workers, while some commenters explicitly disagreed with this suggestion. Numerous other commenters suggested that hospice social workers should be required to have a Master of Social Work (MSW) degree from an accredited university. Of these commenters, several suggested that a waiver should be granted for hospices in rural areas to allow them to use the services of a social worker with a baccalaureate degree under the supervision of an MSW or a licensed mental health

professional with a graduate degree. Still other commenters suggested that, regardless of the degree that the social worker holds, he or she should be required to have one or two years of social work experience in a health care setting. Some commenters explicitly disagreed with this suggestion.

Response: The large number of public comments submitted in reference to the personnel requirements for social workers, coupled with the divergent views expressed in the comments, leads us to believe that there is no standard or consensus in the hospice industry on this issue. Our goal is to balance the needs of patients and families at a very stressful time and the needs of hospices that may have difficulty employing personnel who meet appropriate personnel standards. We believe that all hospices should strive to employ the most qualified individuals possible to provide social work services to patients and families. In order to ensure that hospices employ a qualified individual as a social worker, we are requiring that a hospice social worker must at least meet one of the following options:

- Have a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education, and one year of experience in a health care setting;
- Have a baccalaureate degree in social work (BSW) from a school of social work accredited by the Council on Social Work Education, and one year of experience in a health care setting; or
- Have a baccalaureate degree in psychology, sociology, or other field related to social work, and at least one year of social work experience in a health care setting.

If a hospice chooses to employ a social worker with a baccalaureate degree in social work, psychology, sociology, or other field related to social work, the services of that baccalaureate social worker must be provided under the supervision of a social worker with an MSW from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting. We believe that requiring MSW supervision of BSW services will help ensure that patient and family needs are met in a complete and timely manner. The MSW supervisor role is that of an active advisor, consulting with the BSW on assessing the needs of patients and families, developing and updating the social work portion of the plan of care, and delivering care to patients and families. This supervision may occur in person, over the telephone, through electronic communication, or any combination thereof.

Social workers with a baccalaureate degree from a school of social work accredited by the Council on Social Work Education and who are employed by the hospice before the effective date of this final rule are exempted from the MSW supervision requirement. Therefore, if a hospice currently employs a BSW, unsupervised by an MSW, it is not required to hire an MSW to supervise the BSW. If a hospice hires a new social worker with a baccalaureate degree and one year of experience in a health care setting, then the new baccalaureate social worker must be supervised by an MSW who has one year of experience in a health care setting.

Comment: Many commenters suggested that the final rule should include personnel qualifications for chaplains. Commenters suggested that education (that is, a baccalaureate and graduate-level divinity or theological degree from a university accredited by the Council of Higher Education Accreditation and/or 4 units of clinical pastoral education), experience in the medical field, certification from a national organization, or any combination thereof would be appropriate to qualify a chaplain to care for hospice patients. Other commenters explicitly disagreed with this suggestion, stating that the final rule should not include personnel qualifications for chaplains or require them to be licensed or certified.

Response: Hospices may choose to employ the individual(s) best suited to meet the needs of the hospice and its patients. If a hospice chooses to employ a chaplain, it may choose to use any criteria in selecting the appropriate candidate. We do not believe that it is appropriate to require hospices to use specific criteria to guide the selection of a spiritual counselor. Rather, the needs of the hospice's patient population should drive the selection of the appropriate person.

Comment: A commenter suggested that, if physical therapist assistants furnish care to hospice patients, they should be required to be under the supervision of a physical therapist.

Response: As a general statement, hospices are required to furnish physical therapy services in a manner consistent with accepted standards of practice. In addition, physical therapists and assistants are required to act only within the scope of their State license, certification, or registration. We believe that these requirements ensure that physical therapy services are provided in a safe and effective manner by and under the supervision of the appropriate personnel.

In this final rule we are incorporating changes made by a separate final rule (72 FR 66222, 66406, November 27, 2007) to the personnel qualifications for physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, and speech-language pathologists. That final rule amended § 418.92 of the existing hospice regulations to cross reference the revised personnel requirements contained in 42 CFR 484.4, thereby requiring physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, and speech-language pathologists subject to the requirements of the hospice conditions of participation to meet the same personnel requirements as therapists subject to the requirements of the home health agency conditions of participation. In this final rule, we continue to require therapists who are subject to the requirements of the hospice conditions of participation to meet the same personnel requirements as therapists subject to the requirements of the home health agency conditions of participation, as was required by the November 27, 2007 final rule.

We believe that these revised requirements, which went through the notice-and-comment rulemaking process separate from and more recently than the hospice conditions of participation continue to allow hospices the flexibility to employ or contract with individuals who are well qualified to provide therapy services to hospice patients. However, we are replacing the cross reference to the requirements of 42 CFR part 484 with a duplicate of the requirements of § 484.4. We believe that duplicating the relevant requirements of § 484.4 in § 418.114(b)(4)–(8) will make it easier for hospices to know the personnel requirements that their therapists must meet in order to be considered qualified to provide services to hospice patients.

Comment: A commenter suggested that we should incorporate the definition of the term ''licensed professionals'' from the home health regulations at 42 CFR part 484 in the personnel requirements for registered nurses at § 418.114(c).

Response: The home health regulations at 42 CFR part 484 do not define the term ''licensed professionals''; therefore we cannot incorporate this suggestion into the final rule.

Comment: Some commenters suggested that we should add personnel qualifications for nurse practitioners.

Response: Section 1861(aa)(5) of the Act describes a nurse practitioner for

purposes of Medicare as an individual ''who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.'' A Medicare-participating hospice that employs a nurse practitioner is expected to comply with these statutory requirements, and we believe that they are sufficient.

Comment: Numerous commenters sought clarification about who was required to have a criminal background check. Some commenters suggested that volunteers should not be required to have a background check, while others suggested that only those individuals who provide direct patient care and/or who have access to patient financial information should be required to have background checks. Furthermore, some commenters suggested that only unlicensed hospice personnel should be required to have criminal background checks. Other commenters wanted to know if hospices would be required to obtain background checks on current employees, or only for employees hired after the effective date of this final rule. Still other commenters wanted to know if background checks were needed for individuals employed by a DME supplier or pharmacy that the hospice has a contract with. Some commenters suggested that, if background checks are required for contractors, the contracted entity would be the most appropriate entity to complete criminal background checks for its employees.

Response: We believe that any individual who has direct patient contact or has access to a patient's records, clinical, financial or otherwise, should have a criminal background check because these individuals are in a position that enables them to violate patient rights to both safety and privacy. This includes all current paid hospice employees, volunteers, and contracted employees, as well as any new employees. If an office employee, such as a receptionist, does not have access to patient records, and does not make patient visits, then that employee is not required to have a criminal background check. If a volunteer is a homemaker, and thus has direct patient contact, he or she is required to have a background check. We understand that hospices would likely not actually conduct background checks on contracted employees. We have added a statement to § 418.114(d)(1) that hospices must require, as part of their written agreement with a contractor, that the contractor provides the hospice a background check for each contracted employee who has direct hospice patient contact or access to hospice patient records. We believe that requiring all individuals who have direct patient contact or access to patient records to have background checks will help hospices assure that patient rights are protected at all times.

Comment: Many commenters suggested that the requirements for criminal background checks (that is, scope, frequency, timing, etc.) should apply only in the absence of State requirements. Other commenters suggested that the timeframe for completing a criminal background check should be lengthened because it may take a few weeks to receive a background check from the State police and/or FBI. Still other commenters suggested that the scope of this requirement should be clarified.

Response: We agree that if a State has particular laws or regulations requiring criminal background checks for hospice employees and contractors, then hospice compliance with such State requirements satisfies the intent of this requirement. If a State does not have any requirements, or does not have requirements for a specific discipline, then the requirements of this final rule must be met. In this final rule, we require hospices to obtain a criminal background check within three months of the date of employment for all states that the individual has lived or worked in for the past three years. We believe that it is essential to gather information on the individual's activities in several states to ensure that the criminal background check presents a complete and accurate picture of the individual's compliance with the law. In order to gather such information while allowing hospices to fill vacant positions in a timely fashion, we believe that it is necessary to alter the proposed timeframe from ''before employment'' to ''within three months of the date of employment. * * *'' Therefore, if a State requires a registered nurse to have a State police background check completed within six months of employment, and the hospice complies with this State requirement when conducting background checks on its nurses, then the hospice is in compliance with this final rule even though the state standard is not as stringent. If that same State does not have requirements for background checks of physicians, then the hospice must obtain a criminal background check within three months of the date of employment for all states that the physician (paid, volunteer, or contracted) has lived or worked in for the past three years.

Comment: A few commenters sought clarification on the relationship between the background check obtained by the hospice and the background check conducted by the State licensing body.

Response: Many States require a criminal background check before a health care practitioner can obtain a State license, and some of these states require background checks to be updated when the license is renewed. However, not all states have a background check requirement in place for licensing. As described above, if a State has criminal background check requirements for a specific discipline, and the hospice complies with the State requirements for that discipline, then the hospice is in compliance with this Federal criminal background check requirement. This means an individual does not need a criminal background check if his or her license is current and State licensure requires a background check. If a State does not have such criminal background check requirements, then the hospice must comply with the Federal requirements described above.

Comment: One commenter suggested that we should delay implementing the criminal background check requirement until completion of the background check demonstration project called for by the MMA.

Response: While the results of the MMA background check demonstration project may provide further clarification on the particulars of implementing background check requirements in health care, we do not believe that it is appropriate to delay this important requirement. Hospices must make informed decisions regarding the staff (paid, volunteer, and contracted) that they use to care for patients. Without such vital information patients become vulnerable, and this can lead to negative patient outcomes.

Comment: Some commenters noted that obtaining background checks will have a financial impact on hospices, while others noted that requiring volunteers to submit to background checks may decrease the number of willing volunteers.

Response: We understand that obtaining background checks will have some degree of financial impact on hospices. We believe that this impact will be offset by a decreased level of hospice liability. Hospices will be able to exclude those individuals who may pose a threat to hospice patients, thereby decreasing the likelihood of

patient's rights violations and/or criminal and civil litigation.

We also understand that some volunteers may perceive a criminal background check as an affront. However, we believe that explaining that background checks are a precaution that everyone must take, and that background checks are not meant to single anyone out, will ease volunteer concerns and not deter them from offering their time and services to hospices.

Comment: A few commenters asked us to prescribe the exact offenses that would preclude a hospice from employing a certain individual. A commenter also asked us to include a waiver for individuals who have been reformed as well as protections for hospices to choose to terminate an individual's employment based on the results of the criminal background check.

Response: We do not believe that it is appropriate to prescribe the circumstances under which an individual must be precluded from hospice employment on the basis of his or her criminal background check results. Hospices should consult applicable labor laws and regulations when developing their own policies and procedures for implementing the criminal background check requirement. In addition, hospices should inform current and prospective direct employees (including volunteers) and contracted employees about their criminal background check policy. We believe that a well-designed and openly implemented policy will help hospices choose the individuals best suited for hospice employment and service.

Comment: A commenter suggested that the section for personnel requirements should be re-located to the beginning of the rule, rather than its proposed location at the end of the rule.

Response: This rule is organized into two subparts, Subpart C—Patient Care, and Subpart D—Organizational environment. Subpart C contains the conditions of participation related to providing direct patient care, while Subpart D contains the conditions of participation related to the administration of a hospice. Since the requirements for personnel qualifications relate more to the administration of a hospice than to the delivery of direct patient care, we believe that it is appropriate to keep the personnel qualifications section in its proposed location.

23. Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations Related to the Health and Safety of Patients (§ 418.116)

The provisions concerning licensure requirements for hospices are currently located at § 418.72, ''Condition of participation: Licensure.'' We proposed to expand this condition by making a minor revision to the language at existing § 418.72(a), requiring the hospice and its staff to operate and furnish services in compliance with all Federal, State, and local laws and regulations applicable to hospices related to the health and safety of patients.

Under § 418.116(b), ''Satellite locations,'' we proposed to continue to require that the hospice comply with the requirements of § 420.206 regarding disclosure of ownership and control information. We also proposed that the hospice and any other satellite locations operated under the same provider number be licensed in accordance with applicable State licensure laws before the hospice could be reimbursed for Medicare services. This proposed provision would apply to the hospice as an entity, as well as to any personnel furnishing services to hospice patients. We proposed to recodify the current requirements at § 418.92(b), regarding laboratory services, at § 418.116(c).

Comment: We received a minimal number of comments on the proposed rule concerning multiple location requirements in this section. The commenters requested that hospices be allowed to have multiple locations (previously known as satellite locations) and also asked about the procedures for the approval of such locations.

Response: As previously noted in this preamble, we have deleted the term ''satellite'' and replaced it with ''multiple locations.'' Hospices are permitted to operate in multiple locations if they meet the requirements set forth in § 418.3 and § 418.100(f). The definition of ''multiple location'' as defined in § 418.3 is ''a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.'' The multiple location is part of the hospice and shares administration, supervision, and services with the hospice that was issued the certification number. In § 418.100(f) we state that all multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients. The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care. Procedures for requesting CMS approval of a multiple location will be set forth in the hospice interpretive guidelines, which will be made available after this final rule has been published. The interpretive guidelines will provide sub-regulatory instructions and parameters which will apply to multiple locations.

III. Provisions of the Final Regulations

In this final rule we are adopting the provisions as set forth in the May 27, 2005 proposed rule with the following revisions. We have—

1. Definitions (§ 418.3)

- Deleted proposed revisions to the definition of the term ''attending physician.''
- Amended the definition of ''bereavement counseling'' by adding the term ''before and''.
- Revised the definition of ''clinical note.''
- Added a definition of the term ''comprehensive assessment.''
- Added a definition of the term ''dietary counseling.''
- Deleted the definition of the term ''drug restraint.''
- Added a definition of the term ''initial assessment.''
- Amended the definition of ''licensed professional.''
- Amended the name and definition of ''satellite location,'' now referred to as ''multiple location.''
- Added a definition of the term ''physician.''
- Added a definition of the term ''physician designee.''
- Revised the definition of ''restraint,'' incorporating definitions of the terms ''restraint'', ''drug restraint'', and ''physical restraint'' into a single definition.
- Revised the definition of ''seclusion.''
- Deleted the definitions of the terms ''physical restraint'' and ''progress note.''

2. Condition of Participation: Patient's Rights (§ 418.52)

- Renamed 418.52(a) ''Notice of rights and responsibilities.''
- Revised the phrasing of § 418.52(a)(1).
- Redesignated and revised proposed § 418.52(a)(3) to § 418.106(e)(2)(i).
- Redesignated and revised proposed § 418.52(a)(4) as § 418.52(a)(3).

• Revised § 418.52(b)(4) to clarify the hospice's responsibility for investigating and reporting violations of patient rights.

• Renamed and revised section 418.52(c) ''Rights of the patient'' to include several new patient rights.

• Deleted § 418.52(d) ''Confidentiality of clinical records'' (now at 418.52(c)) and § 418.52(e), ''Patient liability.''

3. Condition of Participation: Initial and Comprehensive Assessment of the Patient (§ 418.54)

Revised the stem statement.

Revised § 418.54(a) to clarify the assessment timeframe.

Revised § 418.54(b) to clarify the role of the patient's attending physician, and expand the timeframe for completing the comprehensive assessment.

Revised § 418.54(c) to include new factors that must be considered during all comprehensive assessments. The new factors are functional status, imminence of death, and severity of symptoms.

Renumbered § 418.54(c)(3)(ii) as § 418.54(c)(6), and revised the title of this section as ''Drug Profile.'' We also revised the factors that hospices must consider in the drug profile assessment.

Revised the requirements for the ''bereavement assessment'' now at § 418.54(c)(7) to require that a hospice incorporate information gathered from the initial assessment into the patient's plan of care and consider such information when developing the bereavement plan of care.

Revised § 418.54(d) to require an update of the comprehensive assessment at least every 15 days. We also deleted the requirement that the comprehensive assessment be updated at the time of each recertification.

4. Condition of Participation: Interdisciplinary Group, Care Planning, and Coordination of Services (§ 418.56)

Revised the stem statement.

Revised § 418.56(a)(1) to maintain consistent terminology throughout the rule. In addition, we retained the existing hospice rule provision that requires the hospice to designate a registered nurse that is a member of the IDG to coordinate patient care, assessment, and care plan implementation.

Revised the IDG requirements at § 418.56(a)(1)(i) to require that the physician member of the IDG be an employee of or under contract with the hospice. We also revised § 418.56 (a)(1)(iv), to retain the existing hospice requirement that the hospice IDG must include a pastoral or other counselor.

Revised § 418.56(a)(2) regarding the members of the IDG responsible for developing day-to-day hospice policies and procedures.

Revised § 418.56(b) to clarify that a patient's plan of care must be individualized to his or her needs and circumstances. Additionally, we revised this section to require a hospice to involve the patient and primary caregiver in developing the plan of care in accordance with the patient's needs. We also clarified which individuals must be educated and trained by the hospice in implementing the plan of care, as well as the extent of that education and training.

Revised § 418.56(c) to specify that the written plan of care must be individualized. We also added a provision that the plan of care must reflect patient and family goals.

Revised § 418.56(c)(1) to simplify the phrasing of the requirement.

Removed the term ''targeted'' from § 418.56(c)(3) to simplify its phrasing.

Revised § 418.56(c)(6) by changing ''family'' to ''representative.''

Revised § 418.56(d). We removed specific mention of the role of the hospice medical director or physician designee in updating each patient's plan of care. We also revised the timeframes for updating the plan of care to at least every 15 days. Additionally, we added a requirement that the IDG must note the patient's progress toward specified goals when updating in the plan of care.

Made several minor revisions to § 418.56(e) that do not change the intent of the proposed and added a new requirement that hospice coordination and communication systems must ensure that information is shared with non-hospice health care providers furnishing services to patient.

5. Condition of Participation: Quality Assessment and Performance Improvement (§ 418.58)

Removed the phrase ''focuses on the end-of-life support services provided'' from § 418.58.

Replaced the phrase ''end-of-life support services'' with ''hospice service'' in § 418.58(a). In addition, we replaced the phrase ''for which there is evidence that improvement in those indicators will improve palliative outcomes'' with the phrase ''related to improved palliative outcomes.''

Revised § 418.58(b) to clarify our intent. In § 418.58(b)(2)(ii), we incorporated a requirement that quality indicator data must be used to identify priorities, as well as opportunities, for improvement. In § 418.58(b)(3), we replaced the term ''specified'' with the term ''approved'' to clarify that the governing body is not necessarily the entity that establishes data collection specifications.

Added a 240-day phase-in period to § 418.58(d) to allow hospices more time to collect the initial program data.

Revised § 418.58(e) by adding a requirement that the governing body annually evaluates the hospice's QAPI program. We also added a requirement that the hospice governing body must identify at least one individual who is responsible for operating the QAPI program. Deleted proposed § 418.58(e)(3) regarding expectations for patient safety.

6. Condition of Participation: Infection Control (§ 418.60)

Expanded the scope of the hospice's infection control program to protect visitors as well as patients, families and hospice personnel.

Replaced the term ''staff'' in proposed § 418.60(c) with the terms ''employees'' and ''contracted providers.''

7. Condition of Participation: Licensed Professional Services (§ 418.62)

Revised § 418.62(b) to clarify that licensed professionals providing care to hospice patients must actively participate in the coordination of all aspects of the patient's hospice care.

8. Condition of Participation: Core Services (§ 418.64)

Revised § 418.64 to permit hospices to utilize contracted staffing sources under extraordinary or other non-routine circumstances (for example, unanticipated periods of peak patient loads, short-term staffing shortages that interrupt patient care, and patient travel). Deleted the proposed requirement at § 418.64(a) that hospice physicians be responsible for meeting a patient's general (that is, non-hospice) medical needs.

Replaced the term ''nurse practitioner'' with ''registered nurse'' in § 418.64(b)(2). We also deleted the proposed requirement at § 418.64(b)(2) that the role and scope of nurse practitioner services be separately specified in the plan of care.

Revised the requirements in § 418.64(d) to clarify the role of counseling services, requiring that hospices make available counseling services, ''* * * to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process.''

Revised § 418.64(d)(1)(i) to permit individuals with education (as well as experience) in grief/loss counseling to supervise a hospice's bereavement

program. Furthermore, we revised § 418.64(d)(1)(ii) by removing the term ''other facility'' and removing the requirement that hospices must offer bereavement services to facility staff. We also revised § 418.64(d)(1)(iv) by changing ''provided'' to ''offered.''

Revised § 418.64(d)(2), renaming it ''Dietary counseling,'' to be more consistent with the terminology used throughout the rest of the rule.

Revised section 418.64(d)(3)(iii) by removing the statement that hospices are not required to go to extraordinary lengths to facilitate clergy, pastoral, or other visits from this section. We added language that indicates that hospices must make all reasonable efforts to facilitate such visits.

9. Condition of Participation: Nursing Services—Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice (§ 418.66)

Removed the requirement at proposed § 418.66(d) that CMS may approve a maximum of two 1-year extensions for each initial waiver.

10. Condition of Participation: Waiver of Requirement—Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Dietary Counseling (§ 418.74)

Revised § 418.74(d) by removing the requirement at 418.66(d) that CMS may approve a maximum of two 1-year extensions for each initial waiver.

11. Condition of Participation: Hospice Aide and Homemaker Services (§ 418.76)

Revised § 418.76 by changing its name from ''Home health aide and homemaker services'' to ''Hospice aide and homemaker services.''

Revised § 418.76(a)(ii) to clarify that the evaluation program used to measure aide competency must meet the specific requirements of § 418.76(c) of this section. Clarified that the training or competency evaluation programs referred to in § 418.76(a)(2) are those programs described in § 418.76(a)(1).

Added an option in § 418.76(a)(1), that a hospice aide may be considered qualified if the aide has completed a training and competency evaluation program in accordance with the content and specifications of the nurse aide training program requirements for long term care facilities at 42 CFR part 483.

Revised the language in § 418.76(b)(1) to describe the training that hospice aides must complete. The revised requirement states that, ''[h]ospice aide training must include classroom and supervised practical training.''

Revised § 418.76(c)(1) to clarify that a competency evaluation program is required to address the areas identified in § 418.76(b)(3) of this section, rather than the requirements of § 418.76(b)(1) through § 418.76(b)(3). Revised the requirement in § 418.76(c)(4) to specify that an aide is not considered to have successfully completed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one required area.

Deleted the proposed requirement in § 418.76(d) that an organization excluded by § 418.76(f) would be excluded from offering in-service training to hospice aides. This paragraph continues to exclude certain organizations from initially training hospice aides.

Revised § 418.76(e) to clarify that the requirements of this section apply to instructors providing both classroom and supervised practical training. We are no longer applying the requirements of this standard to those individuals performing competency evaluations or in-service trainings. Third, we clarified the description of the training instructor by rearranging the language and clarifying that one year of the trainer's health care experience would be in the broad home care environment (that is, hospice or home health care), rather than in the more specific home health care environment.

Revised § 418.76(f) to state that any home health agency that, within the last two years, was out of compliance with the requirements of paragraphs § 418.76(b) or § 418.76(c) of this section was not eligible to train hospice aides, except with respect to in-service training.

Deleted the proposed language in 418.76(g)(1) that an appropriate qualified therapist may make hospice aide assignments or supervise hospice aides. Also in section 418.76(g)(1), we added a new specification requiring the nurse who makes aide assignments for a specific aide and patient to be a member of that patient's hospice IDG.

Revised § 418.76(g)(2) to indicate that the hospice IDG as a whole may order aide services.

Revised § 418.76(h) by removing references to qualified therapists.

Clarified the purpose of the every 14 day aide supervision visit in § 418.76(h)(1)(i).

Added a provision in § 418.76(h)(1)(ii) stating that if during the supervision visit the nurse supervisor notes a potential area of concern regarding the way in which hospice aide services are being furnished, then the supervising registered nurse must make an on-site visit to the patient when the hospice aide is present, to observe and assess the aide while he or she is performing care.

Added § 418.76(h)(1)(iii) to clarify these problems identified during any hospice aide supervisory visits that cannot be resolved at that time by the supervising registered nurse, the hospice aide must complete a competency evaluation in accordance with § 418.76(c). We also redesignated § 418.76(h)(2) as § 418.76(h)(3). We added a new section 418.76(h)(2) to require a hospice registered nurse to make an annual on-site visit to observe each hospice aide furnishing aide services to at least one patient. Hospices may determine the appropriate location to document this annual aide evaluation in accordance with their own policies and procedures.

Deleted proposed 418.76(h)(3).

Added a provision in § 418.76(i)(2) that the individuals providing Medicaid personal care aide services may only be used by the hospice in implementing a patient's plan of care to the same extent that the hospice would routinely use a patient's family in implementing the plan of care.

Added a provision in § 418.76(i)(3) that a hospice must coordinate its hospice aide and homemaker services with the personal care aide services provided by Medicaid to ensure that patient needs are met.

Reorganized § 418.76(j) to clarify that homemakers must either meet the standards of § 418.202(g) (in 42 CFR 418 Subpart F Covered Services) and complete hospice orientation, or meet the requirements for hospice aides at § 418.76 as indicated in revised § 418.76(j)(2). There are no substantive changes to this paragraph.

Revised the qualifications for the supervision of homemakers in § 418.76(k) to require that such services be supervised by the same member of the IDG who coordinates the services.

12. Condition of Participation: Organization and Administration of Services (§ 418.100)

Revised the requirements of § 418.100(a) and § 418.100 (a)(1) to make clear that hospices must structure their operations to fully serve patients and families at the end of life.

Clarified then relationship between a hospice's governing body and administrator in § 418.100(b) by adding a provision that the administrator must be appointed by the governing body.

Revised the requirement in § 418.100(e) to state that hospices must maintain oversight responsibility for services furnished under contract.

Revised the requirement in § 418.100(e)(2) that contracted services

be provided by personnel having at least the same qualifications as hospice employees with a requirement that contracted services by provided by qualified personnel.

Revised and reorganized § 418.100(f) by replacing the term ''satellite location'' with the term ''multiple location,'' and adding new requirements for Medicare approval.

Revised § 418.100(g) by adding (g)(1) and (2) to address the orientation of patient care employees in the hospice philosophy and the initial orientation of a hospice employee to his or her specific job duties. We also redesignated proposed paragraph (g) as (g)(3).

13. Condition of Participation: Medical Director (§ 418.102)

Revised § 418.102 by describing the employment relationship between the medical director and the hospice. We clarified that the medical director is either an employee of the hospice (paid or volunteer) or is an individual under contract with the hospice. We also revised the requirement to state that the hospice is responsible for designating the individual who fulfills the physician designee role in the medical director's absence.

Inserted a new § 418.102(a) to address contracting for medical director services, and redesignated the other paragraphs accordingly. The new paragraph specifies that hospices may choose to make arrangements for medical director services to be met through a contract with a self-employed doctor or through a contract with a professional entity or physicians group. Revised § 418.102 (a)(2) specifies that if a hospice chooses to contract with a professional entity or physicians group for medical director services, the contract must identify a particular physician who will fulfill the hospice medical director's role and responsibilities.

Redesignated § 418.102(a) as § 418.102(b) and revised it to delete the term ''criteria.''

Deleted proposed § 418.102(b)(2), which would have required the medical director to review the patient's and family's expectations and wishes for the continuation of hospice care at the time of each recertification.

Redesignated and revised § 418.102(c) as § 418.102(d). The revision requires the hospice medical director to assume responsibility for the medical component of the hospice's patient care program. We deleted references to the joint responsibility of the IDG.

13. Condition of Participation: Clinical Records (§ 418.104)

Revised § 418.104(a) to clarify which documents must be included in the clinical record.

Revised § 418.104(a) to specify that all versions of the plan of care (initial and updated) must be in the clinical record. Likewise, we clarified that all assessments (initial, comprehensive, and updated comprehensive) must be included in the patient's clinical record. In addition, we removed the language that separate progress notes must be included in the clinical record because all notes, including notes that document a patient's progress, are included under the broad heading of ''clinical notes.'' Furthermore, we removed the requirement that the clinical record must contain a patient's informed consent from this section. In its place, we require that the clinical record contain a copy of the notice of patient rights (in accordance with § 418.52(a)(3)), which requires a hospice to obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights. Deleted the requirement in section § 418.104(b) that, ''[a]ll entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.'' We are requiring authentication and dating in accordance with hospice policy and accepted standards of practice.

Revised § 418.104(d) to specify the length of time that a hospice is required to retain a patient's clinical record after death or discharge from five years to six years in accordance with the HIPAA requirements.

Revised § 418.104(e) by replacing the term ''Medicare/Medicaid-approved facility'' with ''Medicare/Medicaid-certified facility.''

Revised § 418.104(e)(1) and (2) by requiring only that the discharge summary be sent to the receiving facility/physician, and that the clinical record be made available only upon request.

14. Condition of Participation: Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106)

Revised this CoP by combining the requirements of proposed § 418.106 and proposed § 418.110(m) and § 418.110(n).

Revised § 418.106(a) to now require the hospice to ensure that the IDG confers with a qualified individual with education and training in drug management who is an employee of, or under contract with, the hospice to ensure that drugs and biologicals meet each patient's needs. This section also requires a hospice that provides inpatient care directly in its own facility to provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of, or under contract with, the hospice. Incorporated the proposed requirements of § 418.110(n) in section 418.106(b). Drug orders must only be given by a physician or nurse practitioner. If a drug order is given verbally or electronically, it must be given to a licensed nurse, nurse practitioner, pharmacist, or physician, and must be recorded and signed immediately by the receiver. The prescribing individual must sign the order in accordance with State and Federal regulations.

Inserted new section 418.106(c), ''Dispensing of drugs and biologicals,'' to incorporate elements of proposed § 418.110(m) and (n). This new standard requires a hospice to have a written policy to promote dispensing accuracy, maintain current and accurate records of the receipt and disposition of all controlled drugs, and obtain drugs and biologicals from community or institutional pharmacists or its own stock. Some of these requirements (that is, policy for dispensing accuracy and controlled drug records) only apply to those hospices that choose to maintain their own drug and biological stocks.

Revised § 418.106(d) to combine proposed standards § 418.106(a)(2) and § 418.110(n)(2). Revised § 418.106(d) is divided into two elements, one for patients receiving care in their home and another for patients receiving care in a hospice inpatient facility. If a patient is receiving care in his or her home, the hospice IDG must determine the patient's and/or family's ability to safely administer drugs and biologicals in the home. If a patient is receiving care in an inpatient facility operated by the hospice, then drugs may only be administered to the patient by a designated list of individuals working in the inpatient facility.

Revised § 418.106(e) to combine and revise the requirements of § 418.106(b) and § 418.110(n)(3), § 418.110(n)(4), and § 418.110(n)(5). A hospice must ensure that all drugs and biologicals are labeled with appropriate use and cautionary instructions, as well as an expiration date, in accordance with accepted standards of practice. In addition, a hospice must have written policies and procedures for the management and disposal of controlled drugs in a patient's home, and must provide and discuss them with the patient and family at the time when controlled drugs are initially ordered. Furthermore,

a hospice that operates its own inpatient facility must dispose of controlled drugs in compliance with State and Federal requirements and its own policies and procedures. It must also store drugs and biologicals in a secure area. Certain controlled drugs must be stored in locked compartments within the secure area, and access to those locked compartments must be restricted to those individuals who are permitted to administer these drugs. Any discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs in the hospice's inpatient facility must be investigated immediately, and reported, if necessary. An investigation report must be made available to State and/or federal officials, if required.

Revised § 418.106(f) to clarify the hospice's responsibility for durable medical equipment and medical supplies and the hospice's contractual relationship with a durable medical equipment supplier. Specifically, section 418.106(f)(1) and (2) have been revised to state that, regardless of whether the hospice provides durable medical equipment and medical supplies directly or under contract, the hospice must ensure the following: That manufacturer recommendations for routine and preventive maintenance are followed; that maintenance policies are developed when no manufacturer recommendations exist; that equipment is safe; that equipment works as intended; that patients, families, and other caregivers receive instruction in the safe use of equipment and supplies; and that patients, families, and other caregivers are able to demonstrate the safe and appropriate use of equipment and supplies.

Added § 418.106(f)(3) to state that, if a hospice chooses to contract with an entity for durable medical equipment, it may only contract with a durable medical equipment supplier that meets the Medicare Supplier Quality and Accreditation Standards at 42 CFR 424.57.

15. Condition of Participation: Short-Term Inpatient Care (§ 418.108)

Revised 418.108(b)(2) to require a facility providing only the respite level of care to meet the 24-hour nursing needs of all patients in accordance with each patient's plan of care. A facility providing only the respite level of care is not required to automatically have registered nurse present on all shifts to provide direct patient care.

16. Condition of Participation: Hospices That Provide Inpatient Care Directly (§ 418.110)

Revised the opening paragraph of this CoP to clarify that the requirements of § 418.110 apply only to those inpatient facilities operated by a hospice. Where a hospice has its ''own inpatient facility,'' either in a freestanding building or as a section located in the building of another provider type, the requirements of § 418.110 apply to the building or applicable portion thereof as if it were physically located with the hospice administrative offices, as well as to the hospice patients receiving care within that building.

Added a requirement at § 418.110(b)(2), originally at § 418.100(a) of the existing hospice regulations, that at least one registered nurse must provide direct patient care on each shift. However, unlike the current § 418.100(a), this requirement only applies if the hospice inpatient facility is providing general inpatient care to one or more patients.

Removed the proposed requirements § 418.110(c)(1)(i) and (ii), that a hospice must report safety breaches and that hospices must prevent, report, and correct equipment failures.

Deleted § 418.110(d)(4) and § 418.110(d)(5), the phase-in provisions requiring hospices to comply with certain emergency lighting and door latching requirements as of March 13, 2006.

Redesignated proposed paragraph § 418.110(d)(6) as paragraph § 418.110(d)(4).

Added an exception to § 418.110(f)(1)(iv) with respect to the number of patients that may occupy a single room. Redesignated proposed § 418.110(o) as § 418.110(m), and revised it to correspond with the seclusion and restraint requirements for hospitals.

Revised proposed § 418.110(o)(6) as § 418.110(n) to provide more detailed guidance regarding the role of staff training in safely and successfully implementing restraint or seclusion techniques. These changes conform to the requirements of the hospital conditions of participation.

Redesignated proposed § 418.110(o)(7) as § 418.110(o) to provide more detailed requirements regarding death reporting requirements.

16. Condition of Participation: Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/MR (§ 418.112)

Deleted the term ''other facilities'' throughout this section.

Revised § 418.112(b) to clarify a hospice's responsibility for care furnished to hospice patients who reside in a SNF/NF or ICF/MR. A hospice assumes all responsibility for the professional management of all hospice services furnished to residents, including hospice-related inpatient care. All services furnished by the hospice must be in accordance with the individualized plans of care.

Deleted § 418.112 (c) and (d), and redesignated the remaining sections accordingly.

Redesignated § 418.112(e) as § 418.112(c), deleted some provisions, clarified other provisions, and incorporated new provisions regarding the written agreement between a hospice and a SNF/NF or ICF/MR.

Redesignated § 418.112(f) as § 418.112(d) and replaced some of the detailed plan of care requirements included in the proposed standard with a cross reference to the requirements of § 418.56. We also clarified that the hospice must discuss changes in a patient's plan of care with the patient or the patient's representative, as well as with representatives of the SNF/NF or ICF/MR where the patient resides.

Revised § 418.112(g) (redesignated as § 418.112(e)) to clarify the hospice's patient care coordination responsibility.

Deleted proposed § 418.112(h).

Revised § 418.112(i) and redesignated it as § 418.112(f) to clarify that a hospice is not required to provide orientation training itself if another hospice has already done so.

17. Condition of Participation: Personnel Qualifications (§ 418.114)

Revised § 418.114(a) by combining the requirements of proposed standards § 418.114(a) and § 418.116(a). The revised § 418.114 requires that all professionals who furnish hospice services be currently licensed, certified or registered to provide services in accordance with applicable Federal, State, and local laws. Furthermore, all professionals must act only within the scope of their license, certification, or registration.

Revised § 418.114(b) by replacing the proposed term ''home health aides'' with the final term ''hospice aides.'' We also added revised personnel requirements for social workers at § 418.114(b)(3).

Revised personnel requirements for physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and speech-language pathologists to incorporate changes made to these sections in a separate final rule (72 FR 66222, November 27, 2007) Revised § 418.114(d) to provide more specificity

about the timing and scope of the criminal background check requirement.

18. Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations Related to the Health and Safety or Patients (§ 418.116)

Moved proposed § 418.116(a) to a similar provision at final § 418.114(a).

Replaced the term ''satellite locations'' with the term ''multiple locations'' in final § 418.116(a) (proposed § 418.116(b)) to conform to other sections of the final rule.

IV. Crosswalk

Provisions Not Cited in the Crosswalk are Unchanged in the Final Rule

Proposed citation	Proposed condition	Final citation	Final condition
418.3	Definitions	Same	Definitions.
	New	418.3	Initial assessment, Comprehensive assessment, Physician designee, and Dietary counseling.
	Satellite location	Same	Multiple location, New and amended language.
	Bereavement counseling, Clinical note, Employee, Hospice care, Licensed professional, Restraint, Seclusion.	Same	New and amended language.
	Attending physician, Cap period, Drug restraint, Physical restraint, Progress note, Terminally ill.		Deleted.
418.52	Patient Rights	Same	Patient Rights.
418.52(a)(1)	The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care.	Same	New and amended language.
418.52(a)(3)	The hospice must inform the patient and family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances.	418.106(e)(2)(i)	Relocated and amended language.
418.52(a)(4)	The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has demonstrated an understanding of these rights.	418.52(a)(3)	New and amended language.
418.52(b)(4)(i)	The hospice must—Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures.	418.52(b)(4)(i) and 418.52(b)(4)(iv).	New and amended language.
418.52(b)(4)(ii)	Immediately investigate all alleged violations and immediately take action to prevent further potential abuse while the alleged violation is being verified.	Same	New and amended language.
418.52(4)(iv)	Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the complaint.	418.52(b)(4)(ii)	Amended language.
418.52(c)	Pain management and symptom control	418.52(c)(1)	New and amended language.
	New	418.52(c)(2)	New.
	New	418.52(c)(3)	New.
		418.52(c)(4)	New.
		418.52(c)(6)	New.
	New	418.52(c)(7)	New.
		418.52(c)(8)	New.
418.52(d)	Confidentiality of clinical records	418.52(c)(5)	Same.
418.52(e)	Patient liability	Deleted	Deleted.
418.54	Initial and Comprehensive Assessment of the Patient.	Same	Same.
418.54(a)	Initial assessment: The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	Same	New and amended language.
418.54(b)	Timeframe for completion of the comprehensive assessment: The hospice interdisciplinary group in consultation with the individual's attending physician, must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.	Same	New and amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.54(c)	Content of the comprehensive assessment: The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment describes—	Same	New and amended language.
418.54(c)(1)	The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);	Same	New and amended language.
418.54(c)(3)	Factors that must be considered in developing individualized care plan interventions, including—	Same	New and amended language.
418.54(c)(3)(i)	Bereavement. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.	418.54(c)(7)	New and amended language.
418.(c)(3)(ii)	Drug therapy. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—	418.54(c)(6)	New and amended language.
418.54(c)(3)(ii)(A)	Ineffective drug therapy;	418.54(c)(6)(i)	New and amended language.
418.54(c)(3)(ii)(B)	Unwanted drug side and toxic effects; and	418.54(c)(6)(ii)	New and amended language.
418.54(c)(3)(ii)(C)	Drug interactions	418.54(c)(6)(iii)	New and amended language.
	New	418.54(c)(6)(iv)	Duplicate therapy.
	New	418.54(c)(6)(v)	Laboratory monitoring.
418.54(c)(4)	The need for referrals and further evaluation by appropriate health professionals.	418.54(c)(8)	Same.
418.54(d)	Update of the comprehensive assessment	Same	New and amended language.
418.54(d)(1)	As frequently as the patient requires, but no less frequently than every 14 days; and	418.54(d)	Amended language.
418.54(d)(2)	At the time of each recertification	Deleted	Deleted.
418.56	§ 418.56 Condition of participation: Interdisciplinary group care planning and coordination of services. The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment and as it relates to the terminal illness and related conditions.	Same	Amended language.
418.56(a)(1)	Standard: Approach to service delivery. (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:	Same	New and amended language.
418.54(a)(1)(i)	A doctor of medicine or osteopathy (who is not the patient's attending physician).	Same	Amended language.
418.54(a)(1)(iv)	A pastoral, clergy, or other spiritual counselor	Same	Amended language.
418.56(a)(2)	If the hospice has more than one interdisciplinary group, it must designate in advance only one of those groups to establish policies governing the day-to-day provision of hospice care and services.	Same	Amended language.
418.56(b)	Plan of care: All hospice care and services furnished to patients and their families must follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice must ensure that each patient and family and primary caregiver(s) receive education and training provided by the hospice as appropriate to the care and services identified in the plan of care.	Same	New and amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.56(c)	Content of the plan of care: The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include but not be limited to—	Same	New and amended language.
418.56(c)(1)	Interventions to facilitate the management of pain and symptoms;	Same	Amended language.
418.56(c)(3)	Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;	Same	Amended language,
418.56(c)(6)	The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.	Same	Amended language.
418.56(d)	Review of the plan: The medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and the patient's progress toward outcomes specified in the plan of care.	Same	Amended language.
418.56(e)	Coordination of services: The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to—	Same	New and amended language.
418.56(e)(1)	Ensure the interdisciplinary group, through its designated professionals, maintains responsibility for directing, coordinating, and supervising the care and services provided;	Same	Amended language.
418.56(e)(4)	Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or under arrangement.	Same	Amended language.
	New	New 418.56(e)(5)	New.
418.58	Quality assessment and performance improvement: The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; focuses on the end-of-life support services provided; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.	Same	New and amended language.
418.58(a)(1)	Program scope: (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services.	Same	Amended language.
418.58(b)(2)(ii)	Identify opportunities for improvement	Same	Amended language.
418.58(b)(3)	The frequency and detail of the data collection must be specified by the hospice's governing body.	Same	Amended language.
418.58(d)(1)–(d)(2)	Performance improvement projects: (1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations. (2) The hospice must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.	Same	New and amended language.
418.58(e)–(e)(1)	Executive responsibilities: The hospice's governing body is responsible for ensuring the following: (1)That an ongoing program for quality improvement and patient safety is defined, implemented and maintained;	Same	Amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.58(e)(2)	That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness; and	Same	Amended language.
418.58(e)(3)	That clear expectations for patient safety are established.	Deleted	Deleted.
	New	418.58(e)(3)	New.
418.60	Infection Control: The hospice must maintain and document an effective infection control program that protects patients, families and hospice personnel by preventing and controlling infections and communicable diseases.	Same	Amended language.
418.60(b)(2)(ii)	A plan for the appropriate actions that are expected to result in improvement and disease prevention.	Same	Amended language.
418.62	Licensed professional services	Same	Same.
418.62(b)	Licensed professionals must actively participate in the coordination of all aspects of the patient's care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and	Same	Amended language.
418.64	Core Services: A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.	Same	New and amended language.
418.64(a)	Physician services: The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness, conditions related to the terminal illness, and the general medical needs of the patient. (1) All physician employees and those under contract, must function under the supervision of the hospice medical director. (2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician. (3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.	Same	Amended language.
418.64(b)	Nursing services: (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments. (2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the individual's attending physician must be specified in the individual's plan of care. (3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.	Same	Amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.64(d)	Counseling services: Counseling services for adjustment to death and dying must be available to both the patient and the family. Counseling services must include but are not limited to the following:	Same	New and amended language.
418.64(d)(1)(i)	Bereavement counseling. The hospice must: Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling.	Same	Amended language.
418.64(d)(1)(ii)	Make bereavement services available to the family and other individuals in the bereavement plan of care up to one year following the death of the patient. Bereavement counseling also extends to residents and employees of a SNF/NF, ICF/MR, or other facility when appropriate and identified in the bereavement plan of care.	Same	Amended language.
418.64(d)(1)(iv)	Develop a bereavement plan of care that notes the kind of bereavement services to be provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c).	Same	Amended.
418.64(d)(2)	Nutritional counseling. Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.	Same	Renamed: Dietary Counseling.
418.64(d)(3)(i)–(iv)	Spiritual counseling. The hospice must: (i) Provide an assessment of the patient's and family's spiritual needs; (ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires; (iii) Facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability. The hospice is not required to go to extraordinary lengths to do so; and (iv) Advise the patient and family of this service.	Same	Amended language.
418.66	Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.	Same	Same.
418.66(a)	CMS may waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria: (1) The location of the hospice's central office is in a nonurbanized area as determined by the Bureau of the Census. (2) There is evidence that a hospice was operational on or before January 1, 1983 including— (i) Proof that the organization was established to provide hospice services on or before January 1, 1983; (ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and (iii) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983. (3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses: (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Job descriptions for nurse employees; (iii) Evidence that salary and benefits are competitive for the area; and	Same	Amended language.

Proposed citation	Proposed condition	Final citation	Final condition
	(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area).		
418.66(d)	CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.	Same	Amended language.
418.74	Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.	Same	Same.
418.74(a)	A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria: (1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census. (2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include— (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions; (iii) Evidence that salary and benefits are competitive for the area; and (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).	Same	Amended language.
418.74(d)	CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1 year extension, it must submit a request to CMS prior to the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.	Same	Amended language.
418.76	Home health aide and homemaker services: All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.	Same	New and amended language.
418.76(a)(1)	Home health aide qualifications:	Same	New and amended language.
	(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively; or		
	(ii) A competency evaluation program; or	Same	New and amended language.
	(iii) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.	418.76(a)(1)(iv)	Same.
New	New	418.76(a)(1)(iii)	New.

Proposed citation	Proposed condition	Final citation	Final condition
418.76(a)	(2) A home health aide is not considered to have completed a training program, or a competency evaluation program if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24 month lapse in furnishing services, the individual must complete another training and/or competency evaluation program before providing services, as specified in paragraph (a)(1) of this section.	Same	New and amended language.
418.76(b)	Content and duration of home health aide classroom and supervised practical training: (1) Home health aide training must include classroom and supervised practical classroom training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours. (2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours. (3) A home health aide training program must address each of the following subject areas: (4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.	Same	Amended language.
418.76(c)	Competency evaluation: An individual may furnish home health services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.	Same	Amended language.
418.76(c)(1)	(1) The competency evaluation must address each of the subjects listed in paragraphs (b)(1) through (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.	Same	Amended language.
418.76(c)(2)	(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.	Same	Amended language.
418.76(c)(4)	(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation.	Same	New and amended language.
418.76(d)	In-service training: A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient. (1) In-service training may be offered by any organization except one that is excluded by paragraph (f) of this section, and must be supervised by a registered nurse. (2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.	Same	Amended language.
418.76(e)	Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training: Classroom supervised practical training must be performed by or under the supervision of a registered nurse who possesses a minimum of two years nursing experience, at least one year of which must be in home health care. Other individuals may provide instruction under the general supervision of a registered nurse.	Same	Amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.76(f)	Eligible training organizations. A home health aide training program may be offered by any organization except by a home health agency that, within the previous 2 years— (1) Was out of compliance with the requirements of paragraphs (b) or (c) of this section; (2) Permitted an individual that does not meet the definition of a ''qualified home health aide'' as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); (3) Was subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State); (4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; (5) Was found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency; (6) Had all or part of its Medicare payments suspended; or (7) Was found by CMS or the State under any Federal or State law to have:	Same	Amended language.
418.76(g)	Home health aide assignments and duties: A registered nurse or the appropriate qualified therapist that is a member of the interdisciplinary team makes home health aide assignments.	Deleted	Deleted stem.
418.76(g)(1)	Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (i.e., a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section.	Same	New and amended language.
418.76(g)(2)	A home health aide provides services that are: (i) Ordered by the physician or nurse practitioner; (ii) Included in the plan of care; (iii) Permitted to be performed under State law by such home health aide; and (iv) Consistent with the home health aide training.	Same	Amended language.
418.76(g)(3)	The duties of a home health aide include: (i) The provision of hands on personal care; (ii) The performance of simple procedures as an extension of therapy or nursing services; (iii) Assistance in ambulation or exercises; and (iv) Assistance in administering medications that are ordinarily self administered.	Same	Amended language.
418.76(g)(4)	Home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse or other appropriate licensed professional, as the changes relate to the plan of care and quality assessment and improvement activities. Home health aides must also complete appropriate records in compliance with the hospice's policies and procedures.	Same	Amended language.
418.76(h)	Supervision of home health aides: (I) A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.	418.76(h)(1) and (h)(2)	New and amended language.
418.76(h)(2)	The supervising nurse or therapist must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to— (i) Following the patient's plan of care for completion of tasks assigned to the home health aide by the registered nurse or qualified therapist;	418.76(h)(3)	Amended language.

Proposed citation	Proposed condition	Final citation	Final condition
	(ii) Creating successful interpersonal relationships with the patient and family; (iii) Demonstrating competency with assigned tasks; (iv) Complying with infection control policies and procedures; and (v) Reporting changes in the patient's condition.		
418.76(h)(3)	If the hospice chooses to provide home health aide services under contract with another organization, the hospice's responsibilities include, but are not limited to— (i) Ensuring the overall quality of care provided by an aide; (ii) Supervising an aide's services as described in paragraphs (h)(l) and (h)(2) of this section; and (iii) Ensuring that home health aides who provide services under arrangement have met the training and/or competency evaluation requirements of this condition.	Deleted	Deleted.
	New	418.76(h)(3)	New language.
418.76(i)	Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit. An individual may furnish personal care services, as defined in § 440.167 of the Code of Federal Regulations, on behalf of a hospice or home health agency. Before the individual may furnish personal care services, the individual must be found competent by the State to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.	418.76(i) and (i)(1)	Amended language.
		418.76(i)(2)	New language.
		418.76(i)(3)	New language.
418.76(j)	Homemaker qualifications. A qualified homemaker is a home health aide as described in § 418.76 or an individual who meets the standards in § 418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness.	Same	New and amended language.
418.76(k)	Homemaker supervision and duties (1) Homemaker services must be coordinated by a member of the interdisciplinary group. (2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group. (3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.	Same	New and amended language.
Subpart D Conditions of Participation: Organizational Environment			
418.100	Organization and administration of services. The hospice must organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of terminal illness.	Same	New and amended language.
418.100(a)	Serving the hospice patient and family. The hospice must ensure—(1) That each patient receives and experiences hospice care that optimizes comfort and dignity; and (2) That each patient experience hospice care that is consistent with patient and family needs and desires.	Same	New and amended language.
418.100(c)	Services: (1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent within accepted standards of practice: (i) Nursing services. (ii) Medical social services. (iii) Physician services. (iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling. (v) Home health aide, volunteer, and homemaker services. (vi) Physical therapy, occupational therapy and speech-language pathology therapy services. (vii) Short-term inpatient care. (viii) Medical supplies (including drugs and biologicals) and medical appliances.	Same	Amended language.

Proposed citation	Proposed condition	Final citation	Final condition
	(2) Nursing services, physician services, and drugs and biologicals (as specified in § 418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.		
418.100(e)	Professional management responsibility. A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and supervision of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be— (1) Authorized by the hospice; (2) Furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees; and (3) Delivered in accordance with the patient's plan of care.	Same	Amended language.
418.100(f)	Hospice satellite locations: (1) All hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients. The determination that a satellite location does or does not meet the definition of a satellite location, as set forth in this part, is an initial determination, as set forth in § 498.3. (2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care.	Same	Renamed. Amended language.
418.100(g)	In-service training: A hospice must assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.	Same	Renamed. New and amended language.
418.102	Medical director. The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is either employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the medical director assumes the same responsibilities and obligations as the medical director. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.	Same	Amended language.
418.102(a)	Initial certification of terminal illness. The medical director or physician designee reviews the clinical information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following criteria when making this determination: (1) The primary terminal condition. (2) Related diagnosis(es), if any. (3) Current subjective and objective medical findings. (4) Current medication and treatment orders. (5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.	418.102(b)	Amended language.
New		418.102(a)	New.
418.102(b)	Recertification of the terminal illness. Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review: (1) The patient's clinical information; and	418.102(c)	Amended language.
	(2) The patient's and family's expectations and wishes for the continuation of hospice care.	Deleted	Deleted.

Proposed citation	Proposed condition	Final citation	Final condition
418.102(c)	Coordination of medical care. The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.	Deleted	Deleted.
New	New	418.102(d)	New.
418.104(a)	Clinical records. Content. Each patient's record must include the following: (1) The plan of care, initial assessment, comprehensive assessment, and updated comprehensive assessments, clinical notes, and progress notes. (2) Informed consent, authorization, and election forms. (3) Responses to medications, symptom management, treatments, and services. (4) Outcome measure data elements, as described in § 418.54(e) of this subpart. (5) Physician certification and recertification of terminal illness as required in § 418.22 and described in § 418.102(a) and § 418.102(b) respectively. (6) Any advance directives as described in § 418.52(a)(3).	Same	New and amended language.
418.104(b)	Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.	Same	New and amended language.
418.104(d)	Retention of records: Patient clinical records must be retained for 5 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.	Same	Amended language.
418.104(e)	Discharge or transfer of care: (1) If the care of a patient is transferred to another Medicare/Medicaid approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility. (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patient's attending physician. (3) The hospice discharge summary must include— (i) A summary of the patient's stay including treatments, symptoms and pain management; (ii) The patient's current plan of care; (iii) The patient's latest physician orders; and (iv) Any other documentation that will assist in post-discharge continuity of care.	Same	New and amended language.
418.106(a)	Drugs and biologicals, medical supplies, and durable medical equipment. Administration of Drugs and biologicals: (1) All drugs and biologicals must be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient's plan of care.	418.106(d)	Partially deleted and moved to stem.
418.106(a)	(2) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals.	418.106(d)(1)	Renamed. New and amended language.
New	New	418.106(a)	Renamed. New and amended language.
418.106(b)	Controlled drugs: The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the uses and potential dangers of controlled substances. The hospice nurse must document that the policy was discussed with the patient and family.	418.106(e)	Renamed. New and amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.110(n)(1)	New	418.106(b)	Renamed. New and amended language.
418.106(c)	Use and maintenance of equipment and supplies. (1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment. (2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.	418.106(f)	New and amended language.
418.110(m)		418.106(c)	Renamed. New and amended language.
418.110(n)(2)		418.106(d)(2)	Renamed. New and amended language.
418.106(b) and 418.110(n)(3)–(5).		418.106(e)	Renamed. New and amended language.
New	New	418.106(f)(3)	Amended language.
418.108(a)	Inpatient care for symptom management and pain control. Inpatient care for pain control and symptom management must be provided in one of the following: (1) A Medicare-approved hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110. (2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.	Same	Amended language.
418.108(b)	Inpatient care for respite purposes: Inpatient care for respite purposes must be provided by one of the following: (1) A provider specified in paragraph (a) of this section. (2) A Medicare/Medicaid approved nursing facility that also meets the standards specified in § 418.110 (b) and (f).	Same	New and amended language.
418.108(c)	Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies— (1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished; (2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients; (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is available to the hospice at the time of discharge; (4) That the inpatient facility has identified a individual within the facility who is responsible for the implementation of the provisions of the agreement; (5) That the hospice retains responsibility for arranging the training of personnel who will be providing the patient's care in the inpatient facility and that a description of the training and the names of those giving the training is documented; and (6) That a way to verify that requirements in paragraphs (c)(1) through (c)(5) of this section have been met is established.	Same	Amended language.
418.110	Hospices that provide inpatient care directly.		
418.110	A hospice that provides inpatient care directly must demonstrate compliance with all of the following standards:	Same	New language.

Proposed citation	Proposed condition	Final citation	Final condition
418.110(b)	Twenty-four hour nursing services: The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.	Same	New language.
418.110(c)	Physical environment. The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors. (1) Safety management. (i) The hospice must address real or potential threats to the health and safety of the patients, others, and property. The hospice must report a breach of safety to appropriate State and local bodies having regulatory jurisdiction and correct it promptly. (ii) The hospice must take steps to prevent equipment failure and when a failure occurs, report it to the appropriate State and local bodies having regulatory jurisdiction and correct it promptly. (iii) The hospice must have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others.	Same	Amended language.
418.110(c)	(2) Physical plant and equipment. The hospice must develop procedures for managing the control, reliability, and quality of— (i) The routine storage and prompt disposal of trash and medical waste; (ii) Light, temperature, and ventilation/air exchanges throughout the hospice;	Same	Amended language.
418.110(d)	Fire protection	Same	Amended language.
418.110(f)	Patient rooms: (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients. (2) The hospice must accommodate a patient and family request for a single room whenever possible. (3) Each patient's room must— (i) Be at or above grade level; (ii) Contain a suitable bed and other appropriate furniture for each patient; (iii) Have closet space that provides security and privacy for clothing and personal belongings; (iv) Accommodate no more than two patients; (v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and (vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.	Same	New and amended language.
418.110(f)(4)	For an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section for a period of time if it determines that—(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and	Same	New and amended language.
418.110(m)	Pharmaceutical services: Under the direction of a qualified pharmacist, the hospice must provide pharmaceutical services such as drugs and biologicals and have a written process in place that ensures dispensing accuracy.	418.106(a)	New and amended language.
418.110(m)	The hospice will evaluate a patient's response to the medication therapy, identify adverse drug reactions, and take appropriate corrective action.	418.54(a)(6)	New and amended language.
418.110(m)	Drugs and biologicals must be obtained from community or institutional pharmacists or stocked by the hospice.	418.106(c)	New and amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.110(m)	The hospice must furnish the drugs and biologicals for each patient, as specified in each patient's plan care.	418.106 Stem	New and amended language.
418.110(m)	The use of drugs and biologicals must be provided in accordance with accepted professional principles and appropriate Federal, State, and local laws.	418.100(c) and 418.116	New and amended language.
418.110(n)	Pharmacist: A licensed pharmacist must provide consultation on all aspects of the provision of pharmaceutical care in the facility, including ordering, storage, administration, disposal, and record keeping of drugs and biologicals.	418.106(a)	New and amended language.
418.110(n)(1)	Orders for medications (i) A physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, must order all medications for the patient. (ii) If the medication order is verbal or given by or through electronic transmission— (A) The physician must give it only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or another physician; and (B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in accordance with State and Federal regulations.	418.106(b)	New and amended language.
418.110(n)(2)	Administration of medications. Medications must be administered by only the following individuals: (i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice. (ii) An employee who has completed a State-approved training program in medication administration. (iii) The patient, upon approval by the attending physician.	418.106(d)(2)	New and amended language.
418.110(n)(3)	Labeling of drugs and biologicals. Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate accessory and cautionary instructions, as well as an expiration date (if applicable).	418.106(e)(1)	New and amended language.
418.110(n)(4)	Drug management procedures. (i) All drugs and biologicals must be stored in secure areas. All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled medications may have access to the locked compartments. (ii) The hospice must keep current and accurate records of the receipt and disposition of all controlled drugs. (iii) Any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State agency. A written account of the investigation must be made available to State and Federal officials.	418.106(e)(3)	New and amended language.
418.110(n)(5)	Drug disposal. Controlled drugs no longer needed by a patient must be disposed of in compliance with the hospice policy and in accordance with State and Federal requirements.	418.106(e)(2)(ii)	New and amended language.
418.110(o)(1)	Seclusion and restraint: (1) The patient has the right to be free from seclusion and restraint, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.	418.110(m)	Same.
418.110(o)(1)	The term restraint includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that he or she cannot easily remove, that restricts free movement of, normal function of, or normal access to one's body.		

Proposed citation	Proposed condition	Final citation	Final condition
	A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition. Seclusion is the confinement of a person alone in a room or an area where a person is physically prevented from leaving.	418.3	Same.
418.110(o)(2)	Seclusion and restraint can only be used in emergency situations if needed to ensure the patient's or others' physical safety, and only if less restrictive interventions have been tried, determined and documented to be ineffective.	418.110(m) and 418.110(m)(1).	Same.
418.110(o)(3)(i)	The use of restraint and seclusion must be— (i) Selected only when less restrictive measures have been found ineffective to protect the patient or others from harm;	418.110(m)(2)	New and amended language.
418.110(o)(3)(ii)	Carried out in accordance with the order of a physician. The following will be superseded by more restrictive State laws:	418.110(m)(4) and 418.110(m)(7).	New and amended language.
418.110(o)(3)(ii)(A)	Orders for seclusion or restraints must never be written as a standing order or an as needed basis (that is, PRN).	418.110(m)(5)	Amended language.
418.110(o)(3)(ii)(B)	The hospice medical director or physician designee must be consulted as soon as possible if restraint or seclusion is not ordered by the hospice medical director or physician designee.	418.110(m)(6)	Amended language.
418.110(o)(3)(ii)(C)	A hospice medical director or physician designee must see the patient and evaluate the need for restraint or seclusion within 1 hour after initiation of this intervention.	418.110(m)(11) and 418.110(m)(12).	New and amended language.
418.110(o)(3)(ii)(D)	Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician must reassess the patient's need before issuing another seclusion and restraint order.	418.110(m)(7)	New and amended language.
418.110(o)(3)(iii)	In accordance with the interdisciplinary group and a written modification to the patient's plan of care;	418.110(m)(3)(i)	Amended language.
418.110(o)(3)(iv)	Implemented in the least restrictive manner possible not to interfere with the palliative care being provided;	418.110(m)(2)	Amended language.
418.110(o)(3)(v)	In accordance with safe, appropriate restraining techniques.	418.110(m)(3)(ii)	Amended language.
418.110(o)(3)(vi)	Ended at the earliest possible time; and	418.110(m)(8)	Amended language.
418.110(o)(3)(vii)	Supported by medical necessity and the patient's response or outcome, and documented in the patient's clinical record.	418.110(m)(15)	New and amended language.
418.110(o)(4)	A restraint and seclusion may not be used simultaneously unless the patient is— (i) Continually monitored face to face by an assigned staff member; or (ii) Continually monitored by staff using video and audio equipment. Staff must be in immediate response proximity to the patient.	418.110(m)(14)	Amended language.
418.110(o)(5)	The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated by an assigned staff member.	418.110(m)(9)	New and amended language.
418.110(o)(6)	All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.	418.110(n)	New and amended language.
418.110(o)(7)	The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	418.110(o)	New and amended language.
418.112	Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities. In addition to meeting the conditions of participation at § 418.10 through § 418.116, a hospice that provides hospice care to residents of a SNF/NF, ICF/MR, or other residential facility must abide by the following additional standards.	Same	New and amended language.

Proposed citation	Proposed condition	Final citation	Final condition
418.112(a)	Resident eligibility election, and duration of benefits. Medicare patients receiving hospice services and residing in a SNF, NF, or other facility must meet the Medicare hospice eligibility criteria as identified in § 418.20 through § 418.30.	Same	New and amended language.
418.112(b)	Professional management: The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to § 418.100.	Same	New and amended language.
418.112(c)	Core services: A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.	418.64	New and amended language.
418.112(d)	Medical director: The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.	418.112(e)	New and amended language.
418.112(e)	Written agreement: The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services.	418.112(c)	New and amended language.
418.112(e)(1) and (e)(2)	The written agreement must include at least the following: (1) The written consent of the patient or the patient's representative that hospice services are desired. (2) The services that the hospice will furnish and that the facility will furnish.	Deleted	Deleted.
418.112(e)(3)	The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.	418.112(c)(1)	Amended language.
418.112(e)(4)(i) and (ii)	A provision that the facility immediately notifies the hospice if— (i) A significant change in the patient's physical, mental, social, or emotional status occurs; (ii) Clinical complications appear that suggest a need to alter the plan of care;	418.112(c)(2), 418.112(c)(2)(i) and 418.112(c)(2)(ii).	Amended language.
418.112(e)(4)(iii)	A life threatening condition appears;	Deleted	Deleted.
418.112(e)(4)(iv)	A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or	418.112(c)(2)(iii)	Amended language.
418.112(e)(4)(v)	The patient dies	418.112(c)(2)(iv)	Amended language.
418.112(e)(5)	A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided.	418.112(c)(3)	Amended language.
418.112(e)(6)	An agreement that it is the facility's primary responsibility to furnish room and board.	418.112(c)(4)	New and amended language.
New	New	418.112(c)(5)	New.

Proposed citation	Proposed condition	Final citation	Final condition
418.112(e)(7)	A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.	418.112(c)(6)	New and amended language.
418.112(e)(8)	A provision that the hospice may use the facility's nursing personnel where permitted by law and as specified by the facility to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care.	418.112(c)(7)	Amended language.
New	New	418.112(c)(8)	New.
New	New	418.112(c)(9)	New.
418.112(f)	Hospice plan of care: A written plan of care must be established and maintained for each facility patient and must be developed by and coordinated with the hospice interdisciplinary group in consultation with facility representatives and in collaboration with the attending physician. All care provided must be in accordance with this plan.	418.112(d)	New and amended language.
418.112(f)	The plan must reflect the hospice's policies and procedures in all aspects and be based on an assessment of the patient's needs and unique living situation in the facility. It must include the patient's current medical, physical, social, emotional, and spiritual needs. Directives for management of pain and other symptoms must be addressed and updated as necessary to reflect the patient's status.	418.56(b) and (c)	New and amended language.
418.112(f)(1)	The plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the plan of care.	418.112(d)(1)	Amended language.
418.112(f)(2)	The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible.	418.112(d)(2)	Amended language.
418.112(f)(3)	In conjunction with representatives of the facility, the plan of care must be reviewed at intervals specified in the plan but no less often than every 14 calendar days.	418.56(d)	New and amended language.
418.112(f)(4)	Any changes in the plan of care must be discussed among all caregivers and must be approved by the hospice before implementation.	418.112(d)(3)	Amended language.
418.112(g)	Coordination of services: The hospice must designate a member of its interdisciplinary group to coordinate the implementation of the plan of care with the representatives of the facility. The hospice must provide the facility with the following information:	418.112(e)(1)	New and amended language.
418.112(g)(2)–(g)(6)	(1) Plan of care. (2) Patient or patient's representative hospice consent form and advance directives. (3) Names and contact information for hospice personnel involved in hospice care of the patient. (4) Instructions on how to access the hospice's 24-hour on-call system. (5) Medication information specific to the patient. (6) Physician orders.	418.112(e)(3)	New and amended language.
418.112(h)	Transfer, revocation, or discharge from hospice care: Requirements for discharge or revocation from hospice care, § 418.104(e), apply. Discharge from or revocation of hospice care does not directly impact the eligibility to continue to reside in an SNF, NF, ICF/MR, or other facility.	Deleted	Deleted.
418.112(i)	Orientation and training: Hospice staff must orient facility staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.	418.112(f)	Amended language.
418.114	Personnel qualifications for licensed professionals	Same	Renamed.

Proposed citation	Proposed condition	Final citation	Final condition
418.114(a)	General qualification requirements. Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.	Same	New and amended language.
418.114(b)	Personnel qualifications for physicians, speech-language pathologists, and home health aides: The following qualifications must be met:	Same	Renamed. New and amended language.
418.114(b)(1)	Physicians	Same and 418.3	New and amended language.
418.114(b)(2)	Speech language pathologists	418.114(b)(4)	New and amended language.
418.114(b)(3)	Home health aides	418.114(b)(2)	Renamed. New and amended language.
418.114(c)	Personnel qualifications when no State licensing, certification, or registration requirements exist. If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:	Same	New and amended language.
418.114(c)(1)	Occupational therapist	418.114(b)(5)	New and amended language.
418.114(c)(2)	Occupational therapy assistant	418.114(b)(6)	New and amended language.
418.114(c)(3)	Physical therapist	418.114(b)(7)	New and amended language.
418.114(c)(4)	Physical therapist assistant	418.114(b)(8)	New and amended language.
418.114(c)(5)	Registered nurse. A graduate of a school of professional nursing.	418.114(c)(1)	New and amended language.
418.114(c)(6)	Licensed practical nurse. A person who has completed a practical nursing program.	418.114(c)(2)	New and amended language.
418.114(c)(7)	Social worker	418.114(b)(3)	New and amended language.
418.114(d)	Criminal background checks: The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.	Same	New and amended language.
418.116(a)	Standard: Licensure of staff. Any persons who provide hospice services must be licensed, certified, or registered in accordance with applicable Federal, State and local laws.	418.114(a)	Relocated and amended.
418.116(b)	Standard: Multiple locations. Every hospice must comply with the requirements of § 420.206 of this chapter regarding disclosure of ownership and control information. All hospice satellite locations must be approved by CMS and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.	418.116(a)	Amended language.

V. Collection of Information

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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.

Therefore, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Condition of Participation: Patient's Rights (§ 418.52)

Section 418.52(a)(1) states that a hospice must provide the patient or representative with verbal and written notice of the patient's right and responsibilities. The notification must be presented in a manner and language consistent with the patient's ability to comprehend the information. Section 418.52(a)(2) requires a hospice to inform and distribute written information on its policies concerning advance directives. The information must include a description of applicable State laws. Section 418.52(a)(3) states that a hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights.

The burden associated with the notification requirements contained in § 418.52(a) is the time and effort necessary for a hospice to: develop the notification form; provide, both verbally and in writing, the patient or the patient's representative with a notice of patient's rights; inform and distribute information pertaining to its policies on advance directives and applicable State laws; obtain signatures from either the patient or representative confirming receipt of a copy of the notice of rights. There are 2,872 hospices that must comply with the aforementioned requirements. We estimate that it will take each hospice 8 hours to develop the form and 5 minutes to meet the requirements in § 418.52(a)(1–3). We estimate that each hospice will on average provide 303 notifications per year for a total one time burden of 22,976 hours and annual burden of 72,518 hours.

Section 418.52(b) sets out the right of the patients to exercise these patient rights and requires hospices to show respect for property and person. Specifically, § 418.52(b)(4)(i) states that a hospice is accountable for ensuring

that all alleged violations involving mistreatment, neglect or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice are reported immediately to the hospice administrator. Section 418.52(b)(4)(ii) requires a hospice to immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take preventative action to avoid additional violations. As part of the investigation, the hospice must document and maintain all records associated with the alleged violations in accordance with established procedures. Section 418.52(b)(4)(iv) further requires that a hospice report all confirmed violations to the State and local bodies having jurisdiction within 5 working days of becoming aware of the violation.

The burden associated with the recordkeeping and reporting requirements described in § 418.52(b) is the time and effort necessary to report all alleged violations to the hospice administrator, to conduct and document an investigation and to maintain record of the documented investigation. There is also burden associated with reporting all verified allegations to the State and local bodies that have jurisdiction. We anticipate that each of the 2,872 hospices will investigate, document, and report 15 violations per year. We estimate that it will take each hospice 60 minutes per event to satisfy the requirements contained in § 418.52(b). The estimated annual burden associated with the requirements contained in § 418.52(b) is 43,080 hours.

Condition of Participation: Initial and Comprehensive Assessment of the Patient (§ 418.54)

Section 418.54 contains the information collection requirements associated with the initial and comprehensive assessment of the patient. Section 418.54(a) requires a hospice to conduct the initial patient assessment within 48 hours after the patient or representative elects the hospice benefit. Section 418.54(b) states that the hospice IDG must complete the patient's comprehensive assessment no later than 5 calendar days after the patient or representative elects the hospice benefit. Section 418.54(c) sets out the content of the assessment. Section 418.54(d) requires that the comprehensive patient assessment be updated as needed based on the patient's condition, but no less frequently than every 15 days.

The burden associated with the requirements in § 418.54 is the time and effort necessary to document and maintain the patient assessment. While these requirements are subject to the PRA, the associated burden is exempt as stated in 5 CFR 1320.3(b)(2); conducting patient assessments is a usual and customary business practice. The time, effort, and financial resources necessary to comply with a collection of information that would be incurred by a person in the normal course of their activities are considered to be usual and customary and is exempt from the PRA.

Condition of Participation: Interdisciplinary Group Care Planning and Coordination of Services (§ 418.56)

Section 418.56(a) requires a hospice that has more than one IDG to designate a group to establish policies governing the day-to-day provision of hospice care and services. The burden associated with this requirement is the time and effort necessary to draft, implement, and maintain the policies governing the day-to-day provision of hospice care services. While this requirement is subject to the PRA, the burden is considered to be usual and customary and is exempt as stated under 5 CFR 1320.3(b)(2).

Section 418.56(b) requires all hospice care and services furnished to patients and their families to follow an established plan of care established by the hospice IDG and the patient's caregivers. In addition, a hospice must ensure that each patient and the primary caregiver(s) receive education and training provided by the hospice. The education and training must be specific to the individual's responsibilities with respect to the care and services outlined in the plan of care. The burden associated with this requirement is the time and effort associated with educating and training the patient and patient caregiver(s). This requirement is currently approved under OMB control number 0938–0302. The expiration date for the approval is August 31, 2009.

Section 418.56(c) requires hospices to develop an individualized written plan of care for each patient. The plan of care must contain the information described in § 418.56(c)(1)–(6). Section 418.56(d) states that the hospice interdisciplinary team must review, revise, and document the individualized plan of care as frequently as the patient's condition warrants, but no less frequently than every 15 days. The burden associated with these requirements is the time and effort associated with drafting, reviewing, revising, and maintaining the plan of care. This requirement is currently approved under OMB control number 0938–0302, with an expiration date of August 31, 2009.

Section 418.56(e) describes the standard for the coordination of hospice services. Specifically, it states that a hospice must develop and maintain a system of communication and integration to ensure the information contained in § 418.56(e)(1)–(5). The burden associated with this requirement is the time and effort required to develop and maintain the system of communication in accordance with the hospice's policies and procedures. While this requirement is subject to the PRA, the associated burden is considered to be usual and customary as stated in 5 CFR 1320.3(b)(2).

Condition of Participation: Quality Assessment and Performance Improvement (§ 418.58)

Section 418.58 states that a hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement (QAPI) program. In addition, the hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS. Section 418.58(a) describes the required scope of the QAPI program. Specifically, § 418.58(a)(1) discusses the documentation requirements. The QAPI program must be able to demonstrate measurable improvement in indicators related to improved palliative outcomes and hospice services. Section 418.58(a)(2) states that the hospice must measure, analyze, and track quality indicators.

Section 418.58(b)(2) states that a hospice must use the data to monitor the effectiveness and safety of services and quality of care. As part of the monitoring process, the data must be used to identify improvement opportunities. The data must also be used to assist in the prioritization of the aforementioned opportunities for improvement.

Section 418.58(c)(2) states that as part of performance improvement activities, a hospice must track adverse patient events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the hospice. Section 418.58(c)(3) requires a hospice to measure its success and track performance in its performance improvement initiatives to ensure that the improvements are continuous.

Section 418.58(d) discusses that standard for performance improvement projects. Hospices are responsible for developing, implementing, and evaluating performance improvement projects. Section 418.58(d)(2) requires

hospices to document their performance improvement projects, the reason for conducting each project, and the measurable progress achieved as a result of the projects.

The burden associated with the requirements contained in § 418.58 is the time and effort necessary to develop, draft, and implement a QAPI program. As part of the QAPI program, there is also burden associated with recording quality data for performance improvement initiatives. We estimate that for all 2,872 hospices, 1 hour per hospice will be required to comply with the documentation of the domains and measures, 91 hours per hospice for data entry and 48 hours to aggregate the data. This is an annual burden of 140 hours per hospice to meet the requirement of this section. The estimated annual burden associated with the requirements in § 418.58 is 402,080 hours annually.

Condition of Participation: Infection Control (§ 418.60)

Section 418.60(a) requires hospices to maintain and document an effective infection control program. The goal of the program is to protect patients, families, visitors, and hospice staff by preventing and controlling infectious and communicable diseases. Section 418.60(b) provides the standard for effective hospice infection control programs. Section 418.60(c) describes the standard for education with respect to infection control. Hospices must provide infection control education to employees, contracted providers, patients, and family members and other care givers.

The burden associated with the requirements in § 418.60(a)–(c) is the time and effort associated with developing, implementing, documenting, and maintaining an effective infection control program. There is also burden associated with providing infection control education. While these requirements are subject to the PRA, the burden is exempt as stated in 5 CFR 1320.3(b)(2). The existence of an effective infection control program is a usual and customary business practice in the hospice care industry.

Condition of Participation: Core Services (§ 418.64)

Section 418.64 states that hospices may contract for the physician services contained in § 418.64(a). A hospice may also enter into a written agreement with another Medicare-certified hospice program for the provision of the core services. The burden associated with these requirements is the time and effort necessary to develop, draft, sign, and maintain contracts and written agreements. The burden associated with these requirements is exempt from the PRA as stated in 5 CFR 1320.3(b)(2); the use of contracted physicians and the use of written agreements between two Medicare certified hospice programs for the provision of core services constitutes a usual and customary business practice.

Section 418.64(d) describes the standard for counseling services. Hospices are required to make counseling services available to patients and families to provide comfort and assistance with coping and stress management associated with the dying process. Specifically, section § 418.64(d)(1)(iv) states that as part of bereavement counseling, a hospice must develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. Section 418.64(d)(3) states that a hospice must provide an assessment of the patient's and family's spiritual needs, provide spiritual counseling to meet those needs in a manner that is accepted by the patient and family and is consistent with their respective beliefs, facilitate visits by individuals that can meet the patient's spiritual needs, and advise the patient and family of the availability of the aforementioned bereavement counseling services. We believe the requirements in § 418.64(d) are usual and customary business practices; and therefore, the burden is not subject to the PRA as stipulated in 5 CFR 1320.3(b)(2).

Condition of Participation: Nursing Services—Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice (§ 418.66)

Section 418.66(a) allows CMS to waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area. To obtain a waiver, the hospice must provide evidence to CMS that it made good faith efforts to hire a sufficient number of nurses to provide services. As part of CMS' review process, the hospice must meet the criteria outlined in § 418.66(a)(1)–(3). To obtain an extension for a currently approved waiver, a hospice must submit its request to CMS prior to the expiration of the waiver period and certify that the conditions under which the hospice originally requested the waiver have not changed. The burden associated with this requirement is the time and effort associated with a hospice demonstrating good faith efforts for its staffing process and submitting a certified extension request to CMS stating that the circumstances that caused the original waiver request have not changed. We believe this requirement and the associated burden is exempt from the PRA under 5 CFR 1320.3(c)(4). We believe the requirement will affect less than 10 entities on an annual basis.

Waiver of Requirement—Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Dietary Counseling (§ 418.74)

Section 418.74(a) allows CMS to waive the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) on a 24-hour basis for hospices located in non-urbanized areas. In addition, CMS can waive the requirement that a hospice provide dietary counseling directly. To obtain a waiver, a hospice must provide evidence to CMS that it made good faith efforts to meet the requirements for the aforementioned services prior to submitting a waiver request. As part of CMS' review process, a hospice's waiver request must meet the criteria outlined in § 418.74(a)(1)–(2). To obtain an extension for a currently approved waiver as stated in § 418.74(d), a hospice must submit its request to CMS prior to the expiration of the waiver period and certify that the conditions under which the hospice originally requested the waiver have not changed. The burden associated with this requirement is the time and effort associated with a hospice demonstrating good faith efforts for its staffing process and submitting a certified extension request to CMS stating that the circumstances that caused the original waiver request have not changed. We believe this requirement and the associated burden is exempt from the PRA under 5 CFR 1320.3(c)(4). We believe the requirement will affect less than 10 entities on an annual basis.

Condition of Participation: Hospice Aide and Homemaker Services (§ 418.76)

Section 418.76(b) outlines the standard for the content and duration of hospice aide classroom and supervised practical training. A hospice aide training program must meet the criteria in § 418.76(b)(1)–(3). Section 418.76(b)(4) requires that a hospice maintain documentation demonstrating that its training program meets the requirement of the standard contained in § 418.76(b). We estimate that it will take each hospice 5 minutes to document and maintain records that its hospice aide training program met all of the requirements contained in this

section, for a total annual burden of 239 hours.

Section 418.76(c) describes the standard for competency evaluations. In particular, § 418.76(c)(5) states that a hospice must maintain documentation that all individuals furnishing hospice aide services on behalf of a hospice successfully completed a competency evaluation program. The competency evaluation program must meet the requirements specified under § 418.76(b)(3). The burden associated with this requirement is the time and effort necessary to maintain documentation that demonstrates all individuals furnishing hospice aide services on behalf of a hospice successfully completed a competency evaluation program. We estimate it will take each hospice 5 minutes to meet this requirement, for a total annual burden of 239 hours.

Section 418.76(d) discusses the standard for in-service training. Hospices are required to maintain documentation that all hospice aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement is the time and effort necessary to document and maintain record of the required in-service training. We estimate it will take each hospice 2 hours annually to meet this requirement. The estimate total annual burden for this requirement is 5,744 hours.

Section 418.76(g) describes the standard for hospice aide assignments and duties. Specifically, § 418.76(g)(1) states that written patient care instructions for a hospice aide must be drafted by a registered nurse responsible for the supervision of a hospice aide. The burden associated with this requirement is the time and effort necessary for a registered nurse responsible for supervising a hospice aide to draft written patient care instructions for the hospice aide. We believe this is a usual and customary business practice and is thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.76(h) explains the standard for the supervision of hospice aides. In particular, § 418.76(h)(1)(i) stated that a registered nurse must make an onsite visit to a patient's home no less frequently than every 14 days to assess and document the quality of care and services provided by the hospice care aide and to ensure that the services ordered by the hospice's IDG meet the patient's needs. The burden associated with this requirement is the time and effort necessary for a nurse to conduct an onsite evaluation of a hospice care aide in the patient's home, to document the quality of care provided by the hospice care aide, and to evaluate the services ordered by the IDG to ensure that they are consistent with the patient's needs. We believe this is a usual and customary business practice and is thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.76(h)(2) states that a registered nurse must also make an annual onsite visit to the location to the location where a patient is receiving care to observe and evaluate each aide while he or she is performing care. Section 418.76(h)(3) details the contents of the registered nurse's assessment required in 418.76(h)(3). The burden associated with this requirement is the time and effort necessary for a registered nurse to make an annual on site visit to observe and evaluate each hospice aide while they perform care. In addition, they must document the evaluation. We estimate to meet this requirement that 5 supervisory visits will be conducted on an annual basis per hospice with a total of 14,360 visits annually. We believe it will take each nurse 5 minutes to document the onsite visit. The estimated total annual burden associated with this requirement is 1,197 hours.

Section 418.76(i)(1) contains the standard for individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit. Prior to furnishing personal care services, an individual must demonstrate competency in the services they are required to furnish. The burden associated with this requirement is the time and effort necessary to demonstrate competency. While this requirement is subject to the PRA, we believe the associated burden is exempt stated in 5 CFR 1320.3(b)(2). We believe this is a usual and customary business practice.

Section 418.76(k)(2) requires the instructions for homemaker duties to be prepared by a member of the hospice IDG. The burden associated with this requirement is the time and effort necessary for a member of the IDG to develop and draft instructions for homemaker duties. We believe this is a usual and customary business practice and is thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.76(k)(3) states that homemakers must report all concerns about the patient or family to the member of the IDG who is coordinating the homemaker's services. The burden associated with this requirement is the time and effort needed for the homemaker to report all concerns. We believe the burden is exempt as stated in 5 CFR 1320.3(b)(2); this is a usual and customary business practice.

Conditions of Participation—Volunteers (§ 418.78)

Section 418.78(a) states that a hospice must document, maintain, and provide volunteer orientation and training that is consistent with hospice industry standards. We estimate on average that a hospice would provide orientation and training six times per year; we estimate that it will take no longer than five minutes to document each orientation section for a total of 30 minutes per year per hospice. The total annual burden associated with this requirement is 1,436 hours.

Section 418.78(c) requires hospices to document and demonstrate viable and ongoing efforts to recruit and retain volunteers. The burden associated with this requirement is the time and effort necessary to document and demonstrate the recruitment and retention efforts. We estimate that it will take each hospice 3 hours to document and demonstrate its recruitment and retention efforts, for a total annual burden of 8,616 hours.

The cost-saving standard in § 418.78(d) requires hospices to document the cost savings achieved through the use of volunteers. We estimate that complying with this requirement will take 3 hours per hospice per year, or 8,616 annual hours.

Section 418.78(e) requires hospices to document and maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked. The burden associated with this requirement is the time and effort necessary to document and maintain the volunteer records. We estimate that recording these examples would take approximately 600 hours per hospice for a total annual burden of 1,723,200 hours.

Condition of Participation: Organization and Administration of Services (§ 418.100)

Section 418.100(e) describes the standard for professional management responsibilities. A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. The burden associated with this requirement is the time and effort necessary to develop, draft, execute and maintain the written agreements. We believe these written agreements are part of the usual and customary business practices of

hospices and are thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.100(f)(2) states that a hospice must continually monitor and manage all services provided at all of its locations. The burden associated with this requirement is the time and effort necessary to monitor and manage all of the services provided at all of its locations. The burdens associated with this requirement is considered to be usual and customary as stated in 5 CFR 1320.3(b)(2) and is thereby exempt from the PRA.

Section 418.100(g) describes the standard for training. In particular, § 418.100(g)(2) requires a hospice to provide an initial orientation for each employee that addresses the employee's specific job duties. Section 418.100(g)(3) requires a hospice to have written policies and procedures describing its method(s) of assessment of competency. In addition, the hospice must maintain a written description of the in-service training provided during the previous 12 months. The burden associated with the requirements of this section is considered to be usual and customary under 5 CFR 1320.3(b)(2); usual and customary burdens are exempt from the PRA.

Condition of Participation: Medical Director (§ 418.102)

Section 418.102(b) requires hospice medical directors or physician designees to review the clinical information for each hospice patient and provide written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. Prior to making a certification statement, the medical director or physician designee must consider the issues discussed in § 418.102(b)(1)–(5). Section 418.102(c) states that before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review the patient's clinical information.

The burden associated with the requirements contained in § 418.102(b)–(c) is the time and effort necessary to review the written certification. We estimate this process requires 10 minutes per patient. We estimate the burden for each hospice to be 50 hours annually. The total annual burden associated with the requirements of this section is 143,600 hours.

Condition of Participation: Clinical Records (§ 418.104)

Section 418.104 requires a hospice to maintain a clinical record for each patient. The required contents of the record are listed in § 418.104(a). The burden associated with the requirement is the time and effort necessary to document and maintain the information listed in § 418.104(a). The maintenance of clinical records is a usual and customary business practice; the burden associated with maintaining a clinical record is exempt form the PRA under 5 CFR 1320.3(b)(2).

Section 418.104(b) requires that all of the entries in a clinical record be authenticated. The entries must be legible, clear, complete, and consistent with hospice policy. The burden associated with this requirement is considered to be usual and customary under 5 CFR 1320.3(b)(2). This usual and customary burden is therefore exempt from the PRA.

Section 418.104(d) describes the standard for the retention of records. Clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The burden associated with these requirements is the time and effort necessary to maintain records for 6 years after the death or discharge of the patient, and to draft, implement, and maintain the record retention policy in the event that the HHA discontinues operation. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). The development and maintenance of a record retention policy is a usual and customary business practice.

Section 418.104(f) describes the standard for the retrieval of clinical records. Clinical records, whether in hard copy or electronic form, must be made readily available on request by an appropriate authority. The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). Making clinical records available to the appropriate authority is part of the survey and certification process and imposes no additional burden as a usual and customary business practice.

Condition of Participation: Drugs, Controlled Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106)

Section 418.106(b) describes the standard for the ordering of drugs. In particular, § 418.106(b)(2)(ii) states that the individual receiving a drug order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations. The burden associated with this requirement is the time and effort necessary for the recipient of the order record and sign the order and to have the prescribing person sign the prescription. The burden associated with this requirement is exempt under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3). As defined in 5 CFR 1320.3(b)(2), this process is a usual and customary business practice. As defined in 5 CFR 1320.3(b)(3), a State requirement would exist even in the absence of the Federal requirement. The associated burden is thereby exempt from the PRA.

Section 418.106(c)(2) states that a hospice that provides inpatient care directly in its own facility must have a written policy in place that promotes dispensing accuracy. Additionally, this section requires that a hospice that provides inpatient care directly must maintain current and accurate records of the receipt and disposition of all controlled drugs. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, and maintain a written policy that promotes dispensing accuracy and to maintain controlled drug records. The existence of this type of policy and these records are usual and customary business practices. The burden associated with this section is exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.106(e) discusses the standard for labeling, disposing and storing of drugs and biologicals. Specifically, § 418.106(e)(2)(i) states that a hospice must have a written policy for the management and disposal of controlled drugs in the patient's home. As required by § 418.106(e)(2)(i)(A), a hospice must provide a copy of the written policy required in § 418.106(e)(2)(i) to the patient, and his/her representative and family. Additionally, the hospice must discuss the hospice policy for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner they can understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs, as required by § 418.106(e)(2)(i)(B). Section 418.106(e)(2)(i)(C) requires a hospice to document in a patient's clinical record that the written policy for managing controlled drugs was provided and discussed. Section 418.106(e)(2)(ii) states that a hospice maintain current and accurate records of the receipt and disposition of all controlled drugs.

The burden associated with the requirements contained in § 418.106(e)(2) is the time and effort necessary to provide a written copy of the policy on the management and disposal of controlled drugs in the patient's home to the patient representative and family. There is also some burden associated with the hospice explaining the policy to the patient or representative and the family. In addition, there is a burden associated with documenting in the patient's clinical record that the written policy for managing and controlled drugs was provided and discussed. We believe the burden associated with the aforementioned requirements is exempt from the PRA under 5 CFR 1320.3(b)(2), as they are part of the usual and customary business practice for hospices.

Section 418.106(e)(3)(ii) states that the hospice pharmacist and the hospice administrator are required to immediately investigate any discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs. The event must be reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation. The burden associated with this requirement is exempt under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(h)(6). As defined in 5 CFR 1320.3(b)(2), documenting an investigation and reporting the investigation to the appropriate State authority is a usual and customary business practice. Additionally, the burden associated with making a written account of the investigation available to State and Federal officials upon request is exempt from the PRA under 5 CFR 1320.3(h)(6); the information will be collected from individual hospices on a case by case basis. As stated under in 5 CFR 1320.3(h)(6), information collection requests addressed to a single ''person'' as defined in 5 CFR 1320.3(b)(4), are exempt from the PRA.

Section 418.106(f)(1) states that a hospice must ensure that repair and routine maintenance policies are developed in situations when a manufacturer's recommendation for a piece of equipment is nonexistent. Section 418.106(f)(2) requires a hospice to ensure that the patient, family, and other caregivers receive instruction in the safe use of durable medical equipment and supplies. After providing instruction, the patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment. The burden associated with the requirements in § 418.106(f)(1)–(2) is the time and effort necessary to develop, draft, implement, and maintain repair and routine maintenance policies. There is also burden associated with providing proper instruction on the use of durable medical equipment to patient, family members, and caregivers. As defined in 5 CFR 1320.3(b)(2), providing proper instruction on the use of durable medical equipment to patient, family members, and caregivers is a usual and customary business practice.

Condition Of Participation—Short-Term Inpatient Care (§ 418.108)

Section 418.108(c) requires the use of a written agreement if a hospice has an arrangement with a facility to provide short-term inpatient care. At a minimum, the agreement must address the issues outlined in § 418.108(c)(1)–(6). The burden associated with this requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreement. While this requirement is subject to the PRA, the burden is exempt under 5 CFR 1320.2(b)(2). The use of the written agreements between facilities is a usual and customary business practice.

Condition Of Participation: Hospices That Provide Inpatient Care Directly (§ 418.110)

Section 418.110(c)(1)(ii) states that a hospice must have a written disaster preparedness plan in effect to manage emergencies that might compromise the hospice's ability to provide care. Additionally, the plan must be periodically reviewed. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, maintain, and periodically review the disaster preparedness plan. Section 418.110(c)(2) requires hospices to develop procedures for managing physical plant issues.

The burden associated with the requirements in § 418.108(c) is the time and effort necessary to draft, implement, maintain, and review the facility's disaster preparedness plans and procedures to address physical plant issues. While these requirements are subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2).

Section 418.110(m)(3)(i) specifies that the use of restraint and seclusion must be used in accordance with a written modification to the plan of care. The use of restraint and seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law. The burden associated with this requirement is the time and effort necessary to modify the plan of care in writing to include the physician order for restraint and seclusion.

Section 418.110(m)(4) states that the use or restraint or seclusion must be done in accordance with a physician's orders. There is a burden associated with creating a physician's order. However, we believe the burden associated with the aforementioned requirements is exempt from the PRA under 5 CFR 1320.3(b)(2), as they are part of the usual and customary business practice for hospices.

Section 418.110(m)(7)(ii) states that prior to writing a new order for the use of restraint or seclusion, a physician must see and assess the patient. The burden associated with this requirement is the time and effort necessary for the ordering physician to see and assess the patient.

Section 418.110(m)(15) states that when restraint or seclusion is used, a patient's clinical record must contain the documentation outlined in § 418.110(m)(15)(i)–(v). The burden associated with this requirement is the time and effort necessary to compile the documentation specified in § 418.110(m)(15)(i)–(v) in the patient's clinical record. We estimate the collective burden associated with the requirements contained in 418.110(m)(3)(i), 418.110(m)(7)(ii), and 418.110(m)(15) to be 45 minutes per event per hospice for a total of 8,702 events annually. The annual burden associated with the aforementioned information collection requirements is 6,527 hours.

Section 418.110(n) discusses the standard for restraint or seclusion staff training requirements. Specifically, § 418.110(n)(1) states that all patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment and providing care for a patient in restraint or seclusion. Section 418.110(n)(4) states that a hospice must document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency. We estimate that it will take 96 hours to comply with these requirements. The estimated total annual burden associated with these requirements is 275,512 hours.

Section 418.110(o) states that hospices must report deaths associated with the use of restraint or seclusion. The hospice staff must document in the

decedents clinical record the date and time the death was reported to CMS. We cannot accurately estimate the number of deaths that would occur annually as a result of restraint or seclusion. However, we believe the number is less than 10 per year. While this requirement is subject to the PRA, we believe the burden is exempt under 5 CFR 1320.3(c)(4), as it would affect less than 10 entities.

Condition of Participation: Hospices That Provide Hospice Care To Residents of a SNF/NF or ICF/MR (§ 418.112)

Section 418.112(c) discusses the requirement that a hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospices and the SNF/NF or ICF/MR prior to the provision of hospice care services. At a minimum, the written agreements must address the issues listed in § 418.112(c)(1)–(8). The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. However, the use of this type of written agreement is a usual and customary business practice; the associated burden is exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.112(d) discusses the standard for the hospice plan of care. A written plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. The burden associated with this requirement is discussed in detail under our discussion of § 418.56(c).

Condition of Participation: Personnel Qualifications (§ 418.114)

Section 418.114(d)(1) requires hospices to obtain criminal background checks on all hospice employees who have direct patient contact or access to patient records. Additionally, all hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records. The burden associated with this requirement is the time and effort necessary to conduct background checks and the time and effort necessary to develop, draft, and maintain contracts that require all contracted staff to obtain background checks. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). While fulfilling these requirements, a hospice will not incur any burden above and beyond its usual and customary business practice.

TABLE XX.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control No.	Respondents	Responses	Total annual burden (hours)
§ 418.52(a)	0938–New	2,872	870,216	72,518
§ 418.52(b)	0938–New	2,872	43,080	43,080
§ 418.56(b–c)	0938–0302	2,874	2,874	9,930,912
§ 418.58	0938–New	2,872	2,872	402,080
§ 418.76(b)(4)	0938–New	2,872	2,872	239
§ 418.76(c)	0938–New	2,872	2,872	239
§ 418.76(d)	0938–New	2,872	2,872	5,744
§ 418.76(h)(2)	0938–New	2,872	14,360	1,197
§ 418.78(a)	0938–New	2,872	2,872	1,436
§ 418.78(c)	0938–New	2,872	2,872	8,616
§ 418.78(d)	0938–New	2,872	2,872	8,616
§ 418.78(e)	0938–New	2,872	2,872	1,723,200
§ 418.102(b–c)	0938–New	2,872	2,872	143,600
§ 418.110(m)(15)	0938–New	2,872	8,702	6,527
§ 418.110(n)(1–4)	0938–New	2,872	2,872	275,512
Total		2,874	967,952	12,623,516

We have submitted a copy of this final rule to OMB for its review of the information collection requirements contained within this document. These requirements are not effective until they are approved by OMB.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits 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 ($110 million or more in any 1 year). This is not a major rule, since the overall economic impact for all proposed new Conditions of Participation is estimated to be $40.7 million in the first year.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most hospices (approximately 82% of Medicare certified facilities) are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of less than $12.5 million in any one year (for details, see the Small Business Administration's regulation that sets forth size standards for health care industries at 65 FR 69432). We estimate there are approximately 2,872 hospices with average admissions of approximately 303 patients per hospice (based on the number of patients in 2005 divided by the number of hospices in 2005). The National Hospice and Palliative Care

Organization (Facts and Figures—2005 Findings) estimates that 82.4 percent of hospice patients are Medicare beneficiaries; thus we have not considered other sources of revenue in this analysis.

We certify that this rule would not have a significant impact on a substantial number of small entities because the cost of this rule is less than 1 percent of total hospice Medicare revenue. According to the CMS 2005 national expenditure data, Medicare paid $8.2 billion to providers for hospice care in FY 2005. We estimate this rule will cost hospices approximately $40.7 million or approximately $32,223 per average hospice (operating its own inpatient unit and requiring the supervisory services of an MSW) in the first year. An average hospice that does not operate its own inpatient unit and does not need to hire an MSW, accounting for the vast majority of hospices, will expend $11,151 to comply with this final rule in the first year. While we understand that a few very small hospices (described below) may expend a larger percentage of their revenue to comply with this rule, we believe that this group of hospices is quite small.

We understand that there are different sizes of hospices and that the burden for hospices of different sizes will vary. Therefore, we have assessed the burden for hospices that are smaller than the statistically average hospice used for calculations in part B of this section, Anticipated Effects on Hospices. The smaller hospices have been broken up into two categories based on the number of routine home care days, the most common level of hospice care provided. The categories are group 1 hospices providing 0 to 1,754 routine home care days, and group 2 hospices providing 1,755 to 4,373 routine home care days. Group 1 hospices, averaging 67 patients per year, would spend approximately $18,980 or $5,980, depending on the need to hire and MSW supervisor, to comply with these regulations. The average hospice in this group received $229,406 from Medicare for routine home care days under the 2005 hospice payment rates. Group 2 hospices, averaging 167 patients per year, would spend approximately $21,191 or $8,191, also depending on the need to hire an MSW supervisor, to comply with these regulations. The average hospice in this group received $571,945 from Medicare for routine home care days under the 2005 rates.

The time and cost burden for these providers is less than that of the average hospice used in part B of this section because a portion of the burden associated with these regulations is directly related to patient care and the staff necessary to provide care. Therefore, a consistently smaller patient census leads to reduced burden because the smaller hospices have less staff, complete less data collection and less patient rights orientation etc. These estimates of the annual burden for smaller hospices make only minor adjustments to the estimated quality assessment and performance improvement burden described in part B of this section in the area of patient level data collection. Additionally, these figures do not include the time and cost burden estimates associated with a hospice inpatient facility because it is very uncommon for a hospice with a small annual patient census to operate its own inpatient facility. We estimate that the financial burden for group 1 hospices would be approximately 8.25 or 2.5 percent of the payment received for routine home care days, depending on whether or not the hospice needs to hire an MSW supervisor. For group 2 hospices, the financial burden would be 3.75 or 1.5 percent of the payment received for routine home care days, also depending on whether or not the hospice needs to hire an MSW supervisor. Since employing an MSW is considered the standard within the hospice industry, we believe that very few group 1 and 2 hospices will incur the additional expense of hiring an MSW above their present level of staffing (see B., Anticipated Effects on Hospices, Personnel qualifications for a more detailed discussion). These percentages do not include amounts paid by Medicare for continuous home care days, respite care days, and regular inpatient care days. The percentages also do not include amounts paid by Medicaid, private insurers, and individual patients, which account for approximately 18 percent of hospice revenue. Additionally, these percentages do not include additional income from fundraising, donations, foundations, etc. that hospices routinely use to finance operations and programs. Therefore, we believe that the actual cost incurred by a group 1 or a group 2 hospice accounts for a significantly smaller portion of hospice's overall revenue, and does 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals, since there are few hospice programs in those facilities. 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 one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $127 million. This final rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector of $127 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State or local governments, preempts State law, or otherwise has Federalism implications. This rule has no Federalism implications.

B. Anticipated Effects on Hospices

As described in the preamble, this final rule contains both new provisions and provisions that are carried over from the existing hospice regulations. For purposes of this section, we have assessed the impact of all provisions that may present a burden to a hospice.

Within this section, we have made several assumptions and estimates in order to assess the time that it would take for a hospice to comply with the provisions and the associated costs of compliance. We have detailed these assumptions and estimates in the table below. We have also detailed many, but not all, of the standards within each CoP, and have noted whether or not there is an impact for each. However, the requirements contained in many provisions are already standard medical or business practices. These requirements would, therefore, not provide additional burden to hospice providers.

Our assumptions are based on the idea of an average hospice, culled from national averages. While we understand that there is no average hospice, the idea of an average hospice allows us to quantify the impact of this final rule on a hospice's resources. For purposes of this section only, we describe an average hospice as one that is:

Freestanding;
Not-for-profit;

26 day median length of stay (NHPCO Facts & Figures 2005);
303 annual admissions;
40 employees and volunteers;
27% of patients residing in a SNF/NF, ICF/MR or assisted living facility; and

TABLE 1.—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION

# of Medicare hospices nationwide	2,872
# of hospice patients nationwide	869,201
# of patients per average hospice	303
Hourly rate of registered nurse	$35
Hourly rate of office employee	$14
Hourly rate of administrator	$49
Hourly rate of home health aide	$19
Hourly rate of MSW	$25
Hourly rate of pharmacist	$56
Hourly rate of clinical manager	$36
Hourly rate of QAPI coordinator	$35
Hourly rate of medical director	$114

Note: All salary estimates include benefits package worth 30% of the fringe base salary.

Patient Rights (§ 418.52)

The final rule expands on the informed consent section (§ 418.62) of the current rule, recognizing that hospice patients are entitled to certain rights that must be protected and preserved, and that all patients must be able to freely exercise those rights.

(a) Standard: Notice of Rights. A hospice is required to provide patients or their representatives with written and verbal notice of the patient's rights and responsibilities during the initial assessment visit. A hospice is also required to document that the notice of rights was provided by obtaining the patient's or representative's signature. A hospice must also inform and distribute written information to the patient regarding its policies on advance directives. We estimate that it will take eight hours on a one-time basis for a hospice to develop a patient rights form, at a cost of $392, based on the assumption that an administrator will develop the form. We estimate that it will take approximately five minutes per patient to incorporate this information into the existing informed consent process. At the average hourly rate for a registered nurse, it will cost $2.92 per patient to fulfill the requirement.

8 hours x $49 an hour = $392
$35 hour/60 minutes = $0.58 minute x 5 minutes = $3

(b) Standard: Exercise of rights and respect for property and person. A hospice is required to investigate and document all allegations of abuse, unexplained injuries, and misappropriations of patient property involving hospice employees and contractors. Hospice employees and contractors must report alleged patient rights violations to the hospice administrator, and must report verified violations to appropriate State and local bodies having jurisdiction. A hospice must also take action to correct problems once they are identified.

We expect that a hospice administrator will investigate alleged patient rights violations. We estimate that as many as 5% (15) of an average hospice's patients would require a one-hour-long investigational session, for a total of 15 hours per hospice. The cost for the entire hospice industry would be $2,110,920 a year, while the cost for an average hospice would be $735 a year.

15 investigations per hospice x 1 hour per investigation = 15 hours per hospice
$49 hour x 15 hours per hospice = $735 per average hospice
15 hours per hospice x 2872 hospices = 43,080 hours nationwide
$735 per average hospice x 2872 hospices = $2,110,920

(c) Standard: Rights of the patient. There is no burden associated with this standard.

TABLE 2.—PATIENT RIGHTS BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per hospice (hours)	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Develop form (1st year)	N/A	8	22,976	N/A	$392	$1,125,824
Notice of rights (annual)	5	25.25	72,433	$3	885	2,538,130
Exercise of rights (annual)	N/A	15	43,080	N/A	735	2,110,920
Totals	5	48.25	138,489	3	2,012	4,649,379

Comprehensive Patient Assessment (§ 418.54)

(a) Standard: Initial assessment and (b) Standard: Timeframe for completion of the comprehensive assessment. The existing rule (§ 418.58(c)) requires the hospice to assess the patient's needs and to state in detail the scope and frequency of services needed. The final rule goes beyond this by specifying the time for completing the assessment, the factors to be included in the assessment, and the time for updating the assessment. However, we do not believe this will add any additional burden, since this section of the proposed rule reflects the contemporary standard practice of hospice programs.

(c) Standard: Content of the comprehensive assessment. The assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions that must be addressed in order to promote a hospice patient's well-being, comfort and dignity throughout the dying process. The assessment will include factors such as the patient's physical and nutritional needs, pain status, and psychological state. The assessment will also address complications and risk factors, functional status, imminence of death, severity of symptoms, drug profile and bereavement. This differs from the current rule in that it describes what must be included in the assessment. The factors of the comprehensive assessment were identified by the hospice industry and reflect standard industry practice.

(d) Standard: Update of the comprehensive assessment. Updates of the patient's comprehensive assessment must be conducted at least every 15 days or as frequently as the condition of the patient requires. The current regulation allows the plan of care to determine the frequency of updates. However, due to the rapidly changing status of hospice patients, it is standard practice for a hospice to update a patient assessment at least every 15 days, and often more frequently. This 15-day requirement is also in line with the recertification periods, at which time a hospice must review the patient's clinical information to determine whether a patient continues to be terminally ill with a prognosis of 6 months or less if the illness runs its usual course. This new standard simply codifies current industry practice and does not present a burden.

(e) Standard: Patient outcome measures. The comprehensive

assessment must include consistent, pre-determined data elements that allow for the measurement of patient care outcomes. (Note: There is no data reporting element.) We believe this standard will pose a burden on the hospice provider. However, the burden of collecting information related to these outcome measures is calculated as part of a hospice's quality assessment and performance improvement program.

Interdisciplinary Group, Care Planning and Coordination of Services (§ 418.56)

The final rule makes several changes to the existing rule to improve patient care and lessen burden.

(a) Standard: Approach to service and delivery. This standard describes the members of the IDG and its role in patient care planning and delivery. There is no burden associated with this standard.

(b) Standard: Plan of care and (c) Standard: Content of the plan of care. This section describes the general content areas of each patient's plan of care. The items that are required under the final rule are already included in the standard industry patient plan of care.

(d) Standard: Review of the plan of care. The existing rule states that a patient's plan of care must be reviewed at intervals specified in the initial plan of care. The final rule requires that the plan of care be reviewed at least every 15 days. Several commenters noted that documenting an update to a patient's plan of care takes 1–2 hours of a nurse's time per update. We agree that updating a patient's plan of care requires a fair amount of nursing time. However, we do not believe that requiring a hospice to update a patient's plan of care on a regularly scheduled and as needed basis will present a burden because these are already standard practices within the hospice industry.

Quality Assessment and Performance Improvement (§ 418.58)

The quality assessment and performance improvement (QAPI) requirement builds off of the existing quality assurance requirement. Indeed, quality assurance is already part of standard hospice practice. This rule requires a data-driven approach to assessing and improving quality in all aspects of hospice care, from clinical services to staffing to contracts, that enables hospices to develop a clear understanding of their strengths and weaknesses in a wide variety of areas. However, at this time we do not prescribe the precise areas that each hospice must examine, nor do we prescribe the precise mechanisms for these examinations. Rather, we provide a basic outline of what QAPI is and how we expect it to function in the hospice environment. Each hospice is free to decide how to implement the QAPI requirement in a manner that reflects its own unique needs and goals.

In response to public comments stating that we underestimated the impact of the QAPI CoP on the average hospice, we have significantly revised our impact assessment methodology. Rather than describing the impact in proportion to the impact that this same CoP had on hospitals, we have described the impact in three general phases that we believe an average hospice will go through. These phases are based off of our experience in implementing the QAPI requirements of the proposed rule in the Rural Hospice Demonstration project required by section 409 of the MMA, and from discussions with hospice industry representatives who are active in implementing QAPI programs nationwide. The description of these phases, and the hour and dollar estimates that accompany them were not available at the time that the proposed hospice rule was published. We believe that this new information more accurately reflects the hospice environment.

While we have outlined these phases below, we stress that a hospice is not required to approach QAPI in this manner. We are not requiring a hospice to collect data for a specific domain; use specific quality measures, policies and procedures, or forms; submit data to an outside body; or conduct a specified number of performance improvement projects. A hospice may choose to implement a data-driven, comprehensive QAPI program that meets the requirements of this rule in any way that meets its individual needs. These phases described below simply provide a framework for assessing the potential impact of the QAPI requirement upon an average hospice.

In phase one, we believe that a hospice will:

Identify quality domains and measurements that reflect its organizational complexity; involve all hospice services; affect palliative outcomes, patient safety, and quality of care; focus on high risk, high volume, or problem-prone areas; and track adverse patient events;

Develop policies and procedures to ensure that data is consistently collected, documented, retrieved, and analyzed in an accurate manner; and

Educate hospice employees and contractors about the QAPI requirement, philosophy, policies, and procedures.

In phase two, we believe that a hospice will:

Enter data into patient clinical records during patient assessments and IDG meetings;

Aggregate data by collecting the same pieces of data from patient clinical records and other sources (for example, human resource records, pharmacy records, etc.);

Analyze the data that is aggregated through charts, graphs, and various other methods to identify patterns, anomalies, areas of concern, etc. that may be useful in targeting areas for improvement; and

Develop, implement, and evaluate major and minor performance improvement projects based on a thorough analysis of the data collected.

In phase three, we believe that a hospice will:

Identify new domains and measures that may replace or be in addition to the domains and measures already being monitored by the hospice;

Develop and/or revise policies and procedures to accommodate the new domains and measures; and

Educate hospice employees and contractors on the new domains and measures, as well as the policies and procedures for them.

In addition to these three phases, a hospice will likely allocate resources to an individual responsible for the general overall coordination of its QAPI program. For simplicity, we refer to this individual as the QAPI coordinator; however, a hospice is not required to use this title.

Based on these three phases, we have anticipated the impact of the QAPI requirement on a hospice's resources. In phase one, we anticipate that a hospice will use 12 hours to identify quality domains and measures. These hours will be distributed among the three members of the hospice's QAPI committee. While we do not require a hospice to have a QAPI committee, we believe that most hospices will choose to do so. The hospice model is based on the idea of an interdisciplinary group of people working together, and we believe that hospices will choose to use this group decision-making model in the QAPI process as well. We believe that the QAPI committee will include the QAPI coordinator, the hospice administrator, and a clinical manager. We estimate that the QAPI committee will meet four times quarterly for 1 hour each meeting to identify appropriate quality domains and measures. The total cost for an average hospice to identify the domains and measures, then, is $480.

4 meetings × 1 hour per meeting × $35/hour for QAPI coordinator = $140
4 meetings × 1 hour per meeting × $49/hour for administrator = $196
4 meetings × 1 hour per meeting × $36/hour for clinical manager = $144

While we anticipate that a hospice will use resources to develop policies and procedures and educate staff, we believe that these activities are part of standard business practice and do not pose an additional burden to a hospice. For example, a hospice already conducts a regular in-service training program for its employees in accordance with the in-service training requirement at existing § 418.64. A hospice can incorporate QAPI training into this existing in-service training program with no associated increase in burden.

In phase two, we anticipate that a hospice will use 91 hours to enter data (at the time of each assessment, 40.4 hours + at the time of each IDG meeting, 50.5 hours), 48 hours to aggregate data, and 12 hours to analyze data. Although thoroughly assessing a patient is already standard practice, we believe that collecting quality measure data during the patient assessment will be a new practice for many hospices. We estimate that a hospice will spend 40.4 hours a year to collect patient-level quality data during patient assessments, and that a registered nurse is the most likely person to perform this data collection.

4 minutes per patient assessment to collect quality data × 2 assessments per patient × 303 patients = 40.4 hours × $35/hr for a registered nurse = $1,414

The QAPI CoP requires a hospice to use the quality data collected during the patient assessment during the IDG meeting to monitor the effectiveness of interventions in helping the patient and family achieve desired outcomes. While a hospice IDG already makes decisions based on the information contained in the patient's clinical record, they may not be systematically documenting this analysis and its results. We believe that documenting the results of the data analysis (for example, any changes to the plan of care based on the specific quality measure data) during the IDG meeting will require additional time for each patient. We estimate that this activity will require 50.5 hours for an average hospice, based on an assumed five minutes per patient to document quality measure analysis. We believe that the registered nurse assigned to coordinate the patient's plan of care is the individual most likely to document this information.

5 minutes per patient to document during IDG meeting × 2 IDG meetings per patient × 303 patients = 50.5 hours × $35/hour for a registered nurse = $1,768

In addition to using quality measure data on a patient level, a hospice must gather the patient-level data and other data. Once gathered, a hospice must organize the data in a meaningful way. We estimate that, in order to ensure that the volume of gathered data is manageable, a hospice will gather its data once a month. A hospice may choose to gather data on a more or less frequent basis to suit its needs and circumstances. Some hospices may choose to gather all patient-level data, while others may choose to gather data from a sample of all patient-level data. Likewise, some hospices may choose to gather data from a wide variety of administrative files, while others may choose to select only a few administrative data sources. There are many combinations that a hospice may choose to use when it comes to gathering data, and no single approach is considered preferable to another. Given this variability, it is difficult to estimate how long an average hospice may spend gathering and organizing data. For purposes of this analysis only, we assume that an average hospice will use four hours per month to gather data, for a total of 48 hours a year. We believe that an office employee will perform the data aggregation and organization.

4 hours a month to gather and organize data × 12 months = 48 hours × $14/hr for an office employee = $672

Following data gathering and organization, a hospice must analyze the data to identify trends, patterns, anomalies, areas of strength and concern, etc. We believe that this data analysis will be done by the QAPI committee described previously. In order to identify trends and patterns, the committee would need to examine several months of data at the same time. Therefore, we assume that the committee will meet once every quarter to examine the data and make decisions based off of it. We assume that these meetings will be one hour each, for a total cost of $480.

4 meetings × 1 hour per meeting × $35/hour for QAPI coordinator = $140
4 meetings × 1 hour per meeting × $49/hour for administrator = $196
4 meetings × 1 hour per meeting × $36/hour for clinical manager = $144

Performance improvement projects follow all of the data entry, gathering, organization, and analysis. A hospice must conduct projects to improve its performance in areas where a weakness is identified. Performance improvement projects must reflect the hospice's scope, complexity, and past performance. They must also be data-driven, and affect palliative outcomes, patient safety, and quality of care. Although this final rule more clearly describes a performance improvement project, its basis, and its purpose, are fundamentally the same as the current requirement at § 418.66, ''Quality assurance.'' That requirement states that, ''A hospice must * * * correct identified problems and * * * revise hospice policies if necessary * * * [and] [m]ake suggestions for improving patient care.'' Since a hospice already makes an organized effort to improve patient care in all of its facets, and since providing safe and effective care at all times for all patients is the essential charge of all health care providers, including hospices, we believe that conducting both major and minor performance improvement projects is already a standard of practice within the hospice industry. Therefore there is no additional burden associated with this provision.

Phase three of the QAPI process builds upon the QAPI program that a hospice already has in place. We estimate that a hospice will use three hours a year to identify new domains and quality measures, and we believe that the QAPI committee will perform this task. Just as in phase one, we believe that the tasks of developing and/or updating the hospice's policies and procedures and educating the hospice's staff and contractors are standard practice within the hospice industry.

1 meeting × 1 hour per meeting × $35/hour for QAPI coordinator = $35
1 meeting × 1 hour per meeting × $49/hour for administrator = $49
1 meeting × 1 hour per meeting × $36/hour for clinical manager = $36

In order to ensure the adequate functioning of a hospice's QAPI program, a hospice must designate an individual to be responsible for its QAPI program. We estimate that a QAPI coordinator will spend 1.5 hours per week overseeing the QAPI program, performing various functions as needed, for a total of 78 hours per year.

1.5 hours/week × 52 weeks = 78 hours × $35/hour = $2,730

TABLE 3.—QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per hospice (hours)	Total time (hours)	Cost per hospice	Total cost
Identify domains and measures (1st year)	12	34,464	$480	$1,378,560
Enter data [1] (1st year and annual)	91	261,352	3,182	9,138,704
Aggregate data [1] (1st year and annual)	48	137,856	672	1,929,984
Data analysis (1st year and annual)	12	34,464	480	1,378,560
QAPI coordinator (1st year and annual)	78	224,016	2,730	7,840,560
Update domains and measures (annual)	3	8,616	120	344,640
Total 1st year	241	*692,152	7,544	*21,666,368
Total annually	232	*666,304	7,184	*20,632,448

*Note: The overall national estimates are based on the assumption that every hospice will begin to develop and implement a QAPI program upon the effective date of this final rule. Anecdotal evidence suggests that many hospices began developing and implementing QAPI programs upon publication of the proposed hospice rule, and therefore will not be impacted to the same extent as we have estimated above. Thus, we expect that the actual impact of this final requirement will be less than estimated in this section.

Infection Control (§ 418.60)

There is no specific existing requirement for infection control other than what is briefly mentioned in the existing § 418.100(i), ''Standard: Isolation areas.'' However, we believe that hospice clinicians such as nurses, physicians, and therapists are already using infection control practice as part of the current requirement that hospice clinicians provide services to patients in accordance with accepted standards of practice. It is an accepted standard of practice to use infection control methods when caring for patients. This final regulation reinforces those positive infection control practices and addresses the serious nature of infectious and communicable diseases. Infection control and standard precautions are long-standing clinical practices that are standard throughout the medical industry.

This final CoP requires a hospice to continue to take specific and appropriate actions to address the prevention and control of infections, including patient, staff, and caregiver education. We acknowledge that this is a new focus; however, we do not believe this will add any regulatory burden, since this section of the final rule reflects contemporary standard practice in hospice programs.

Core Services (§ 418.64)

The final rule allows core services to be provided under contract in certain extraordinary or other non-routine circumstances as described, allowing hospices more flexibility. One specific provision allows a hospice to contract for highly specialized nursing services, providing even more staffing flexibility. The option to contract out for highly specialized nursing services allows a hospice to provide such highly specialized services at a lower cost than if it directly employed an individual(s) to perform such services. A hospice that chooses to contract for core services or highly specialized nursing services must have a contract with the entity providing the contracted services. Negotiating, documenting and signing a business contract is standard business practice and does not impose a burden.

(d) Standard: Counseling services. The final rule also requires a hospice to offer bereavement services to appropriate residents of a SNF/NF or ICF/MR. Residents of a facility often act as a patient's family, providing care, support, and companionship throughout the terminal illness. In such cases, we believe that it is appropriate for a hospice to offer bereavement services to the affected residents in the same manner that bereavement services are offered to a patient's family. Since offering and subsequently providing bereavement services to a patient's family is standard practice, we do not believe that extending such services to those who act as a patient's family in a SNF/NF or ICF/MR imposes an additional burden upon a hospice relative to the burden of providing bereavement services to a patient's family.

Waiver of Requirement—Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Dietary Counseling (§ 418.74)

This waiver, currently implemented through a memorandum from CMS's Center for Medicaid and State Operations, will reduce the compliance burden on hospices located in non-urbanized areas. If the hospice program demonstrates that recruitment efforts were unsuccessful, it may request certain waivers with respect to PT, OT, speech-language pathology, and dietary counseling. There have been no applications for this waiver in the past 5 years; therefore we believe that the burden is negligible.

Hospice Aide and Homemaker Services (§ 418.76)

Hospice aide and homemaker services are an integral part of hospice care, yet they receive little attention in the current regulation. These services are briefly addressed in § 418.94 with a standard regarding the supervision of home health aide services and a standard regarding written patient care instructions. These two standards appear in the final regulation, with some minor alterations. The final regulation also adds several new requirements.

(b) Standard: Content and duration of hospice aide classroom and supervised practical training; (c) Standard: Competency evaluation; (d) Standard: In-service training.

These three standards describe the ways in which a hospice aide can meet the qualification requirements. All of these standards require the hospice to maintain documentation that each hospice aide meets these qualifications. The burden associated with these standards is the time to complete the required documentation. We estimate that it will take five minutes to document the information and that an office employee will complete this task. In addition, we have calculated the burden based on an employee turnover rate of 30% (2002 NHPCO National Data Set Summary Report), meaning that we expect that the average hospice would replace 30% of its hospice aides in a given year, or roughly one hospice aide a year based on the employment of 5 hospice aides. Based on the above-mentioned estimates and assumptions, we estimate that will cost an average hospice $1.17 to document that its hospice aides meet the qualification

requirements, for a total cost of $3,360 nationwide.

$14 an hour for an office employee to document compliance/60 minutes = $0.23 minute × 5 minutes per aide to document compliance = $1.17 × 1 document per year = $1.17 per hospice

$1.17 per hospice × 2,872 hospices = $3,360

5 min to document × 2872 hospices = 14,360/60min = 239 hours

(g) Standard: Hospice aide assignments and duties. The hospice aide is required to report changes in the patient's needs to a registered nurse, and complete appropriate records in compliance with the hospice's policies and procedures. This new requirement reflects the standard industry practice of maintaining communication between all healthcare providers and maintaining a complete patient record.

(h) Standard: Supervision of hospice aides. This standard retains the current rule's requirement that a registered nurse visit the patient's home to assess hospice aide services every 14 days. This standard also requires that a registered nurse visit the patient's home annually or more frequently when there are care/performance issues, when the aide is providing services in the home. We believe that thoroughly supervising employees is standard practice and does not increase burden.

(j) Standard: Homemaker qualifications. The final regulation requires homemakers to complete a hospice orientation program addressing the needs and concerns of patients and families coping with a terminal illness. We believe that this standard does not impose any additional regulatory burden because hospices train all of their employees, including homemakers, to deal with the realities of hospice care.

(k) Standard: Homemaker supervision and duties. A member of the IDG is required to develop written instructions for the homemaker. We have also added a requirement that a member of the IDG must coordinate and supervise the homemaker services. We believe that providing patient care instructions, coordinating care, and supervising homemakers are usual and customary practice; therefore, this requirement would not impose any additional regulatory burden.

TABLE 4.—HOSPICE AIDE AND HOMEMAKER SERVICES BURDEN ASSESSMENT

Standard	Time per aide (minutes)	Time per hospice (minutes)	Total time (hours)	Cost per aide	Cost per average hospice	Total cost
Documentation (based on 1 new hospice aide per year)	5	5	239	$1.17	$1.17	$3,360
Totals	5	5	239	1.17	1.17	3,360

Organization and Administration of Services (§ 418.100)

The revised requirements for the organization and administration of services are essentially the same as those in the previous conditions of participation. We added a requirement to clarify the relationship between the hospice governing body and the hospice administrator. This clarification presents no burden for a hospice.

(f) Standard: Hospice multiple locations. We also added a requirement that a hospice must apply to CMS to receive authorization for the opening of a multiple location. This practice is currently mandated through a June 1997 memorandum from CMS' Center for Medicaid and State Operations. Requesting approval from CMS to provide services to Medicare and Medicaid patients from a particular location is standard practice in the industry and does not present a burden for a hospice.

(g) Standard: Training. Finally, we added two employee training requirements. First, we added a requirement that a hospice must provide an initial orientation for each employee that addresses the employee's specific job duties. Second, we added a specification for the maintenance of in-service training records to help a hospice document its compliance with the provision of in-service training requirement. These additions reflect standard practice in the industry and present no additional burden.

Medical Director (§ 418.102)

This rule includes a new requirement that a hospice must designate a physician to assume the role and responsibilities of the medical director when the medical director is not available. All hospices routinely meet the medical needs of their patients 24 hours a day, including the need for physician services. As such, they must already have a physician available at all times. A single physician cannot fulfill this 24-hour a day hospice physician role; therefore hospices already have more than one physician available. We believe that identifying the alternative physician as the physician designee, ready and able to fulfill the medical director role in the medical director's absence, does not pose a burden to a hospice.

(a) Standard: Medical director contract. We added a provision permitting the medical director to work under a contractual arrangement, reducing the program and hiring burden on the hospice. If a hospice chooses to secure medical director services through a contract, this rule requires the contract to specify the physician who will serve as the medical director. Identifying a single individual to serve as the hospice medical director is standard practice in the hospice industry and does not present a burden.

(b) Standard: Initial certification of terminal illness and (c) Standard: Recertification of the terminal illness. This rule codifies the current standards of practice to which medical directors adhere for certifying and recertifying a patient's terminally ill status.

(d) Standard: Medical director responsibility. This rule re-codifies the requirement that the medical director or designee has responsibility for the medical component of the hospice's patient care program. It is standard practice for the hospice medical director to lead, and thus bear responsibility for, the medical component of the hospice's patient care services. Therefore, this re-codified provision does not impose a burden upon a hospice.

Clinical Records (§ 418.104)

This rule adds specificity in regard to content, authentication, retrievability, retention, and transfer of records. It requires a hospice to include all relevant patient care information in each patient's clinical record in order to facilitate communication and coordination among all disciplines involved in a patient's care. It also requires a hospice to ensure that clinical record entries are legible, clear, complete, and authenticated in

accordance with its own policies. Furthermore, this rule requires a hospice to protect and retain the information contained in the clinical record in accordance with the Department's rules regarding personal health information at 45 CFR parts 160 and 164. All of these requirements reflect standard hospice practices and do not pose a burden.

(e) *Standard: Discharge or transfer of care.* This rule requires a hospice to prepare and send a comprehensive discharge summary for all patients that are discharged alive. The discharge summary must include a summary of the patient's stay, the patient's current plan of care, the most recent physician orders, and any other documentation to aid in post-discharge care of the patient. These are standard elements for discharge summaries in the health care industry, including the hospice industry. This rule also requires a hospice to send a copy of the patient's clinical record to the provider assuming care of the patient, if the provider assuming care requests a copy of the clinical record. A comprehensive discharge summary should remove any reason for the provider assuming care to request a copy of the patient's clinical record. Therefore, we do not believe that this requirement will pose a burden to a hospice. We believe that these discharge requirements reflect standard industry practice and add no burden.

Drugs, Medical Supplies and Durable Medical Equipment (§ 418.106)

(a) Standard: Managing drugs and biologicals. We added a requirement that a hospice must ensure that its IDG(s) confers with an individual with education and training in drug management to ensure that drugs and biologicals meet each patient's needs. A hospice may meet this requirement in a variety of ways that is, by hiring or contracting with a pharmacist(s), by contracting with a pharmacy benefit management company, by hiring or contracting with a physician or other clinician with the necessary education and training in drug management (for example, a physician who is board certified in palliative care once board certification is available in October 2008), or by ensuring the appropriate education and training of one or more existing hospice employees.

For purposes of our analysis only, we are estimating the impact of this provision based on the assumption that an average hospice will choose to use a pharmacist to meet this requirement. We have made this assumption based on two factors. First, pharmacists are relatively easier to access in most parts of the country as compared to clinicians who have specialized drug management education and training. Second, pharmacist services can be easily accessed by phone and electronic communications through a local pharmacy or a pharmacy benefit management company. Hospices are in no way required to use a pharmacist to fulfill this role. We estimate that an average hospice already spends $123,842 annually to provide drugs and biologicals for its patients ($15.72 per patient day (dollar figure is not adjusted for inflation) for drugs and biologicals based on 2001 Millman USA report titled ''The Costs of Hospice Care: An Actuarial Evaluation of the Medicare Hospice Benefit'' and consistent with the 2002 NHPCO National Data Set). Based on discussions with the leading hospice pharmacy benefit management company, for approximately this same price ($12–18 per patient day), a hospice may contract with a pharmacy benefit management company to provide all drugs and biologicals for its patients. In addition, the pharmacy benefit management company allows a hospice IDG to speak with a pharmacist on a 24-hour basis to gather information, input, and advice from the pharmacist regarding an individual patient's drug and biological profile. Contracting with a pharmacy benefit management company and utilizing its pharmacists satisfies the new requirement without increasing a hospice's expenditures beyond what it is currently spending to provide drugs and biologicals alone. Since hospices currently have the option of contracting with a pharmacy benefit management company to comply with this requirement without increasing overall pharmacy costs, we do not believe that this new requirement poses a burden to a hospice. As of January 2008 approximately 1,600 hospices currently use the services of pharmacy benefit management companies.

If a hospice decides not to use a pharmacy benefit management company, it may also choose to employ or contract with a pharmacist(s) for pharmacist advisement services. A hospice that chooses to use the services of a pharmacist (or other individual with specialized education and training in drug management) in lieu of a pharmacy benefit management company retains the responsibility and flexibility of managing the purchase of drugs and biologicals. We estimate that it requires 30 minutes for an individual such as a pharmacist to initially review a patient's drug and biologicals profile and advise the IDG during the time of the patient's comprehensive assessment and development of the plan of care. Additionally, we estimate that it requires 15 minutes of a individual's time to review updates to the patient's drug profile and advise the IDG about updates to the patient's plan of care. Based on a 26 day median length of stay, patients would likely receive two updates to their plans of care. Using these estimates, a hospice would expend $56 per patient to secure pharmacist advisement services. An average hospice would expend $16,968 annually to secure pharmacist advisement services for all of its patients. We have not estimated the cost associated with a hospice using an individual from another clinical discipline who has specialized education and training in drug management because we are unsure of what disciplines would be used in this role, depending upon the needs of each hospice.

30 minute initial advisement per patient at $28 + 15 minute update advisement per patient at $14 + 15 minute update advisement per patient at $14 = $56 per patient for all pharmacists advisement services

$56 per patient × 303 patients = $16,968

(b) Standard: Ordering of drugs, (c) Standard: Dispensing of drugs and biologicals and (d) Standard: Administration of drugs and biologicals. We added requirements governing the ordering, dispensing, and administration of drugs and biologicals. Having written policies and procedures in place to manage drugs and biologicals, and educating patients and families about these policies and procedures is standard practice in the hospice industry. Therefore, these requirements pose no burden to a hospice.

(e) Standard: Labeling, disposing and storing of drugs and biologicals. This standard requires a hospice to ensure safe labeling of all drugs and biologicals in accordance with current standards of practice. This standard also requires a hospice-operated inpatient facility to investigate discrepancies involving controlled drugs and to document an account of the investigation. Of the 2,533 deficiencies issued by State surveyors in 1,161 surveys in 2006, two were potentially related to controlled drug discrepancies. The 1,161 surveys in 2006 represent approximately 30 percent of all hospices. Therefore, we can expect that if all hospices were surveyed, six deficiencies would be issued that are potentially related controlled drug discrepancies. We do not expect a significant increase in

discrepancies, and estimate that six investigations would be conducted and documented throughout the hospice industry.

The rule requires the hospice's pharmacist and administrator to conduct controlled drug investigations. We estimate that a thorough investigation, including an examination of the records of incoming and outgoing drugs and biologicals, and report would require one hour per incident. The entire industry would thus spend six hours annually at a cost of $624 to fulfill this requirement. Maintaining inventory records incoming and outgoing drugs and biologicals is a usual and customary business practice and is not a burden.

$55 hour + $49 hour = $104 hour × 1 hour investigation = $104 per investigation
$104 per investigation × 6 investigations = $624 industry wide

In addition, we added a requirement regarding documentation of patient and family drug education. A hospice must document in the patient's clinical record that it provided a copy of its controlled drug policy to the patient and family at the time when a controlled drug is first ordered. A hospice must also document that it discussed the controlled drug policy with the patient and family. Documenting the provision of the material and the education session requires approximately five minutes, and will likely be completed by a registered nurse. Fulfilling the requirement would cost $2.25 per patient based upon the average hourly rate for a registered nurse.

$27 hour/60 minutes = $0.45 minute × 5 minutes = $2.25
$2.25 per patient × 303 patients = $682
$2.25 per patient × 303 patients × 2872 hospices = $1,957,986

(f) Standard: Use and maintenance of equipment and supplies. We added a requirement that a hospice must ensure that manufacturer recommendations for routine and preventive maintenance of equipment are followed. If manufacturer recommendations do not exist, a hospice must ensure that maintenance policies are developed. A hospice must also ensure that the patient and family receive instruction regarding the use of equipment and supplies, and that the patient and family can safely demonstrate the use of the equipment and supplies. Hospices already require their equipment and supply vendors to properly maintain the equipment supplied to hospice patients. Therefore, we believe that this maintenance requirement does not impose a burden. Additionally, hospices already assure that patients and families can operate the supplied equipment. When a patient and family safely and effectively use equipment, the hospice does not need to continually send its staff to the patient's home for equipment problems. Since this routine education already occurs, benefiting both the patient and the hospice, this requirement does not impose a burden.

The vast majority of hospices provide durable medical equipment and supplies under contract with one or more vendors. For this reason, we added a requirement that a hospice may only contract with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Standards at 42 CFR 424.57. We do not believe that this requirement will compromise a hospice's ability to secure a contract or significantly increase the cost of that contract because most vendors choose to meet the Medicare Supplier Standards in order to furnish equipment and supplies to Medicare beneficiaries. Therefore, there is sufficient competition among vendors to provide high quality services at a reasonable cost to hospices seeking contracts.

TABLE 5.—DRUGS, MEDICAL SUPPLIES AND DURABLE MEDICAL EQUIPMENT BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per average hospiace (hours)	Total industry time (hours)	Cost per patient	Cost per average hospice	Total industry cost
Drug Policy Education	5	25.25	72,518	$2.25	$681.75	$1,957,986
Drug Discrepancy Investigation	N/A	N/A	6	N/A	N/A	624
Total	5	25.25	72,524	2.25	681.75	1,958,610

Short Term Inpatient Care (§ 418.108)

(b) Standard: Inpatient care for respite purposes. This rule allows a hospice to contract for respite care with a facility that does not have a registered nurse on-duty providing direct patient care 24-hours a day. This provision will make it easier for hospices to contract with long term care facilities.

(c) Standard: Inpatient care provided under arrangements. This rule provides additional guidance with respect to the substance of the written agreement between a hospice and an inpatient facility, which we believe is a usual and customary business practice. Therefore, this provision therefore does not increase regulatory burden.

(d) Standard: Inpatient care limitation and (e) Standard: Exemption from limitation. This rule also maintains the 20 percent limitation on inpatient days and the exemption to this limitation. These requirements are statutory and have been in place since the inception of the Medicare hospice benefit. They reflect the goal of the hospice movement and benefit to keep patients in their home, where most patients prefer to stay. Therefore, they are standard practice.

Hospices That Provide Inpatient Care Directly (§ 418.110)

(b) Standard: Twenty-four hour nursing services. This rule includes the 24-hour nursing requirement from the existing rule. In short, a hospice that provides general inpatient care directly must have a registered nurse who provides direct patient care on each shift. This requirement has been in place since the inception of the Medicare hospice Conditions of Participation. As such, it is standard practice and does not pose a burden.

(c) Standard: Physical environment through (l) Standard: Meal service and menu planning. This rule requires a hospice to maintain a safe physical environment in its inpatient facility. A hospice must:

Have and rehearse a disaster preparedness plan;

Manage all aspects of the building (that is, waste, water supply, and ventilation);

Comply with applicable fire safety requirements;

Have a home-like atmosphere with sufficient space and amenities;

Have an adequate infection control program;

Have clean linens and properly handle soiled ones; and

Serve meals to meet patient needs.

These requirements are standard practice in hospice-operated inpatient facilities and pose no additional burden.

(m) Standard: Restraint or seclusion, (n) Standard: Restraint or seclusion staff training requirements and (o) Standard:

Death reporting requirements. This rule adds considerable detail in regard to seclusion and restraint. This section is adapted from the language of the Patient's Rights Condition of Participation for hospitals published as a Final Rule in the **Federal Register** in December 2006, and codified at 42 CFR 482.13. While we anticipate that hospices with their own inpatient facilities will be impacted by this rule, we do not have the benefit of several key pieces of information. For example, we do not have reliable data on the prevalence of restraint and seclusion use, data on the volume of staff in inpatient hospices, or data on the varying levels and qualifications of hospice staff who may be involved in restraint and seclusion use. Factors such as size, services rendered, staffing, and patient populations vary as well. We are hesitant to make impact estimates in this final rule that may not account for these and other unforeseen variations. Thus, we reserve the right to provide estimates when feasible. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

(m) Standard: Restraint or seclusion. Standard 418.110(m) sets out the patient's rights in the event he or she is restrained or secluded, and limits when and by whom restraint or seclusion can be implemented. We recognize that there will be some impact associated with performing patient assessment and monitoring to ensure that seclusion and restraint are only used when necessary and are implemented in a safe and effective manner. However, patient assessment and monitoring are standard components of patient care, and this requirement does not pose a burden to a hospice.

Section 418.110(m)(6) requires that the medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. Although this may minimally increase burden to hospices, we believe it is a best practice for patient safety.

We have added elements at § 418.110(m)(14) that monitoring must occur face-to-face by trained staff or by using both video and audio equipment, when there is simultaneous use of restraint and seclusion. We have added elements at § 418.110(m)(15) regarding the documentation that must be included in the patient's medical record when the patient is restrained or secluded, including the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior, the patient's behavior and intervention used, alternatives or other less restrictive interventions attempted (as applicable), the patient's condition or symptom(s) that warranted restraint or seclusion use, and the patient's response to the use of the restraint or seclusion intervention, including the need for continued use of restraint or seclusion. We do not believe additional burdens are imposed by this requirement since it is a routine and customary practice to document the circumstances surrounding such an event for comprehensiveness of patient care.

In response to the December 19, 1997 proposed rule that we published concerning the use of seclusion and restraint in hospitals, the National Association of Psychiatric Health Systems (NAPHS) supplied data from fifty members for the time and cost of complying with the CMS requirements that a physician evaluate a patient face-to-face within 1 hour of the initiation of restraint or seclusion. The NAPHS stated their respondents reported it took an estimated 30 minutes to 1 hour to document all the specific elements required by CMS after a restraint or seclusion episode. This included several elements unique to the rule such as physician notification if the restraint was ordered by someone other than the patient's attending physician.

We believe that the time associated with documenting seclusion or restraint episode in a hospice is similar to that in a hospital. Thus, our burden estimate is based on a median timeframe (that is, 45 minutes) that we believe it takes to complete the required documentation in the patient's clinical record. However, since we are unable to estimate the prevalence of restraint and seclusion, we can not apply this estimate to assess the associated burden across hospices.

(n) Standard: Restraint or seclusion staff training requirements. Standard 418.110(n) identifies the training requirements for all staff involved in the use of seclusion and restraint in the hospice inpatient facility. While we have tried to minimize the burden which will be placed on hospices in order to meet this requirement, we believe it is important for the provision of safe and effective restraint or seclusion use. We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded patient, or provide care for a restrained or secluded patient, the staff must be trained and able to demonstrate competency in the performance of these actions. The staff training requirements address the following broad areas: Training intervals, training contents, trainer requirements, and trainer documentation.

To reduce burden and create a reasonable requirement while assuring patient safety, we have mandated that only those staff who are involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for restrained or secluded patients have this training. While we expect physicians to be trained in the proper use of restraint or seclusion, we do not expect that they will be trained with the other hospice staff. Thus, we have not included physicians in the burden associated with these requirements. Instead, we require the remaining hospice staff who have direct contact with patients must be trained in restraint or seclusion use.

In this final rule, we have specified broad topics to be covered in training, and have not required that staff be trained by an outside organization. We believe that in-house training may be more economical than sending staff off-site for instruction. However, hospices have the option of sending either selected or all staff to outside training if they believe that this is warranted.

Thus, we have based our burden estimate on having the actual number of trainers attend the training from an outside organization one time. We believe that most hospices would, in turn, have these trained individuals function as program developers and trainers of the appropriate hospice staff. We believe in most instances this professional will be a registered nurse.

Train-the-trainer programs are the way many hospices provide staff instruction. The four day instructor certification program given by the Crisis Prevention Institute (CPI, INC.) costs $1,200 dollars in tuition plus travel, lodging, and participant salary (HYPERLINK ''*http://www.crisisprevention.com''* *www.crisisprevention.com*).

We estimate, on average, that roundtrip travel for each nurse will cost approximately $400 to cover the need for either local or distant travel, lodging for each nurse will costs approximately $120 per night × 3 nights, and the meals and incidental expenses (M&IE) will be approximately $50 per day depending upon the location within the designated state. Thus, we anticipate the cost to train one nurse would be $3,280. If all 906 hospices (estimate based on March 2006 Hospice Facts & Statistics report from the Hospice Association of America that 31.54 percent of hospices have their own inpatient facilities) with inpatient facilities were to send one

nurse to such training, the total cost for the 906 hospices would be $2,971,680.

$1,200 for instructor certification program + $400 airfare + $360 for 3 days lodging + $200 for 4 days M&IE + $1120 for nurse salary at $35 per hour × 8 hours per day × 4 days = $3,280 per nurse per hospice inpatient facility.
$3,280 per nurse per hospice × 906 hospices = $2,971,680

We believe that hospices will add seclusion and restraint training onto their existing in-service training programs. The train-the-trainer program described above will provide hospices with the necessary personnel and materials to implement a staff-wide seclusion and restraint training program. We estimate that developing this staff-wide training program will require 40 hours of the trainer's time on a one-time basis for all affected hospices, at a cost of $1,400 per hospice inpatient facility.

We require that each individual who will potentially be involved in restraint and seclusion of a patient have training in the proper techniques. According to the NAPHS, initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Using data from a March 2006 Hospice Association of America report, there were 116,148 total hospice employees and volunteers in 2005. Of these employees and volunteers, 32,412 employees and volunteers were nurses and physicians. Thus the average hospice operating its own inpatient facility has 11 nurse and physician employees and volunteers. We realize that some hospices will have more or less employees and volunteers to train. Based on one nurse trainer conducting an 8 hour training course for 11 hospice inpatient employees and volunteers, we estimate that this requirement will cost $3,360.

8 trainer hours at $35/hr = $280
88 trainee hours at $35/hr = $3080
$280 trainer cost + $3080 trainee costs = $3,360

We require that each individual will receive annual updates to the training and that the annual training will also be documented. Again, according to NAPHS, annual updates are about 4 hours of staff and instructor time per each employee who has direct patient contact. Again, an average size hospice has 11 employees who have direct patient contact that must to be trained in de-escalation techniques. Therefore, we estimate that it will cost $1,680 annually to update each person's training.

4 trainer hours at $35/hr = $140
44 trainee hours at $35/hr = $1540
$140 trainer costs + $1540 trainee costs = $1,680

Additionally, we required recordkeeping for documenting in each trained individual's personnel record that he or she has successfully completed training. We estimate that it will take the trainer 5 minutes per trainee to document each participant's completion of the training. As described above, we estimate that 11 hospice employees and volunteers will be trained.

5 minutes per trainee × 11 trainees = 55 minutes annually
55 minutes × $35/hr = $32 annually
55 minutes per hospice × 906 hospices = 830.5 hours industry wide
830.5 hours industry wide × $35/hr = $29,067.5 industry wide

Finally, we require that each hospice revise its training program annually as needed. We estimate this task, completed by the trainer, to take approximately 4 hours annually per hospice.

4 hours × $35/hr = $140 per hospice
$140 per hospice × 906 hospices = $126,840 industry wide

(o) Standard: Death reporting requirements. This requirement applies to all deaths associated with the use of restraint or seclusion throughout the hospice inpatient facility. A hospice must report to CMS each death that occurs while a patient is in restraint or seclusion at the hospice inpatient facility, each death that occurs within 24 hours after the patient has been removed from restraint or seclusion, and the hospice must report each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that the use of restraint seclusion contributed directly or indirectly to a patient's death.

Each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. We have no data from which to base an estimate on the number of deaths in hospice that may be related to the use of seclusion and restraint. However, based on a lack of family complaints to State agencies or CMS we believe such deaths to be a rare occurrence. Although our goal is to ensure the safe and appropriate use of seclusion and restraint and reduce associated deaths, we are aware that the actual number of reported deaths from seclusion and restraint may increase due to these reporting requirements.

Thus, we anticipate there will be burden associated with this requirement due to the increased number of deaths that will be reported by the hospice industry. Given the lack of historical data, we assume the number of reports certainly should average less than one per hospice inpatient facility per year. Thus, we believe the impact associated with this provision (that is, making a telephone call and filling in a written report) to be negligible.

TABLE 6.—HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY BURDEN ASSESSMENT (ONE TIME)

Standard	Time per average hospice	Total time (hours)	Cost per average hospice	Total # of hospice inpatient facilities	Total cost
4 day trainer training	32 hours	16,896	$3,280	906	$2,971,680
Staff training program development	40 hours	21,120	1,400	906	1,268,400
Staff training	96 hours	50,688	3,360	906	3,044.160
Staff training records	55 minutes	830.5	32	906	29,068
Totals 1st year	169 hours	89,535	$8,072	906	$7,313,308

TABLE 7.—HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY BURDEN ASSESSMENT (ANNUAL)

Standard	Time per average hospice	Total time (hours)	Total # of hospice inpatient facilities	Cost per average hospice	Total cost
Staff training update	48 hours	43,488	906	$1,680	$1,522,080
Staff training records	55 minutes	830.5	906	32	29,068
Staff training program update	4 hours	3,624	906	140	126,840
Totals annually	53 hours	47,943	906	1,852	1,677,988

Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/MR (§ 418.112)

(c) Standard: Written agreement. This rule establishes the minimum content of the written agreement that a hospice provider must have with a SNF/NF or ICF/MR if the hospice is caring for a resident of the facility. Establishing a contract with another provider to coordinate patient care is standard practice and does not pose a burden to a hospice that chooses to care for patients in these settings.

(d) Standard: Hospice plan of care. This rule also includes several requirements for a patient's plan of care that are in addition to the plan of care requirements in § 418.56(b), (c), and (d). If a hospice patient is a resident of a SNF/NF or ICF/MR, the hospice plan of care for the patient must reflect the participation of the hospice, the facility, the patient, and the family to the extent possible. In addition, the hospice plan of care must identify which provider (the hospice or the facility) is responsible for each activity identified in the plan of care. Any changes in the hospice plan of care must be discussed by the hospice with the patient or representative, and facility representatives. The hospice must approve all changes to the hospice plan of care before the changes are implemented.

(e) Standard: Coordination of services. In addition to the plan of care requirements, we added a coordination of services standard. This new standard requires a hospice to designate an IDG member to coordinate a patient's care with facility representatives, and communicate with facility representatives and other health care providers. The standard also requires the hospice IDG to communicate with all physicians involved in the care of a particular patient. These communication and coordination requirements are essential to providing safe, quality patient care.

Any additional effort by hospice personnel to meet these requirements will, we believe, be offset by the reduced costs associated with the provision of more effective and efficient patient care. For example, by communicating and coordinating with a facility, a hospice can avoid situations where duplicative or contradictory orders are issued by the hospice physician and the facility physician. If duplicative orders are avoided, the hospice may be able to eliminate the duplicative service, thereby decreasing hospice expenditures while maintaining quality patient care. If contradictory orders are avoided, a hospice can avoid furnishing care that is rendered ineffective by the opposing care furnished by the facility. This, too, would decrease hospice expenditures, while at the same time improving the patient's well being.

Furthermore, the standard requires a hospice to provide a facility with specified information about the patient's care. With the exception of the election and advanced directives forms, certification forms, and physician orders, all of the specified information is routinely provided to a patient's caregiver(s). Since the facility is the caregiver, providing this information presents no burden to a hospice. We estimate that providing the facility with the election and advanced directives forms, certification forms, and physician orders for each patient would cost $2.33 per patient, based on 10 minutes of an office employee's time to fax the required documents to the facility. According to a March 2006 report from the Hospice Association of America (''Hospice Facts & Statistics''), 27.19 percent of hospice patients nationwide resided in a SNF or other long term care facility. Therefore, we estimate that hospices will provide forms to SNFs/NFs and ICFs/MR for 236,336 hospice patients residing in those facilities. We also estimate that the average hospice will provide care to 82 patients residing in a SNF/NF or ICF/MR (236,336 patients nationwide / 2,872 hospices).

82 patients in a facility × 10 minutes per patient to provide forms / 60 minutes = 13.7 hours per hospice

13.7 hours × office employee at $14/hr = $192

10 minutes per patient × 236,336 patients nationwide / 60 minutes = 39,389 hours industry wide

39,389 hours × $14/hr = $551,446

$551,446/236,336 patients = $2.33 per patient

(f) Standard: Orientation and training of staff. Finally, this rule requires a hospice to assure the orientation of SNF/NF and ICF/MR staff caring for hospice patients. Staff orientation must address the following topics: hospice philosophy; hospice policies regarding patient comfort methods, pain control, and symptom management; principles about death and dying; individual responses to death; patient rights; appropriate forms; and record keeping requirements. As many commenters noted, not every hospice will conduct the orientation itself because several hospices may serve residents of a single facility. Rather, many hospices will rely on the orientation already provided by another hospice. We do not know exactly how many hospices serve patients residing in a SNF/NF or ICF/MR, or how many of those facilities are served by multiple hospices. Therefore, we cannot estimate the number of hospices that will conduct orientation sessions for SNF/NF and ICF/MR staff. We believe that any burden associated with orienting SNF/NF and ICF/MR will be minimal because hospices already orient patients and families/caregivers about many of the topics covered in this standard (that is, hospice philosophy and principles about death and dying). Since the SNF/NF or ICF/MR staff act as the patient's care giver, orienting them would be very similar to orienting the patient's family/caregiver.

TABLE 8.—HOSPICES THAT PROVIDE HOSPICE CARE TO RESIDENTS OF A SNF/NF OR ICF/MR BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per average hospice (hours)	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Providing forms to facility	10	13.7	39,389	$2.33	$192	$551,446
Totals	10	13.7	39,389	2.33	192	551,446

Personnel Qualifications (§ 418.114)

(b) Standard: Personnel qualifications for certain disciplines and (c) Standard: Personnel qualifications when no State licensing, certification or registration requirements exist. The final rule establishes personnel qualifications for a variety of positions within a hospice. In particular, this rule establishes the personnel qualifications for hospice social workers. A social worker in a hospice must meet one of the following qualifications:

- Have a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting;
- Have a baccalaureate degree in social work (BSW) from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting; or
- Have a baccalaureate degree in psychology, sociology, or other field related to social work and at least one year of social work experience in a health care setting.

If a hospice chooses to employ a social worker with a baccalaureate degree in social work, psychology, sociology, or other field related to social work, the services of the baccalaureate social worker (BSW) must be provided under the supervision of a social worker with an MSW from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting. The MSW supervisor role is that of an active advisor, consulting with the BSW on assessing the needs of patients and families, developing and updating the social work portion of the plan of care, and delivering care to patients and families. This supervision may occur in person, over the telephone, through electronic communication, or any combination thereof.

Social workers with a baccalaureate degree from a school of social work accredited by the Council on Social Work Education and who are employed by the hospice before the effective date of this final rule are exempted from the MSW supervision requirement. Therefore, if a hospice currently employs a BSW, it is not required to hire an MSW to supervise the BSW. If a hospice hires a new social worker with a baccalaureate degree and one year of experience in a health care setting, then the new baccalaureate social worker must be supervised by an MSW who has one year of experience in a health care setting.

The impact associated with this social work qualification requirement is the expense of employing an MSW to supervise a BSW. By virtue of the personnel qualifications for social workers in hospice that have been in effect since 1983, all hospices are already required to have, at minimum, a social worker with a baccalaureate degree in social work from a school of social work accredited by the Council on Social Work Education. Therefore, all hospices should qualify for the exemption for MSW supervision described above.

We are aware that many hospices already employ at least one MSW to provide direct patient care. In fact, when tracking the number of social workers serving hospice patients, the Hospice Association of America only reports the number of MSWs (6,177 in 2005) working in the hospice industry, rather than the number of BSWs, precisely because an MSW is the standard level of care within hospice. Thus, we believe that the number of hospices currently solely relying on BSWs is relatively low. We do not know the precise number of hospices without an MSW. For purposes of this estimate only, we assume that 33 percent of hospices (944) rely solely on BSWs to provide social work services to patients. Of the 944 hospices without an MSW, we estimate that 25 percent will hire a social worker after the effective date of this rule (based on a 25% social worker turnover rate described in the ''Hospice Salary & Benefits Report 2006–2007'' issued by the Hospital & Healthcare Compensation Service and the ''2002 NHPCO National Data Set Summary Report''). Therefore, an estimated 236 hospices a year would be required to employ an MSW on a part-time basis to supervise the services of a BSW.

Based on information from the ''Hospice Facts & Statistics 2006'' report, the ''Assuring the Sufficiency of Frontline Workforce: A National Study of Licensed Social Workers'' report, and the ''Licensed Social Workers in the United States, 2004'' report, we estimate that the annual compensation for a full-time, supervisory, MSW working in the hospice industry is $52,811 ($25/hr). Furthermore, we estimate that a hospice would employ an MSW for 10 hours a week to supervise the care and services provided by a BSW. As such, we estimate that an affected hospice would spend $13,000 annually to employ a part-time supervisory MSW to meet the requirements of this rule.

10 hours per week for MSW at $25/hour × 52 weeks = $13,000
$13,000 × 236 hospices = $3,068,000
10 hours per week × 52 weeks = 520 hours annually
520 hours × 236 hospices = 122,720 hours industry wide

(d) Standard: Criminal background checks. Additionally, this final rule requires a background check for each employee providing direct patient contact or accessing patient records. In 2006, 40 states required criminal background checks for hospice employees. In these states, approximately 92,920 hospice employees already received a criminal background check, thus greatly reducing the overall potential burden. We estimate that hospices that have not previously performed background checks, accounting for approximately 23,228 hospice employees, will each obtain 40 criminal background checks initially. Each background check request form will take 6 minutes to prepare and send, for a total of 4 hours per hospice the first year. For each year thereafter, we estimate that hospices in states that do not require background checks will complete background checks on approximately 10 new employees per year, for a total of 1 hour per affected hospice per year, and 582 hours nationally per year.

116,148 employees in 2005 according to National Association for Home Care 2005 Hospice Facts and Statistics/50 states = 2,323 average number of employees per

state × 40 states already requiring background checks = 92,920 already required to have background checks

116,148 total employees − 92,920 already required to have background checks = 23,228 employees not already required to have background checks

116,148 employees/2,872 hospices in 2005 = 40 employees per average hospice

40 employees × 6 minutes per check = 4 hours per hospice

23,228 employees × 6 minutes per check = 2,323 hours nationwide

2,872 hospices nationwide/50 states = 57.4 average number of hospices per state × 10 states not currently requiring background checks = 574 affected hospices.

574 affected hospice × 10 new employees requiring background checks per year × 6 minutes per check/60 minutes = 96 hours

We researched a wide variety of agencies that perform criminal background checks and determined that the average cost for an individual background check is $17.00 plus $1 for 6 minutes of clerical time per background check to process the paper work. We understand that some agencies or states may charge more or less than this fee to conduct a background check. In addition, some hospices may choose to conduct more extensive background checks that may cost more.

We are not requiring that hospices conduct a specific type of background check (that is, State or Federal) or obtain such a check from a specific source (that is, State police or FBI). The flexibility of the requirement will allow hospices to identify the most cost efficient method of meeting the requirement.

$18 per check × 40 employees requiring checks = $720

$18 per check × 23,228 employees not already requiring checks = $418,104

$18 per check × 10 new employees requiring checks = $180.00 per hospice

$180 per hospice × 574 affected hospices = $103,320

TABLE 9.—PERSONNEL QUALIFICATIONS BURDEN ASSESSMENT

Standard	Time per average hospice	Total industry time	Total # of affected hospices	Total cost per average hospice	Total industry cost
MSW supervisor	520 hours	122,720 hours	236	$13,000	$3,068,000
Criminal background check.	1st year—4 hours—annually 1 hour.	1st year—2,323 hours—annually 96 hours.	574	1st year—$720—annually $180.	1st year—$418,104—annually $103,320
Total	1st year—524 hours—Annually 521 hours.	1st year—125,043 hours—Annually 122,816 hours.	N/A	1st year—$13,720—Annually $13,180.	1st Year—$3,486,104—Annually $3,171,320

Compliance with Federal, State, and Local Laws and Regulations Related to the Health and Ssafety of Patients (§ 418.116)

This final condition of participation requires that the hospice operate and furnish services in compliance with applicable Federal, State, and local laws and regulations related to the health and safety of patients. We do not believe this will add any regulatory burden, since this section of the final rule reflects current requirements and contemporary standard practice in hospice.

TABLE 10.—TOTAL BURDEN ASSESSMENT FOR ALL REQUIREMENTS IN THE FIRST YEAR COP

	Total time per patient	Total time per average hospice	Total industry time	Total cost per patient	Total cost per average hospice	Total industry cost
Patient rights	5 minutes	48.25 hours	138,489 hours	$3	2,012	4,649,379
QAPI	N/A	241 hours	692,152 hours	N/A	7,544	21,666,368
Hospice aide	N/A	5 minutes	239 hours	N/A	1.17	3,360
Drugs and DME	5 minutes	25.25 hours	72,524 hours	2.25	681.75	1,958,610
Inpatient care directly.	N/A	169 hours	89,535 hours	N/A	8,072	7,313,308
SNF/NF or ICF/MR	10 minutes	13.7 hours	39,389 hours	2.33	192	551,446
Personnel qualifications.	N/A	524 hours	125,043 hours	N/A	13,720	3,486,104
Total	20 minutes	1,021.3 hours	1,157,371 hours	7.58	*32,222.92	40,754,007

* Includes cost of operating an inpatient facility and hiring a MSW supervisor. Most hospices will not incur these expenses. Therefore, this rule will cost most hospices $11,151 in the first year.

We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all hospice patients. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and budget.

2. Effects on other providers:

Effects on other providers: We do not expect this regulation to affect any other provider.

List of Subjects in 42 CFR Part 418

Health Facilities, Hospice Care, Medicare, Incorporation by reference, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provision and Definitions

■ 2. Section 418.2 is revised to read as follows:

§ 418.2 Scope of the part.

This part establishes requirements and the conditions of participation that hospices must meet, and be in compliance with, in order to participate in the Medicare program. Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B of this part specifies the eligibility requirements and the benefit periods. Subpart C of this part specifies the conditions of participation that hospice providers must meet regarding patient and family care. Subpart D of this part specifies the organizational environment that hospice providers must meet as conditions of participation. Subpart E is reserved for future use. Subpart F specifies coinsurance amounts applicable to hospice care.

■ 3. Section 418.3 is amended by:
■ a. Revising the definitions of ''Bereavement counseling,'' ''Employee,'' ''Hospice,'' ''Physician,'' ''Representative,'' and ''Terminally ill''; and
■ b. Adding the definitions of ''Clinical note,'' ''Comprehensive assessment,'' ''Dietary counseling,'' ''Hospice care,'' ''Initial assessment,'' ''Licensed professional'' ''Multiple location,'' ''Palliative care,'' ''Physician designee,'' ''Restraint,'' and ''Seclusion.''

The revisions and additions read as follows:

§ 418.3 Definitions.

For the purposes of this part—

* * * * *

Bereavement counseling means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

* * * * *

Clinical note means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional, psychosocial or spiritual condition during a given period of time.

Comprehensive assessment means a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

Dietary counseling means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care.

Employee means a person who: (1) Works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf; (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

Initial assessment means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs.

Licensed professional means a person licensed to provide patient care services by the State in which services are delivered.

Multiple location means a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

Physician means an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and implemented at § 410.20 of this chapter.

Physician designee means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical director when the medical director is not available.

Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.

Restraint means—(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or

(2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

■ 4. Subparts C and D are revised and Subpart E is removed and reserved to read as follows:

Subpart C—Conditions of Participation: Patient Care

Sec.

418.52 Condition of participation: Patient's rights.
418.54 Condition of participation: Initial and comprehensive assessment of the patient.

418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.
418.58 Condition of participation: Quality assessment and performance improvement.
418.60 Condition of participation: Infection control.
418.62 Condition of participation: Licensed professional services.

CORE SERVICES

418.64 Condition of participation: Core services.
418.66 Condition of participation: Nursing services waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

NON-CORE SERVICES

418.70 Condition of participation: Furnishing of non-core services.
418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.
418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology and dietary counseling.
418.76 Condition of participation: Hospice aide and homemaker services.
418.78 Condition of participation: Volunteers.

Subpart D—Conditions of Participation: Organizational Environment

418.100 Condition of participation: Organization and administration of services.
418.102 Condition of participation: Medical director.
418.104 Condition of participation: Clinical records.
418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.
418.108 Condition of participation: Short-term inpatient care.
418.110 Condition of participation: Hospices that provide inpatient care directly.
418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.
418.114 Condition of participation: Personnel qualifications.
418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

Subpart E—[Removed and Reserved]

Subpart C—Conditions of Participation: Patient Care

§ 418.52 Condition of participation: Patient's rights.

The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.

(a) Standard: Notice of rights and responsibilities.

(1) During the initial assessment visit in advance of furnishing care the hospice must provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands.

(2) The hospice must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law.

(3) The hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) Standard: Exercise of rights and respect for property and person. (1) The patient has the right:

(i) To exercise his or her rights as a patient of the hospice;

(ii) To have his or her property and person treated with respect;

(iii) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and

(iv) To not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to state law to act on the patient's behalf.

(3) If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

(4) The hospice must:

(i) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

(ii) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures;

(iii) Take appropriate corrective action in accordance with state law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and

(iv) Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of becoming aware of the violation.

(c) *Standard: Rights of the patient.* The patient has a right to the following:

(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

(2) Be involved in developing his or her hospice plan of care;

(3) Refuse care or treatment;

(4) Choose his or her attending physician;

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property;

(7) Receive information about the services covered under the hospice benefit;

(8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

§ 418.54 Condition of participation: Initial and comprehensive assessment of the patient.

The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

(a) *Standard: Initial assessment.* The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with § 418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

(b) *Standard: Timeframe for completion of the comprehensive assessment.* The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), must complete the comprehensive assessment no later than

5 calendar days after the election of hospice care in accordance with § 418.24.

(c) *Standard: Content of the comprehensive assessment.*

The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors:

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints).

(2) Complications and risk factors that affect care planning.

(3) Functional status, including the patient's ability to understand and participate in his or her own care.

(4) Imminence of death.

(5) Severity of symptoms.

(6) Drug profile. A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(i) Effectiveness of drug therapy.

(ii) Drug side effects.

(iii) Actual or potential drug interactions.

(iv) Duplicate drug therapy.

(v) Drug therapy currently associated with laboratory monitoring.

(7) Bereavement. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.

(8) The need for referrals and further evaluation by appropriate health professionals.

(d) *Standard: Update of the comprehensive assessment.*

The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished as frequently as the condition of the patient requires, but no less frequently than every 15 days.

(e) *Standard: Patient outcome measures.* (1) The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.

(2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.

§ 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.

(a) *Standard: Approach to service delivery.* (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group, in its entirety, must supervise the care and services. The hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice).

(ii) A registered nurse.

(iii) A social worker.

(iv) A pastoral or other counselor.

(2) If the hospice has more than one interdisciplinary group, it must identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services.

(b) *Standard: Plan of care.* All hospice care and services furnished to patients and their families must follow an individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire. The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

(c) *Standard: Content of the plan of care.* The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including the following:

(1) Interventions to manage pain and symptoms.

(2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs.

(3) Measurable outcomes anticipated from implementing and coordinating the plan of care.

(4) Drugs and treatment necessary to meet the needs of the patient.

(5) Medical supplies and appliances necessary to meet the needs of the patient.

(6) The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

(d) *Standard: Review of the plan of care.* The hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) must review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every 15 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and must note the patient's progress toward outcomes and goals specified in the plan of care.

(e) *Standard: Coordination of services.* The hospice must develop and maintain

a system of communication and integration, in accordance with the hospice's own policies and procedures, to—

(1) Ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that the care and services are provided in accordance with the plan of care.

(3) Ensure that the care and services provided are based on all assessments of the patient and family needs.

(4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement.

(5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

§ 418.58 Condition of participation: Quality assessment and performance improvement.

The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.

(2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including patient care, and other relevant data, in the design of its program.

(2) The hospice must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the hospice's governing body.

(c) *Standard: Program activities.* (1) The hospice's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect palliative outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

(3) The hospice must take actions aimed at performance improvement and, after implementing those actions, the hospice must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* Beginning February 2, 2009 hospices must develop, implement, and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.

(2) The hospice must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained, and is evaluated annually.

(2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

§ 418.60 Condition of participation: Infection control.

The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.

(a) *Standard: Prevention.* The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

(b) *Standard: Control.* The hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that—

(1) Is an integral part of the hospice's quality assessment and performance improvement program; and

(2) Includes the following:

(i) A method of identifying infectious and communicable disease problems; and

(ii) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

(c) *Standard: Education.* The hospice must provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

§ 418.62 Condition of participation: Licensed professional services.

(a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under § 418.114 and who practice under the hospice's policies and procedures.

(b) Licensed professionals must actively participate in the coordination of all aspects of the patient's hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and

(c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.

Core Services

§ 418.64 Condition of participation: Core services.

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in paragraph (a) of this section. A hospice

may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.

(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness.

(1) All physician employees and those under contract, must function under the supervision of the hospice medical director.

(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.

(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial assessment, comprehensive assessment, and updated assessments.

(2) If State law permits registered nurses to see, treat, and write orders for patients, then registered nurses may provide services to beneficiaries receiving hospice care.

(3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.

(d) *Standard: Counseling services.* Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process. Counseling services must include, but are not limited to, the following:

(1) *Bereavement counseling.* The hospice must:

(i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience or education in grief or loss counseling.

(ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to residents of a SNF/NF or ICF/MR when appropriate and identified in the bereavement plan of care.

(iii) Ensure that bereavement services reflect the needs of the bereaved.

(iv) Develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c).

(2) *Dietary counseling.* Dietary counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

(3) *Spiritual counseling.* The hospice must:

(i) Provide an assessment of the patient's and family's spiritual needs.

(ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires.

(iii) Make all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

(iv) Advise the patient and family of this service.

§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) CMS may waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria:

(1) The location of the hospice's central office is in a non-urbanized area as determined by the Bureau of the Census.

(2) There is evidence that a hospice was operational on or before January 1, 1983 including the following:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983.

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983.

(iii) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.

(ii) Job descriptions for nurse employees.

(iii) Evidence that salary and benefits are competitive for the area.

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.

Non-Core Services

§ 418.70 Condition of participation: Furnishing of non-core services.

A hospice must ensure that the services described in § 418.72 through § 418.78 are provided directly by the hospice or under arrangements made by the hospice as specified in § 418.100. These services must be provided in a manner consistent with current standards of practice.

§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.

Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

§ 418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.

(a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria:

(1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census.

(2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include the following:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.

(ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions.

(iii) Evidence that salary and benefits are competitive for the area.

(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) An initial waiver will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

§ 418.76 Condition of participation: Hospice aide and homemaker services.

All hospice aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.

(a) *Standard: Hospice aide qualifications.* (1) A qualified hospice aide is a person who has successfully completed one of the following:

(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.

(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.

(iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.

(2) A hospice aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

(b) *Standard: Content and duration of hospice aide classroom and supervised practical training.* (1) Hospice aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse, or a licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training as part of the 75 hours.

(3) A hospice aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist:

(A) Bed bath.

(B) Sponge, tub, and shower bath.

(C) Hair shampoo (sink, tub, and bed).

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training hospice aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.

(c) *Standard: Competency evaluation.* An individual may furnish hospice aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be

evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a hospice aide with a patient.

(2) A hospice aide competency evaluation program may be offered by any organization, except as described in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A hospice aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation. A hospice aide is not considered to have successfully completed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one of the required areas.

(5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.

(d) *Standard: In-service training.* A hospice aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization, and must be supervised by a registered nurse.

(2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.

(e) *Standard: Qualifications for instructors conducting classroom and supervised practical training.* Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home care, or by other individuals under the general supervision of a registered nurse.

(f) *Standard: Eligible competency evaluation organizations.* A hospice aide competency evaluation program as specified in paragraph (c) of this section may be offered by any organization except by a home health agency that, within the previous 2 years:

(1) Had been of compliance with the requirements of § 484.36(a) and (b) of this chapter.

(2) Permitted an individual that does not meet the definition of a ''qualified home health aide'' as specified in § 484.36(a) of this chapter to furnish home health aide services (with the exception of licensed health professionals and volunteers).

(3) Had been subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State).

(4) Had been assessed a civil monetary penalty of $5,000 or more as an intermediate sanction.

(5) Had been found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency.

(6) Had all or part of its Medicare payments suspended.

(7) Had been found by CMS or the State under any Federal or State law to have:

(i) Had its participation in the Medicare program terminated.

(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies.

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled.

(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients.

(v) Been closed by CMS or the State, or had its patients transferred by the State.

(g) *Standard: Hospice aide assignments and duties.*

(1) Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section.

(2) A hospice aide provides services that are:

(i) Ordered by the interdisciplinary group.

(ii) Included in the plan of care.

(iii) Permitted to be performed under State law by such hospice aide.

(iv) Consistent with the hospice aide training.

(3) The duties of a hospice aide include the following:

(i) The provision of hands-on personal care.

(ii) The performance of simple procedures as an extension of therapy or nursing services.

(iii) Assistance in ambulation or exercises.

(iv) Assistance in administering medications that are ordinarily self-administered.

(4) Hospice aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse, as the changes relate to the plan of care and quality assessment and improvement activities. Hospice aides must also complete appropriate records in compliance with the hospice's policies and procedures.

(h) *Standard: Supervision of hospice aides.* (1) A registered nurse must make an on-site visit to the patient's home:

(i) No less frequently than every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aide does not have to be present during this visit.

(ii) If an area of concern is noted by the supervising nurse, then the hospice must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete a competency evaluation in accordance with § 418.76(c).

(2) A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(3) The supervising nurse must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to—

(i) Following the patient's plan of care for completion of tasks assigned to the hospice aide by the registered nurse.

(ii) Creating successful interpersonal relationships with the patient and family.

(iii) Demonstrating competency with assigned tasks.

(iv) Complying with infection control policies and procedures.

(v) Reporting changes in the patient's condition.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of this chapter, on behalf of a hospice agency.

(1) Before the individual may furnish personal care services, the individual must be found competent by the State (if regulated by the State) to furnish those services. The individual only

needs to demonstrate competency in the services the individual is required to furnish.

(2) Services under the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care.

(3) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure the patient receives the hospice aide and homemaker services he or she needs.

(j) *Standard: Homemaker qualifications.* A qualified homemaker is—

(1) An individual who meets the standards in § 418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness; or

(2) A hospice aide as described in § 418.76.

(k) *Standard: Homemaker supervision and duties.*

(1) Homemaker services must be coordinated and supervised by a member of the interdisciplinary group.

(2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group.

(3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.

§ 418.78 Conditions of participation—Volunteers.

The hospice must use volunteers to the extent specified in paragraph (e) of this section. These volunteers must be used in defined roles and under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must maintain, document, and provide volunteer orientation and training that is consistent with hospice industry standards.

(b) *Standard: Role.* Volunteers must be used in day-to-day administrative and/or direct patient care roles.

(c) *Standard: Recruiting and retaining.* The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include the following:

(1) The identification of each position that is occupied by a volunteer.

(2) The work time spent by volunteers occupying those positions.

(3) Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) of this section for the amount of time specified in paragraph (d)(2) of this section.

(e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked.

Subpart D—Conditions of participation: Organizational Environment

§ 418.100 Condition of Participation: Organization and administration of services.

The hospice must organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of the terminal illness and related conditions.

(a) *Standard: Serving the hospice patient and family.*

The hospice must provide hospice care that—

(1) Optimizes comfort and dignity; and

(2) Is consistent with patient and family needs and goals, with patient needs and goals as priority.

(b) *Standard: Governing body and administrator.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement. A qualified administrator appointed by and reporting to the governing body is responsible for the day-to-day operation of the hospice. The administrator must be a hospice employee and possess education and experience required by the hospice's governing body.

(c) *Standard: Services.* (1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent with accepted standards of practice:

(i) Nursing services.

(ii) Medical social services.

(iii) Physician services.

(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.

(v) Hospice aide, volunteer, and homemaker services.

(vi) Physical therapy, occupational therapy, and speech-language pathology services.

(vii) Short-term inpatient care.

(viii) Medical supplies (including drugs and biologicals) and medical appliances.

(2) Nursing services, physician services, and drugs and biologicals (as specified in § 418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

(d) *Standard: Continuation of care.* A hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

(e) *Standard: Professional management responsibility.* A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be—

(1) Authorized by the hospice;

(2) Furnished in a safe and effective manner by qualified personnel; and

(3) Delivered in accordance with the patient's plan of care.

(f) *Standard: Hospice multiple locations.*

If a hospice operates multiple locations, it must meet the following requirements:

(1) Medicare approval.

(i) All hospice multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients.

(ii) The multiple location must be part of the hospice and must share administration, supervision, and services with the hospice issued the certification number.

(iii) The lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice, and must be traced to the location that issued the certification number.

(iv) The determination that a multiple location does or does not meet the definition of a multiple location, as set forth in this part, is an initial determination, as set forth in § 498.3.

(2) The hospice must continually monitor and manage all services

provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care, in accordance with the requirements of this subpart and subparts A and C of this section.

(g) *Standard: Training.*

(1) A hospice must provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.

(2) A hospice must provide an initial orientation for each employee that addresses the employee's specific job duties.

(3) A hospice must assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.

§ 418.102 Condition of participation: Medical director.

The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is an employee, or is under contract with the hospice. When the medical director is not available, a physician designated by the hospice assumes the same responsibilities and obligations as the medical director.

(a) *Standard: Medical director contract.* (1) A hospice may contract with either of the following—

(i) A self-employed physician; or

(ii) A physician employed by a professional entity or physicians group. When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations.

(b) *Standard: Initial certification of terminal illness.* The medical director or physician designee reviews the clinical information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following when making this determination:

(1) The primary terminal condition;

(2) Related diagnosis(es), if any;

(3) Current subjective and objective medical findings;

(4) Current medication and treatment orders; and

(5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(c) *Standard: Recertification of the terminal illness.* Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review the patient's clinical information.

(d) *Standard: Medical director responsibility.* The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

§ 418.104 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) *Standard: Content.* Each patient's record must include the following:

(1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.

(2) Signed copies of the notice of patient rights in accordance with § 418.52 and election statement in accordance with § 418.24.

(3) Responses to medications, symptom management, treatments, and services.

(4) Outcome measure data elements, as described in § 418.54(e) of this subpart.

(5) Physician certification and recertification of terminal illness as required in § 418.22 and § 418.25 and described in § 418.102(b) and § 418.102(c) respectively, if appropriate.

(6) Any advance directives as described in § 418.52(a)(2).

(7) Physician orders.

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

(c) *Standard: Protection of information.* The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.

(d) *Standard: Retention of records.* Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

(e) *Standard: Discharge or transfer of care.* (1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with § 418.26, the hospice must forward to the patient's attending physician, a copy of—

(i) The hospice discharge summary; and

(ii) The patient's clinical record, if requested.

(3) The hospice discharge summary as required in paragraph (e)(1) and (e)(2) of this section must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management.

(ii) The patient's current plan of care.

(iii) The patient's latest physician orders. and

(iv) Any other documentation that will assist in post-discharge continuity of care or that is requested by the attending physician or receiving facility.

(f) *Standard: Retrieval of clinical records.* The clinical record, whether hard copy or in electronic form, must be made readily available on request by an appropriate authority.

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(a) *Standard: Managing drugs and biologicals.*

(1) The hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or

under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

(2) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(b) *Standard: Ordering of drugs.*

(1) Only a physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, may order drugs for the patient.

(2) If the drug order is verbal or given by or through electronic transmission—

(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.

(c) *Standard: Dispensing of drugs and biologicals.*

The hospice must—

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(2) The hospice that provides inpatient care directly in its own facility must:

(i) Have a written policy in place that promotes dispensing accuracy; and

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

(d) *Standard: Administration of drugs and biologicals.*

(1) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home.

(2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;

(ii) An employee who has completed a State-approved training program in medication administration; and

(iii) The patient, upon approval by the interdisciplinary group.

(e) *Standard: Labeling, disposing, and storing of drugs and biologicals.*

(1) Labeling. Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) Disposing. (i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

(3) Storing. The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements—

(i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

(f) *Standard: Use and maintenance of equipment and supplies.*

(1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR § 424.57.

§ 418.108 Condition of participation: Short-term inpatient care.

Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom management and pain control.* Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110.

(2) A Medicare-certified hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (e) regarding 24-hour nursing services and patient areas.

(b) *Standard: Inpatient care for respite purposes.*

(1) Inpatient care for respite purposes must be provided by one of the following:

(i) A provider specified in paragraph (a) of this section.

(ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in § 418.110(f).

(2) The facility providing respite care must provide 24-hour nursing services

that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a written agreement, coordinated by the hospice, and at a minimum specifies—

(1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients;

(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;

(5) That the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training are documented; and

(6) A method for verifying that the requirements in paragraphs (c)(1) through (c)(5) of this section are met.

(d) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12-month period in a particular hospice may not exceed 20 percent of the total number of hospice days consumed in total by this group of beneficiaries.

(e) *Standard: Exemption from limitation.* Before October 1, 1986, any hospice that began operation before January 1, 1975, is not subject to the limitation specified in paragraph (d) of this section.

§ 418.110 Condition of participation: Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards:

(a) *Standard: Staffing.* The hospice is responsible for ensuring that staffing for all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided.

(b) *Standard: Twenty-four hour nursing services.* (1) The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

(c) *Standard: Physical environment.* The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

(1) *Safety management.*

(i) The hospice must address real or potential threats to the health and safety of the patients, others, and property.

(ii) The hospice must have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(2) *Physical plant and equipment.* The hospice must develop procedures for controlling the reliability and quality of—

(i) The routine storage and prompt disposal of trash and medical waste;

(ii) Light, temperature, and ventilation/air exchanges throughout the hospice;

(iii) Emergency gas and water supply; and

(iv) The scheduled and emergency maintenance and repair of all equipment.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospices.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal

Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/codeof federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes.

(e) *Standard: Patient areas.* The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients.

(1) The hospice must provide—

(i) Physical space for private patient and family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night; and

(iii) Physical space for family privacy after a patient's death.

(2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.

(f) *Standard: Patient rooms.* (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

(2) The hospice must accommodate a patient and family request for a single room whenever possible.

(3) Each patient's room must—

(i) Be at or above grade level;

(ii) Contain a suitable bed and other appropriate furniture for each patient;

(iii) Have closet space that provides security and privacy for clothing and personal belongings;

(iv) Accommodate no more than two patients and their family members;

(v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and

(vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare-participating hospice on December 2, 2008, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section if it determines that—

(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and

(ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

(g) *Standard: Toilet and bathing facilities.* Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

(h) *Standard: Plumbing facilities.* The hospice must—

(1) Have an adequate supply of hot water at all times; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(i) *Standard: Infection control.* The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in § 418.60.

(j) *Standard: Sanitary environment.* The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.

(k) *Standard: Linen.* The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.

(l) *Standard: Meal service and menu planning.* The hospice must furnish meals to each patient that are—

(1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet;

(2) Palatable, attractive, and served at the proper temperature; and

(3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

(m) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(3) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.

(4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.

(5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(7) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

(ii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospice policy.

(8) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(9) The condition of the patient who is restrained or secluded must be

monitored by a physician or trained staff that have completed the training criteria specified in paragraph (n) of this section at an interval determined by hospice policy.

(10) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.

(11) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician; or

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(12) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m)(11)(i) of this section.

(13) If the face-to-face evaluation specified in § 418.110(m)(11) is conducted by a trained registered nurse, the trained registered nurse must consult the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

(14) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(15) When restraint or seclusion is used, there must be documentation in the patient's clinical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(n) *Standard: Restraint or seclusion staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* All patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospice policy.

(2) *Training content.* The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(o) *Standard: Death reporting requirements.* Hospices must report deaths associated with the use of seclusion or restraint.

(1) The hospice must report the following information to CMS:

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.

(ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.

In addition to meeting the conditions of participation at § 418.10 through § 418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/MR must abide by the following additional standards.

(a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF, NF, or ICF/MR are subject to the Medicare hospice eligibility criteria set out at § 418.20 through § 418.30.

(b) *Standard: Professional management.* The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make

any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to § 418.100 and § 418.108.

(c) *Standard: Written agreement.* The hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/MR before the provision of hospice services. The written agreement must include at least the following:

(1) The manner in which the SNF/NF or ICF/MR and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.

(2) A provision that the SNF/NF or ICF/MR immediately notifies the hospice if—

(i) A significant change in a patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

(iii) A need to transfer a patient from the SNF/NF or ICF/MR, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness and related conditions; or

(iv) A patient dies.

(3) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

(4) An agreement that it is the SNF/NF or ICF/MR responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.

(5) An agreement that it is the hospice's responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/MR resident were in his or her own home.

(6) A delineation of the hospice's responsibilities, which include, but are not limited to the following: Providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work; provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

(7) A provision that the hospice may use the SNF/NF or ICF/MR nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/MR to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.

(8) A provision stating that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the SNF/NF or ICF/MR administrator within 24 hours of the hospice becoming aware of the alleged violation.

(9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/MR to provide bereavement services to SNF/NF or ICF/MR staff.

(d) *Standard: Hospice plan of care.* In accordance with § 418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. All hospice care provided must be in accordance with this hospice plan of care.

(1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.

(2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/MR, and the patient and family to the extent possible.

(3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/MR representatives, and must be approved by the hospice before implementation.

(e) *Standard: Coordination of services.* The hospice must:

(1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/MR. The designated interdisciplinary group member is responsible for:

(i) Providing overall coordination of the hospice care of the SNF/NF or ICF/MR resident with SNF/NF or ICF/MR representatives; and

(ii) Communicating with SNF/NF or ICF/MR representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.

(2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.

(3) Provide the SNF/NF or ICF/MR with the following information:

(i) The most recent hospice plan of care specific to each patient;

(ii) Hospice election form and any advance directives specific to each patient;

(iii) Physician certification and recertification of the terminal illness specific to each patient;

(iv) Names and contact information for hospice personnel involved in hospice care of each patient;

(v) Instructions on how to access the hospice's 24-hour on-call system;

(vi) Hospice medication information specific to each patient; and

(vii) Hospice physician and attending physician (if any) orders specific to each patient.

(f) *Standard: Orientation and training of staff.* Hospice staff must assure orientation of SNF/NF or ICF/MR staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

§ 418.114 Condition of participation: Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

(b) *Personnel qualifications for certain disciplines.*

The following qualifications must be met:

(1) *Physician.* Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at § 410.20 of this chapter.

(2) *Hospice aide.* Hospice aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at § 418.76.

(3) *Social worker.* A person who—

(i)(A) Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or

(B) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b)(3)(i)(A) of this section; and

(ii) Has 1 year of social work experience in a healthcare setting; or

(iii) Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before December 2, 2008, and is not required to be supervised by an MSW.

(4) *Speech language pathologist.* A person who meets either of the following requirements:

(i) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.

(ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(5) *Occupational therapist.* A person who—

(i)(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(B) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(C) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(B) When licensure or other regulation does not apply—

(*1*) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(*2*) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(iii) On or before January 1, 2008—

(A) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(B) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapist; and

(B) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States—

(A) Must meet both of the following:

(*1*) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:

(*i*) The Accreditation Council for Occupational Therapy Education (ACOTE).

(*ii*) Successor organizations of ACOTE.

(*iii*) The World Federation of Occupational Therapists.

(*iv*) A credentialing body approved by the American Occupational Therapy Association.

(*v*) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(*2*) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

(6) *Occupational therapy assistant.* A person who

(i) Meets all of the following:

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does apply.

(B) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(C) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(B) Must meet both of the following:

(*1*) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(*2*) After January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.

(iii) After December 31, 1977 and on or before December 31, 2007—

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(B) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapy assistant; and

(B) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States, on or after January 1, 2008—

(A) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(*1*) The Accreditation Council for Occupational Therapy Education (ACOTE).

(*2*) Its successor organizations.

(*3*) The World Federation of Occupational Therapists.

(*4*) By a credentialing body approved by the American Occupational Therapy Association; and

(*5*) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(7) *Physical therapist.* A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(D) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(ii) On or before December 31, 2009—

(A) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(B) Meets both of the following:

(*1*) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(*2*) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(iii) Before January 1, 2008—

(A) Graduated from a physical therapy curriculum approved by one of the following:

(*1*) The American Physical Therapy Association.

(*2*) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(*3*) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(iv) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(A) Has 2 years of appropriate experience as a physical therapist.

(B) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) Before January 1, 1966—

(A) Was admitted to membership by the American Physical Therapy Association;

(B) Was admitted to registration by the American Registry of Physical Therapists; and

(C) Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(vi) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(vii) If trained outside the United States before January 1, 2008, meets the following requirements:

(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(8) *Physical therapist assistant.* A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(A) On or before December 31, 2009, meets one of the following:

(*1*) Is licensed, or otherwise regulated in the State in which practicing.

(*2*) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

(*3*) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(*4*) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.* If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:

(1) *Registered nurse.* A graduate of a school of professional nursing.

(2) *Licensed practical nurse.* A person who has completed a practical nursing program.

(d) *Standard: Criminal background checks.* (1) The hospice must obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

(2) Criminal background checks must be obtained in accordance with State requirements. In the absence of State requirements, criminal background checks must be obtained within three months of the date of employment for all states that the individual has lived or worked in the past 3 years.

§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of patients. If State or local law provides for licensing of hospices, the hospice must be licensed.

(a) *Standard: Multiple locations.* Every hospice must comply with the

requirements of § 420.206 of this chapter regarding disclosure of ownership and control information. All hospice multiple locations must be approved by Medicare and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

(b) *Standard: Laboratory services.* (1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

Subpart E [Removed and Reserved]

§ 418.200 [Amended]

■ 5. Section 418.200 is amended by revising the reference ''§ 418.58'' to read ''§ 418.56''.

§ 418.202 [Amended]

■ 6. In § 418.202, paragraph (e) is amended by revising the reference ''§ 418.98(b)'' to read ''§ 418.108(b)'' and paragraph (g) is amended by revising the reference ''§ 418.94'' to read ''§ 418.76''.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)
(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 19, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 23, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. 08–1305 Filed 5–27–08; 4:00 pm]

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Part III

Securities and Exchange Commission

17 CFR Parts 200, 201, 202 et al.
Regional Office Reorganization; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 200, 201, 202, 203, 209, 230, 232, 240, 249, 249b, 260, 270, 274, 275, and 279

[Release No. 34–57877]

Regional Office Reorganization

AGENCY: Securities and Exchange Commission.

ACTION: Final rule amendments.

SUMMARY: The Securities and Exchange Commission is amending its rules to reflect the reorganization of its former five regional and six district offices into eleven regional offices reporting directly to SEC Headquarters. The Commission also is correcting addresses appearing in its rules.

DATES: Effective Date: June 5, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen Jung, (202) 551–5162, Assistant General Counsel, Office of the General Counsel; Michael Bloise, (202) 551–5116, Senior Counsel, Office of the General Counsel, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is amending 17 CFR parts 200, 201, 202, 203, 209, 230, 232, 240, 249, 249b, 260, 270, 274, 275, and 279.

I. Discussion

On March 30, 2007, the Chairman of the Securities and Exchange Commission announced a new structure for the Commission's regional and district offices and changes to the designation of the offices and their chief supervisory personnel.[1] These changes, which became effective on April 1, 2007, were intended to facilitate the regional offices' cooperation with state and federal regulators, law enforcement agencies and consumer groups at the local level to better protect investors no matter where they live or with whom they invest.

As a result of the reorganization, the former structure, in which there were six district offices reporting to five regional offices that, in turn, reported to Commission headquarters, was replaced by a new structure in which there are eleven regional offices, each reporting directly to Commission headquarters. Each regional office is now designated by the name of the city in which it is located, as follows: Atlanta Regional Office, Boston Regional Office, Chicago Regional Office, Denver Regional Office, Fort Worth Regional Office, Los Angeles Regional Office, Miami Regional Office, New York Regional Office, Philadelphia Regional Office, Salt Lake City Regional Office, and San Francisco Regional Office.

Pursuant to the reorganization, the title ''District Administrator'' was discontinued, and the heads of all of the regional offices are now called ''Regional Directors.'' The term ''Regional Director'' also replaced the term ''District Administrator'' in the titles of subordinate managers in the regional offices. The regional offices report, on enforcement matters, to the Deputy Director of the Division of Enforcement who is responsible for regional office enforcement matters and, on examination matters, to the Director of the Office of Compliance Inspections and Examinations. The Director of Regional Office Operations continues to oversee regional office operational and management issues.

To reflect this reorganization, the Commission is amending certain of its rules to delete the term ''district office'' or replace it with the term ''regional office,'' as appropriate. Likewise, the Commission is amending certain of its rules to delete the term ''District Administrator'' or replace it with the term ''Regional Director,'' as appropriate. The Commission also is removing rules that describe the duties of District Administrators and delegate functions to these persons. In addition, because a number of Commission offices have relocated since the adoption of the current rules, the Commission is amending its rules to update the addresses that appear in its rules for all of its offices.

The rule amendments also update the geographic allocation of examination and enforcement jurisdiction to each Regional Director. This geographic allocation also determines where brokers, dealers, transfer agents, clearing agents, registered securities associations, investment advisers, and others must file reports that are required to be filed in regional offices. These registrants should note changes in the geographic allocation resulting from the reorganization.

II. Administrative Procedure Act and Other Administrative Laws

The Commission has determined that these amendments to its rules relate solely to the agency's organization, procedure, or practice. Therefore, the provisions of the Administrative Procedure Act (''APA'') regarding notice of proposed rulemaking and opportunity for public participation are not applicable.[2] For the same reason, and because these amendments do not substantially affect the rights or obligations of non-agency parties, the provisions of the Small Business Regulatory Enforcement Fairness Act are not applicable.[3] In addition, the provisions of the Regulatory Flexibility Act, which apply only when notice and comment are required by the APA or other law, are not applicable.[4] Finally, these amendments do not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995, as amended.[5]

III. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. The rule amendments the Commission is adopting today update the Commission's rules to reflect the reorganization of the Commission's regional offices. The amendments also update addresses for the Commission's offices that appear in the Commission's rules.

The Commission believes that the reorganization of the Commission's regional offices will produce the benefit of facilitating the offices' cooperation with state and federal regulators, law enforcement agencies and consumer groups at the local level to better protect investors no matter where they live or with whom they invest. The reorganization also should help eliminate the potential for redundancy and overlap in the Commission's inspection and enforcement procedures. Updating addresses in the Commission's rules will help registrants, investors, and others avoid misdirecting their communications with the Commission. The Commission does not believe that the rule amendments will impose any costs on non-agency parties, or that if there are any such costs, they are negligible.

IV. Consideration of Burden on Competition

Section 23(a)(2) of the Securities Exchange Act of 1934 (''Exchange Act'') requires the Commission, in making rules pursuant to any provision of the Exchange Act, to consider among other matters the impact any such rule would have on competition. The Commission does not believe that the amendments that the Commission is adopting today will have any impact on competition.

[1] Press Rel. No. 2007–59 (March 30, 2007).

[2] 5 U.S.C. 553(b).

[3] 5 U.S.C. 804.

[4] 5 U.S.C. 601–12.

[5] 44 U.S.C. 3501–20.

V. Statutory Basis

The Commission is adopting amendments to 17 CFR parts 200, 201, 202, 203, 209, 229, 230, 232, 239, 240, 249, 249b, 260, 269, 270, 274, 275, and 279 pursuant to 15 U.S.C. 77s, 78d–1, 78w, 80a–37, 80b–11, 7202, and the authorities set forth therein.

VI. Text of Final Amendments

List of Subjects

17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies), Classified information, Environmental impact statements, Equal employment opportunity, Freedom of information, Government employees, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements.

17 CFR Parts 201

Administrative practice and procedure.

17 CFR Part 202

Administrative practice and procedure, Securities.

17 CFR Part 203

Administrative practice and procedure, Investigations, Securities.

17 CFR Part 209

Administrative practice and procedure.

17 CFR Parts 230 and 232

Reporting and recordkeeping requirements, Securities.

17 CFR Part 240

Brokers, Reporting and recordkeeping requirements, Securities.

17 CFR Parts 249, 249b, and 260

Reporting and recordkeeping requirements.

17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

17 CFR Parts 274, 275, and 279

Reporting and recordkeeping requirements.

■ In accordance with the foregoing, 17 CFR, Chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

■ 1. The authority citation for part 200, subpart A, is amended by revising the following sub-authorities to read as follows:

Authority: 15 U.S.C. 77o, 77s, 77sss, 78d, 78d–1, 78d–2, 78w, 78*ll*(d), 78mm, 80a–37, 80b–11, and 7202, unless otherwise noted.

Sections 200.27 and 200.30–6 are also issued under 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77q, 77u, 78e, 78g, 78h, 78i, 78k, 78m, 78o, 78o–4, 78q, 78q–1, 78t–1, 78u, 77hhh, 77uuu, 80a–41, 80b–5, and 80b–9.

* * * * *

Section 200.30–3 is also issued under 15 U.S.C. 78b, 78d, 78f, 78k–1, 78q, 78s, and 78eee.

* * * * *

■ 2. Section 200.11 is revised to read as follows:

§ 200.11 Headquarters Office—Regional Office relationships.

(a)(1) Division and Office Heads in the Headquarters Office (100 F Street, NE., Washington, DC 20549) have Commission-wide responsibility to the Commission for the overall development, policy and technical guidance, and policy direction of the operating programs under their jurisdiction.

(2) Each Regional Director is responsible for the direction and supervision of his or her work force and for the execution of all programs in his or her office's region as shown in paragraph (b) of this section, in accordance with established policy, and reports, on enforcement matters, to the Deputy Director of the Division of Enforcement who is responsible for Regional Office enforcement matters and, on examination matters, to the Director of the Office of Compliance Inspections and Examinations. The Director of Regional Office Operations interacts with the Regional Directors and their staff on operational and administrative/management issues and serves as their representative in the Commission's Washington Headquarters in those areas.

(b) Regional Directors of the Commission.

Atlanta Regional Office: Alabama, Georgia, North Carolina, South Carolina, and Tennessee—Regional Director, 3475 Lenox Road, NE., Suite 1000, Atlanta, GA 30326–1232.

Boston Regional Office: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont—Regional Director, 33 Arch Street, 23rd Floor, Boston, MA 02110–1424.

Chicago Regional Office: Kentucky, Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin—Regional Director, 175 West Jackson Boulevard, Suite 900, Chicago, IL 60604–2908.

Denver Regional Office: Colorado, Kansas, Nebraska, New Mexico, North Dakota, South Dakota, and Wyoming—Regional Director, 1801 California Street, Suite 1500, Denver, CO 80202–2656.

Fort Worth Regional Office: Arkansas, Kansas (for certain purposes), Oklahoma, and Texas—Regional Director, Burnett Plaza, Suite 1900, 801 Cherry Street, Unit #18, Fort Worth, TX 76102–6882.

Los Angeles Regional Office: Arizona, Southern California (zip codes 93599 and below, except 93200–93299), Guam, Hawaii, and Nevada—Regional Director, 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036–3648.

Miami Regional Office: Florida, Louisiana, Mississippi, Puerto Rico, and the Virgin Islands—Regional Director, 801 Brickell Avenue, Suite 1800, Miami, FL 33131–4901.

New York Regional Office: New York and New Jersey—Regional Director, 3 World Financial Center, Suite 400, New York, NY 10281–1022.

Philadelphia Regional Office: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia—Regional Director, 701 Market Street, Suite 2000, Philadelphia, PA 19106–1532.

Salt Lake City Regional Office: Utah—Regional Director, 15 W. South Temple Street, Suite 1800, Salt Lake City, UT 84101–1573.

San Francisco Regional Office: Alaska, Northern California (zip codes 93600 and up, plus 93200–93299), Idaho, Montana, Oregon, and Washington—Regional Director, 44 Montgomery Street, Suite 2600, San Francisco, CA 94104–4716.

(c) The geographic allocation set forth in paragraph (b) of this section determines where registered brokers, dealers, transfer agents, clearing agents, registered securities associations, investment advisers, and others as designated in this chapter must file reports required to be filed in regional offices.

§ 200.12 [Amended]

■ 3. Section 200.12 is amended by removing from the first sentence the phrase ''and District Administrators'' and the authority citation following the section.

§ 200.21a [Amended]

■ 4. Section 200.21a, paragraph (b)(2), is amended by removing the phrase ''District Administrators,''.

■ 5. Section 200.27 is revised to read as follows:

§ 200.27 The Regional Directors.

Each Regional Director is responsible for executing the Commission's programs within his or her geographic region as set forth in § 200.11(b), subject to review, on enforcement matters, by the Deputy Director of the Division of Enforcement who is responsible for Regional Office enforcement matters and, on examination matters, by the Director of the Office of Compliance Inspections and Examinations, and subject to policy direction and review by the other Division Directors, the General Counsel, and the Chief Accountant. The Regional Directors' responsibilities include particularly the investigation of transactions in securities on national securities exchanges, in the over-the-counter market, and in distribution to the public; the examination of members of national securities exchanges and registered brokers and dealers, transfer agents, investment advisers and investment companies, including the examination of reports filed under § 240.17a–5 of this chapter; the prosecution of injunctive actions in U.S. District Courts and administrative proceedings before Administrative Law Judges; the rendering of assistance to U.S. Attorneys in criminal cases; and the making of the Commission's facilities more readily available to the public in that area. In addition, the Regional Director of the New York Regional Office is responsible for the Commission's participation in cases under chapters 9 and 11 of the Bankruptcy Code in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; the Regional Director of the Atlanta Regional Office is responsible for such participation in Alabama, Delaware, District of Columbia, Florida, Georgia, Louisiana, Maryland, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virgin Islands, Virginia, and West Virginia; the Regional Director of the Chicago Regional Office is responsible for such participation in Arkansas, Colorado, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, New Mexico, North Dakota, Ohio, Oklahoma, South Dakota, Texas, Wisconsin, and Wyoming; and the Regional Director of the Los Angeles Regional Office is responsible for such participation in Alaska, Arizona, California, Guam, Hawaii, Idaho, Montana, Nevada, Oregon, Utah, and Washington.

§ 200.27a [Removed]

■ 6. Section 200.27a is removed.

§ 200.28 [Amended]

■ 7. Section 200.28, paragraph (a), is amended by removing the phrase ''Regional Administrators'' and adding in its place ''Regional Directors''.

§ 200.30–6a [Removed]

■ 8. Section 200.30–6a is removed.

§ 200.30–11 [Amended]

■ 9. Section 200.30–11, paragraph (c)(2), is amended by removing the phrase ''or district'' and by removing the authority citation following the section.

Subpart D—Information and Requests

■ 10. The general authority citation for part 200, subpart D, is revised to read as follows:

Authority: 5 U.S.C. 552, as amended, 15 U.S.C. 77f(d), 77s, 77ggg(a), 77sss, 78m(F)(3), 78w, 80a–37, 80a–44(a), 80a–44(b), 80b–10(a), and 80b–11.

* * * * *

■ 11. Section 200.80 is amended by:

■ a. In paragraph (a)(2), the introductory text, revising the phrase ''during normal business hours at the public reference room located at 450 Fifth Street, NW., Room 1024, Washington, DC and at the Northeast and Midwest Regional Offices of the Commission,'' to read ''from 10 a.m. to 3 p.m., E.T., at the public reference room located at 100 F Street, NE., Washington, DC,'';

■ b. Revising paragraph (c)(1);

■ c. In paragraph (c)(2), in the first sentence, removing the phrase ''or at its other public reference facilities''; in the second sentence, removing the phrase ''and District''; and in the third sentence, removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place ''100 F Street, NE., Washington, DC 20549'';

■ d. In paragraph (d)(1):

■ i. In the first sentence, revising the phrase ''reference facilities may be made in person during normal business hours at those facilities'' to read ''reference facility may be made in person from 10 a.m. to 3 p.m., E.T., at this facility'';

■ ii. In the second sentence, revising the phrase ''reference facilities'' to read ''reference facility''; and

■ iii. In the last sentence, revising the phrase ''Operations Center, 6432 General Green Way, Alexandria, VA 22312–2413. The request may also be made by facsimile (703–914–1149) or by Internet'' to read ''100 F Street, NE., Washington, DC 20549. The request may also be made by facsimile (202–772–9337) or by Internet'';

■ e. In paragraphs (d)(2) and (d)(4), first sentence, revising the phrase ''reference facilities'' to read ''reference facility'';

■ f. In paragraph (d)(2), first sentence, removing the word ''appropriate'';

■ g. Revising paragraph (d)(6)(ii);

■ h. In paragraph (d)(7)(i) in the third and fourth sentences, removing the phrase ''or district'';

■ i. In the introductory text of paragraph (e), second sentence, removing the phrase ''or district'';

■ j. In paragraph (e)(2), first and third sentences, revising the phrase ''reference facilities'' to read ''reference facility'' and in the second sentence revising the phrase ''450 Fifth Street, NW., Room 1024, Washington, DC'' to read ''100 F Street, NE., Washington, DC'';

■ k. In paragraph (e)(7)(i), first sentence, by removing the phrase ''Washington, DC, Northeast, or Midwest public reference rooms'', and adding in its place ''Washington, DC public reference room'';

■ l. In paragraph (e)(7)(i), first sentence, removing the phrase ''450 Fifth Street, NW., room 1024, Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''; and

■ m. In paragraph (e)(7)(ii), last sentence, removing ''450 Fifth Street, NW., Room 1024, Washington, DC'' to read ''100 F Street, NE., Washington, DC'';

■ n. In paragraph (e)(7)(iii), second sentence, removing the phrase ''450 Fifth Street, NW., Room 1024, Washington, DC.'' and adding in its place the phrase ''100 F Street, NE., Washington, DC'', and removing the phrase ''and district''.

The revisions read as follow:

§ 200.80 Commission records and information.

* * * * *

(c)(1) *Public reference facility.* In order to disseminate records, including those listed in appendix A to this section, the Commission has a specially staffed and equipped public reference room located at 100 F Street, NE., Washington, DC. Copying machines, which are available to requestors on a self-service or contractor-operated basis, can be used to make immediate copies up to 8½ by 11 inches in size of materials that are available for inspection in the Washington, DC Headquarters. Fees and levels of service are set out in the Commission's schedule of fees in appendix E to this

section and in information available from the public reference room. The Commission accepts only written requests for copies of documents.

(i) The public reference room in Washington, DC has available for public inspection all of the publicly available records of the Commission as described in paragraph (a) of this section. Upon request, and only when suitable arrangements can be made with respect to the transportation, storage, and inspection of records, records may be sent to any other Commission office for inspection at that office, if the records are not needed by the Commission or the staff in connection with the performance of official duties. When the records are sent to another office at the request of a member of the public, the requestor shall be charged all costs incurred by the Commission in transporting the records.

(ii) All regional offices of the Commission have available for public examination the materials set forth in paragraph (a)(2) of this section and the *SEC Docket, SEC News Digest,* and other SEC publications. Blank forms as well as other general information about the operations of the Commission described in paragraph (a)(1) of this section may also be available at particular regional offices.

(iii) The addresses of the Commission's regional offices are:

Atlanta Regional Office—3475 Lenox Road, NE., Suite 1000, Atlanta, GA 30326–1232. Office hours—9 a.m. to 5:30 p.m. E.T.

Boston Regional Office—33 Arch Street, 23rd Floor, Boston, MA 02110–1424. Office hours—9 a.m. to 5:30 p.m. E.T.

Chicago Regional Office—175 West Jackson Boulevard, Suite 900, Chicago, IL 60604–2908. Office hours—8:45 a.m. to 5:15 p.m. C.T.

Denver Regional Office—1801 California Street, Suite 1500, Denver, CO 80202–2656. Office hours—8 a.m. to 4:30 p.m. M.T.

Fort Worth Regional Office—Burnett Plaza, Suite 1900, 801 Cherry Street, Unit #18, Fort Worth, TX 76102–6882. Office hours—8:30 a.m. to 5 p.m. C.T.

Los Angeles Regional Office—5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036–3648. Office hours—8:30 a.m. to 5 p.m. P.T.

Miami Regional Office—801 Brickell Avenue, Suite 1800, Miami, FL 33131–4901. Office hours—9 a.m. to 5:30 p.m. E.T.

New York Regional Office—3 World Financial Center, Suite 400, New York, NY 10281–1022. Office hours—9 a.m. to 5:30 p.m. E.T.

Philadelphia Regional Office—701 Market Street, Suite 2000, Philadelphia, PA 19106–1532. Office hours—9 a.m. to 5:30 p.m. E.T.

Salt Lake City Regional Office—15 W. South Temple Street, Suite 1800, Salt Lake City, UT 84101–1573. Office hours—8 a.m. to 4:30 p.m. M.T.

San Francisco Regional Office—44 Montgomery Street, Suite 2600, San Francisco, CA 94104–4716. Office hours—8:30 a.m. to 5 p.m. P.T.

* * * * *

(d) * * *

(6) * * *

(ii) The appeal must be mailed to the Office of Freedom of Information and Privacy Act Operations, SEC, 100 F Street, NE., Washington, DC 20549, and a copy of it must be mailed to the General Counsel, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549.

* * * * *

§ 200.80e [Amended]

■ 12. The last paragraph of § 200.80e is amended by revising the phrase ''public reference rooms'' to read ''public reference room'' in the first sentence, and in the third sentence of the same paragraph removing the phrase ''450 Fifth Street, NW., room 1024, Washington, DC 20549 or calling 202–272–3100'' and adding in its place ''100 F Street, NE., Washington, DC 20549 or calling 202–551–8090''.

§ 200.83 [Amended]

■ 13–14. Section 200.83 is amended by

■ a. Removing the phrase ''Operations Center, 6432 General Green Way, Alexandria, VA 22312–2413'', and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'', in the first sentence of paragraph (c)(3) and the second sentence of paragraph (c)(7); and

■ b. In paragraph (e)(2) by removing the phrase ''Operations Center, 6432 General Green Way, Alexandria, VA 22312–2413, or by facsimile (703–914–1149)'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549, or by facsimile (202–772–9337)'', in the second sentence, and by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'' in the third sentence.

Subpart G—Plan of Organization and Operation Effective During Emergency Conditions

■ 15. The authority citation for part 200, subpart G, continues to read as follows:

Authority: 15 U.S.C. 77s, 78d, 78d–1, 78w, 77sss, 80a–37, 80b–11; Reorganization Plan No. 10 of 1950 (15 U.S.C. 78d nt).

§ 200.202 [Amended]

■ 16. Section 200.202(a), second sentence, is amended by removing the phrase ''and District'' and by removing the phrase ''or District Administrator''.

§ 200.203 [Amended]

■ 17. In § 200.203 paragraph (c)(1)(v) is removed.

§ 200.204 [Amended]

■ 18. Section 200.204 is amended by removing the phrase ''and District Administrators''.

Subpart H—Regulations Pertaining to the Privacy of Individuals and Systems of Records Maintained by the Commission

■ 19. The authority citation for part 200, subpart H, continues to read in part as follows:

Authority: 5 U.S.C. 552a(f), unless otherwise noted.

* * * * *

■ 20. Section 200.303 is amended by:

■ a. Revising the phrase ''Privacy Act Officer, SEC, Operations Center, 6432 General Green Way, Alexandria, VA 22312–2413, or by facsimile (703–914–1149)'' in the introductory text of paragraph (a), first sentence, to read ''Office of Freedom of Information and Privacy Act Operations, SEC, 100 F Street, NE., Washington, DC 20549, or by facsimile (202–772–9337)'';

■ b. Revising paragraph (a)(2); and

■ c. Revising the phrase ''Office of Freedom of Information and Privacy Act Operations, SEC, Operations Center, 6432 General Green Way, Alexandria, VA 22312–2413, or at one of its Regional or District'' to read ''Office of Freedom of Information and Privacy Act Operations, SEC, 100 F Street, NE., Washington, DC 20549, or at one of its Regional'' in the first sentence of paragraph (b)(2).

The revision reads as follows:

§ 200.303 Times, places and requirements for requests pertaining to individual records in a record system and for the identification of individuals making requests for access to the records pertaining to them.

(a) * * *

(2) *Verification of identity.* When the fact of the existence of a record is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, or when a record as to which access has been requested is not required to be disclosed under that Act, the individual seeking the information or requesting access to the

record shall be required to verify his or her identity before access will be granted or information given. For this purpose, individuals shall appear at the Office of Freedom of Information and Privacy Act Operations, SEC, 100 F Street, NE., Washington, DC 20549, during normal business hours of 9 a.m. to 5:30 p.m. E.S.T., Monday through Friday, or at one of the Commission's Regional Offices. The addresses and business hours of those offices are listed below:

Atlanta Regional Office—3475 Lenox Road, NE., Suite 1000, Atlanta, GA 30326–1232. Office hours—9 a.m. to 5:30 p.m. E.T.

Boston Regional Office—33 Arch Street, 23rd Floor, Boston, MA 02110–1424. Office hours—9 a.m. to 5:30 p.m. E.T.

Chicago Regional Office—175 West Jackson Boulevard, Suite 900, Chicago, IL 60604–2908. Office hours—8:45 a.m. to 5:15 p.m. C.T.

Denver Regional Office—1801 California Street, Suite 1500, Denver, CO 80202–2656. Office hours—8 a.m. to 4:30 p.m. M.T.

Fort Worth Regional Office—Burnett Plaza, Suite 1900, 801 Cherry Street, Unit #18, Fort Worth, TX 76102–6882. Office hours—8:30 a.m. to 5 p.m. C.T.

Los Angeles Regional Office—5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036–3648. Office hours—8:30 a.m. to 5 p.m. P.T.

Miami Regional Office—801 Brickell Avenue, Suite 1800, Miami, FL 33131–4901. Office hours—9 a.m. to 5:30 p.m. E.T.

New York Regional Office—3 World Financial Center, Suite 400, New York, NY 10281–1022. Office hours—9 a.m. to 5:30 p.m. E.T.

Philadelphia Regional Office—701 Market Street, Suite 2000, Philadelphia, PA 19106–1532. Office hours—9 a.m. to 5:30 p.m. E.T.

Salt Lake City Regional Office—15 W. South Temple Street, Suite 1800, Salt Lake City, UT 84101–1573. Office hours—8 a.m. to 4:30 p.m. M.T.

San Francisco Regional Office—44 Montgomery Street, Suite 2600, San Francisco, CA 94104–4716. Office hours—8:30 a.m. to 5 p.m. P.T.

None of the Commission's offices is open on Saturday, Sunday or the following legal holidays: New Year's Day, Martin Luther King, Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Veterans' Day, Columbus Day, Thanksgiving Day, and Christmas Day.

* * * * *

§ 200.309 [Amended]

■ 21. Section 200.309 is amended by removing the phrase ''or District'' in the third and fourth sentences of paragraph (a)(1), and removing the authority citation at the end of the section.

Subpart J—Classification and Declassification of National Security Information and Material

■ 22. The authority citation for part 200, subpart J, continues to read as follows:

Authority: Sec. 19, Securities Act of 1933, as amended, 48 Stat. 84, 15 U.S.C. 77s. E.O. 12356, (47 FR 14874, Apr. 6, 1982). Information Security Oversight Office Directive No. 1 (47 FR 27836, June 25, 1982).

§ 200.503 [Amended]

■ 23. Section 200.503, introductory text of the section, second sentence, is amended by removing the phrase ''450 5th Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

§ 200.508 [Amended]

■ 24. Section 200.508, paragraph (a), second sentence, is amended by removing the phrase ''450 5th Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

Subpart K—Regulations Pertaining to the Protection of the Environment

■ 25. The authority citation for part 200, subpart K, continues to read as follows:

Authority: 15 U.S.C. 78w(a)(2).

§ 200.554 [Amended]

■ 26. Section 200.554, paragraph (b), is amended by removing the phrase ''450 Fifth Street, NW., Room 1024, Washington, DC'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

Subpart L—Enforcement of Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the Securities and Exchange Commission

■ 27. The authority citation for part 200, subpart L, continues to read as follows:

Authority: 29 U.S.C. 794.

§ 200.670 [Amended]

■ 28. Section 200.670, paragraph (c), is amended by removing the phrase ''450 Fifth Street NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

Subpart M—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

■ 29. The authority citation for part 200, subpart M, is revised to read as follows:

Authority: 15 U.S.C. 77s, 77sss, 78w, 80a–37, 80b–11; E.O. 11222, 3 CFR, 1964–1965 Comp., p.36; 5 CFR 735.104, unless otherwise noted.

§ 200.735–3 [Amended]

■ 30. Section 200.735–3 is amended by:
■ a. In the second sentence of paragraph (a)(3), third sentence of paragraph (b)(3)(i), and third sentence of paragraph (b)(10)(i), removing the phrase ''Regional Administrators'' and adding in its place the phrase ''Regional Directors''; and
■ b. In the fourth sentence of paragraph (b)(3)(i), first sentence of paragraph (b)(6)(i) and second sentence of paragraph (b)(10)(i), removing the phrase ''Regional Administrator'' and adding in its place the phrase ''Regional Director''.

§ 200.735–4 [Amended]

■ 31. Section 200.735–4 is amended by:
■ a. In the first sentence of paragraph (b)(6)(iii)(A)(*1*), first and second sentences of paragraph (b)(6)(iii)(B), and third sentence of paragraph (f), removing the phrase ''Regional Administrators'' and adding in its place the phrase ''Regional Directors''; and
■ b. In the first sentence of introductory text of paragraph (b)(6)(iii)(A) and second sentence of paragraph (f), removing the phrase ''Regional Administrator'' and adding in its place the phrase ''Regional Director''.

§ 200.735–5 [Amended]

■ 32. Section 200.735–5, is amended by:
■ a. In the first sentence of paragraph (f)(2), removing the phrase ''Regional Administrator'' and adding in its place the phrase ''Regional Director''; and
■ b. In the second sentence of paragraph (f)(2), removing the phrase ''Regional Administrators'' and adding in its place the phrase ''Regional Directors''.

§ 200.735–6 [Amended]

■ 33. Section 200.735–6 is amended by:
■ a. In the first and fourth sentences, removing the phrase ''Regional Administrator'' and adding in its place the phrase ''Regional Director''; and
■ b. In the second sentence, removing the phrase ''Regional Administrators'' and adding in its place the phrase ''Regional Directors''.

■ 34. Section 200.735–11 is amended by revising paragraph (c)(2)(v) to read as follows:

§ 200.735–11 Statement of employment and financial interests.

* * * * *

(c) * * *

(2) * * *

(v) Regional Offices

(A) Directors

(B) Associate Directors

(C) Assistant Directors

* * * * *

§ 200.735–15 [Amended]

■ 35. Section 200.735–15, paragraph (b), first sentence, is amended by removing the phrase ''Administrator of each regional office'' and adding in its place ''Regional Director of each regional office''.

PART 201—RULES OF PRACTICE

■ 36. The authority citation for part 201, is revised to read as follows:

Authority: 15 U.S.C. 77s, 77sss, 78w, 78x, 80a–37, and 80b–11; 5 U.S.C. 504(c)(1).

Subpart C—Procedures Pertaining to the Payment of Bounties Pursuant to Subsection 21A(e) of the Securities Exchange Act of 1934

■ 37. The authority citation for part 201, Subpart C, continues to read as follows:

Authority: 15 U.S.C. 78u–1 and 78w.

§ 201.63 [Amended]

■ 38. Section 201.63, last sentence, is amended by removing ''450 Fifth Street NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

PART 202—INFORMAL AND OTHER PROCEDURES

■ 39. The authority citation for part 202 is revised to read as follows:

Authority: 15 U.S.C. 77s, 77t, 77sss, 77uuu, 78d–1, 78u, 78w, 78*ll*(d), 80a–37, 80a–41, 80b–9, 80b–11, 7202 and 7211 *et seq.*, unless otherwise noted.

Section 202.5 is also issued under sec. 20, 48 Stat. 86, sec. 21, 48 Stat. 899, sec. 18, 49 Stat. 831, sec. 321, 53 Stat. 1174, sec. 1, 76 Stat. 394, 15 U.S.C. 77t, 77uuu, 78d–1, 78u, 80a–4*l*, and 80b–9.

Section 202.9 is also issued under sec. 223, 110 Stat. 859 (Mar. 29, 1996).

§ 202.2 [Amended]

■ 40. Section 202.2 is amended by removing the phrase ''or district'' from the last sentence.

§ 202.5 [Amended]

■ 41. Section 202.5, paragraph (c), third sentence, is amended by revising the phrase ''Division Director, Regional Director, or District Administrator'' to read ''Division Director or Regional Director''.

§ 202.7 [Amended]

■ 42. Section 202.7, paragraph (a), second sentence, is amended by removing the phrase ''or district'', in both places it appears.

PART 203—RULES RELATING TO INVESTIGATIONS

■ 43. The authority citation for part 203 is revised to read as follows:

Authority: 15 U.S.C. 77s, 77sss, 78w, 80a–37, and 80b–11, unless otherwise noted.

§ 203.2 [Amended]

■ 44. Section 203.2 is amended by removing the phrase ''Regional Offices at the level of Assistant Regional Director or District Administrator or higher'' and adding in its place ''Regional Offices at the level of Assistant Regional Director or higher''.

§ 203.7 [Amended]

■ 45. Section 203.7 is revised by:

■ a. In paragraph (a), second sentence, removing the phrase ''Regional or District Offices at the level of Assistant Regional Director or District Administrator or higher'' and adding in its place ''Regional Offices at the level of Assistant Regional Director or higher''; and

■ b. In paragraph (e), second sentence, removing the phrase ''§ 201.2(e) of this chapter (Rule 2(e) of the Commission's rules of practice),'' and adding in its place the phrase ''§ 201.102(e) of this chapter (Rule 102(e) of the Commission's rules of practice),''.

PART 209—FORMS PRESCRIBED UNDER THE COMMISSION'S RULES OF PRACTICE

■ 46. The authority citation for part 209 is revised to read as follows:

Authority: 15 U.S.C. 77h–1, 77u, 78u–2, 78u–3, 78v, 78w, 80a–9, 80a–37, 80a–38, 80a–39, 80a–40, 80a–41, 80a–44, 80b–3, 80b–9, 80b–11, and 80b–12, unless otherwise noted.

§ 209–0,1 [Amended]

■ 47. Section 209.0–1 is amended by:

■ a. Revising the phrase ''450 Fifth Street, NW., Washington, DC 20549'' to read ''100 F Street, NE., Washington, DC 20549'' in the first sentence of paragraph (b); and

■ b. Removing the phrase ''and district'' in the second and third sentences of paragraph (b).

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 48. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l*, 78m, 78n, 78o, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

§ 230.497 [Amended]

■ 49. Section 230.497, paragraph (k)(2)(ii), second sentence, is amended by removing the phrase ''450 Fifth St., NW., Mail Stop 5–6, Washington, DC 20549–6009'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549–4720''.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 50. The authority citation for part 232 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*, 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350.

* * * * *

§ 232.12 [Amended]

■ 51. Section 232.12, paragraph (a), is amended by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 52. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

§ 240.15b7–3T [Amended]

■ 53. Section 240.15b7–3T, paragraph (c), second sentence and paragraph (e)(2) are amended by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549–1002'', each time that it appears, and by adding in its place the phrase ''100 F Street, NE., Washington, DC 20549–6628''.

§ 240.15c3–1 [Amended]

■ 54. Section 240.15c3–1 is amended:

■ a. In paragraph (a)(6)(iv), second sentence, by removing the phrase ''or district'' each time it appears;
■ b. In paragraph (a)(6)(v), second sentence, by removing the phrase ''or district'' each time it appears;
■ c. In paragraph (c)(2)(x)(C)(1), by removing the phrase ''district or'' both times it appears;
■ d. In paragraph (c)(12), by removing the phrase ''or District''; and
■ e. In paragraph (e)(1)(iv), by removing the phrase ''or district'' both times it appears.

§ 240.15c3–1d [Amended]

■ 55. Section 240.15c3–1d is amended by:
■ a. Removing the phrase ''or District'' in the first and fourth sentences of paragraph (c)(6)(i) and the first sentence of paragraph (c)(6)(ii), each time that it appears; and
■ b. Removing the phrase ''or district'' in the first sentence of paragraphs (c)(6)(i) and (c)(6)(ii); and
■ c. Removing the authority citation at the end of the section.

■ 56. Section 240.17a–3 is amended by removing the phrase ''or district'' in the first sentence of paragraph (b)(2) and the first sentence of the legend following paragraph (b)(2).

§ 240.17a–5 [Amended]

■ 57. Section 240.17a–5 is amended by removing the phrase ''or district'' each time that it appears in:
■ a. The first sentence of paragraph (a)(3);
■ b. The second sentence of paragraph (b)(1);
■ c. The introductory text of paragraph (c)(1);
■ d. Paragraph (c)(2)(iii);
■ e. Paragraph (c)(2)(iv);
■ f. The last sentence of paragraph (d)(1)(i);
■ g. The first sentence of paragraph (d)(6);
■ h. The last sentence of the introductory text of paragraph (e)(4);
■ i. The first sentence of paragraph (f)(2)(i);
■ j. The introductory text of paragraph (f)(4); and
■ k. Paragraph (n)(1).

§ 240.17a–7 [Amended]

■ 58. Section 240.17a–7 is amended by removing the phrase ''or District'' in:
■ a. Paragraph (b)(1);
■ b. The first sentence of the legend following paragraph (b)(1); and
■ c. The last sentence of paragraph (b)(2).

§ 240.17a–11 [Amended]

■ 59. Section 240.17a–11 is amended, in paragraph (g), by revising the phrase ''regional or district office of the Commission for the region or district'' to read ''regional office of the Commission for the region''.

§ 240.17Ad–2 [Amended]

■ 60. Section 240.17Ad–2 is amended by:
■ a. In paragraph (h)(1), revising the phrase ''Regional or District Office of the Commission for the region or district'' to read ''regional office of the Commission for the region''; and
■ b. Removing the authority citation at the end of the section.

§ 240.17Ad–21T [Amended]

■ 61. Section 240.17Ad–21T, paragraphs (c) and (e)(2), second sentences, is amended by removing the phrase ''450 Fifth Street, NW, Washington, DC 20549–1002'', each time that it appears, and by adding in its place the phrase ''100 F Street, NE., Washington, DC 20549–6628''.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 62. The authority citation for part 249 continues to read, in part, as follows:

Authority: 15 U.S.C. 78a *et seq.*, and 7202, 7233, 7241, 7262, 7264, and 7265; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

§ 249.322 [Amended]

■ 63. Section 249.322 is amended by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'', in the last sentence of paragraph (a).

PART 249b—FURTHER FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 64. The authority citation for part 249b continues to read, in part, as follows:

Authority: 15 U.S.C. 78a *et seq.*, unless otherwise noted;

* * * * *

§ 249b.100 [Amended]

■ 65. Section 249b.100 is amended by removing the phrase ''450 Fifth Street, NW, Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'' and removing the phrase ''and district'' in footnote 1.

§ 249b.102 [Amended]

■ 66. Section 249b.102 is amended by removing the phrase ''450 Fifth Street, NW, Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'' and removing the phrase ''and district'' in footnote 1.

§ 249b.200 [Amended]

■ 67. Section 249b.200 is amended by removing the phrase ''450 Fifth Street, NW, Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'' and removing the phrase ''and district'' in footnote 1.

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

■ 68. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 77sss, 78*ll*(d), 80b–3, 80b–4, and 80b–11.

§ 260.0–5 [Amended]

■ 69. Section 260.0–5, paragraph (a), is amended by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 70. The authority citation for part 270 continues to read, in part, as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, and 80a–39, unless otherwise noted.

* * * * *

§ 270.17f–4 [Amended]

■ 71. Section 270.17f–4, paragraph (c)(1), fourth sentence, is amended by removing the phrase ''450 5th Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549''.

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 72. The authority citation for part 274 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l*, 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, and 80a–29, unless otherwise noted.

* * * * *

§ 274.0–1 [Amended]

■ 73. Section 274.0–1 is amended, in paragraph (b), by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'' in the first sentence, and removing the phrase ''and district'' in the second and third sentences.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 74. The authority citation for part 275 continues to read, in part, as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

§ 275.204–2 [Amended]

■ 75. Section 275.204–2 is amended by removing the phrase ''or District'' in

■ a. The first sentence of paragraph (j)(3)(i);

■ b. The first sentence of the legend following paragraph (j)(3)(i); and

■ c. The last sentence of paragraph (j)(3)(ii).

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

■ 76. The authority citation for part 279 continues to read as follows:

Authority: The Investment Advisers Act of 1940, 15 U.S.C. 80b–1 *et seq.*

§ 279.0–1 [Amended]

■ 77. Section 279.0–1 is amended, in paragraph (b), by removing the phrase ''450 Fifth Street, NW., Washington, DC 20549'' and adding in its place the phrase ''100 F Street, NE., Washington, DC 20549'' in the first sentence, and removing the phrase ''and district'', in the second and third sentences.

Dated: May 28, 2008.

By the Commission.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–12244 Filed 6–4–08; 8:45 am]

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Federal Register

Thursday,
June 5, 2008

Part IV

The President

Proclamation 8268—National Oceans Month, 2008

Federal Register
Vol. 73, No. 109
Thursday, June 5, 2008

Presidential Documents

Title 3—

The President

Proclamation 8268 of June 2, 2008

National Oceans Month, 2008

By the President of the United States of America

A Proclamation

Oceans have provided an important part of our heritage, economy, and recreation, and they are a vital resource for our country and the world. During National Oceans Month, we reaffirm our commitment to protect and wisely use these precious waters and the habitat beneath them.

We have a solemn responsibility to care for our seas and show concern for the plant and animal life that inhabit them. Oceans bring enjoyment and prosperity to countless people, from boating and fishing, to transporting goods, to traveling the waterways. By being good stewards of the oceans, we can ensure that future generations are able to enjoy the great blessings of our natural heritage.

My Administration is committed to safeguarding the oceans and ensuring effective conservation. Since the release of my Ocean Action Plan in 2004, we have taken steps to prevent pollution and improve the health of marine wildlife by working with State, tribal, and local governments, as well as private sector and international partners. We are working to end overfishing in U.S. waters and to stop destructive fishing practices on the high seas. We are also supporting ocean programs to educate the public on the need to prevent marine debris and improve the quality of the marine environment, as well as other projects such as the International Coral Reef Initiative that can help conserve and restore delicate and essential ecosystems. By working to protect our oceans, we ensure that natural wonders like the Papahānaumokuākea Marine National Monument in the Northwestern Hawaiian Islands will be enjoyed for generations to come.

This month is an opportunity to show our gratitude toward all those who work to protect the oceans, to learn more about the vital role oceans play in the life of our country, and to discover ways we can conserve their many natural treasures.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim June 2008 as National Oceans Month. I encourage all our citizens to observe this month with appropriate ceremonies and activities.

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

[FR Doc. 08–1330
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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 2356/P.L. 110–239
To amend title 4, United States Code, to encourage the display of the flag of the United States on Father's Day. (June 3, 2008; 122 Stat. 1559)

H.R. 2517/P.L. 110–240
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H.R. 4008/P.L. 110–241

Credit and Debit Card Receipt Clarification Act of 2007 (June 3, 2008; 122 Stat. 1565)

S. 2829/P.L. 110–242

To make technical corrections to section 1244 of the National Defense Authorization Act for Fiscal Year 2008, which provides special immigrant status for certain Iraqis, and for other purposes. (June 3, 2008; 122 Stat. 1567)

S.J. Res. 17/P.L. 110–243

Directing the United States to initiate international discussions and take necessary steps with other Nations to negotiate an agreement for managing migratory and transboundary fish stocks in the Arctic Ocean. (June 3, 2008; 122 Stat. 1569)

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