AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

Federal Register

4–15–08 Tuesday
Vol. 73 No. 73 Apr. 15, 2008

Pages 20149–20524

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

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 731

RIN 3206–AL08

Suitability

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: In support of its mission to ensure the Federal Government has an effective civilian workforce, the Office of Personnel Management (OPM) is issuing final regulations governing Federal employment suitability. The final regulations authorize agencies to debar from employment for up to three years those found unsuitable, extend the suitability process to those applying for or who are in positions that can be non-competitively converted to the competitive service, provide additional procedural protections for those found unsuitable for Federal employment, and clarify the scope of authority for the Merit Systems Protection Board (MSPB) to review actions taken under the regulations. The changes also make the regulations more readable.

DATES: *Effective Date:* The rule is effective June 16, 2008.

FOR FURTHER INFORMATION CONTACT: Gary D. Wahlert by telephone at (202) 606–2930; by FAX at (202) 606–2613; or by e-mail at *CWRAP@opm.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

On January 18, 2007, OPM published at 72 FR 2203 (2007) proposed amendments to the regulations in part 731 of title 5, Code of Federal Regulations (CFR), to modify and more precisely define and clarify the regulations' coverage, the procedural requirements for taking suitability actions, the respective authorities of OPM and agencies, and Merit Systems Protection Board (MSPB or Board) review of suitability actions. OPM also proposed various revisions to make the regulations more readable. The public comment period on the proposed amendments ended on March 19, 2007. OPM received comments from five Federal agencies or departments and from three unions. Of the agency comments, three were received from security offices, two from human resources offices, and one from a legal office. OPM has carefully considered the comments received.

Coverage

OPM proposed to amend the regulations to provide that part 731 also applies to persons who can be noncompetitively converted to the competitive service because of service in their excepted service positions. OPM noted that the expansion of the regulation's scope to include suitability determinations of persons applying for, entering, or employed in the excepted service when that appointment can lead to their noncompetitive conversion to the competitive service is consistent with OPM's suitability authority. The process for employing this limited group of persons in the competitive service is a continuous one, beginning with initial appointment to the excepted service and ending in (noncompetitive) conversion to the competitive service. Because these persons can (and most do) enter into the competitive service as a result of their excepted service appointment, albeit through a longer process than others appointed directly, they should be treated in the same manner as those appointed directly, including the same review of their suitability for employment. Already, under part 302 of this chapter, persons in the excepted service are subject to investigation and disqualifying factors similar to those found in part 731. OPM believes that procedural protections should be extended to this limited group of persons in the excepted service.

One commenter had doubts about OPM's statutory authority to extend suitability to persons in the excepted service, notwithstanding OPM's statement that to do so would be consistent with OPM's suitability authority. OPM has carefully reviewed its authority under statute and Executive Order (E.O.) and again has concluded it does have the required authority.

Under rules II and V of E.O. 10577, as amended, OPM has the authority to regulate standards of fitness for entry in the competitive service, to investigate suitability for the competitive service, and to establish investigative requirements for competitive service appointments. Section 1103(a)(5)(A) of title 5, U.S. Code, requires OPM to execute, administer, and enforce these rules. The law does not contemplate that the suitability standards and other requirements for appointment to a competitive service position would not apply because of the means by which an applicant initially enters service.

While the positions at issue here do not begin in the competitive service, they end up in the competitive service if converted. The triggering events for this method of entering the competitive service are the persons' appointments to the excepted service. Because of the continuity of this method, from appointments in the excepted service to conversions to the competitive service, OPM concludes that OPM's suitability authority applies to these persons and applies as soon as they are appointed to the excepted service position. Accordingly, there is no requirement that the positions must have been converted before the incumbents are subject to investigation and determinations as to fitness for Federal employment. Thus, OPM declines to adopt a commenter's recommendation that the regulations be revised to state that suitability determinations for persons in these positions can only take place upon ''application to a competitive appointment'' or when the conversion is ''imminent.''

Several commenters asked for examples of positions in the excepted service from which persons may be noncompetitively converted to the competitive service. While this is not a complete list of positions, some are under the Federal Career Intern Program, the Veterans Recruitment Appointment Program, the Student Career Experience Program, and the Presidential Management Fellows Program.

One commenter asked what authority would permit the removal of an excepted service employee for suitability reasons such as misconduct

prior to appointment. As we stated in our proposed rule, the revised regulations clarify that they apply to persons who can be noncompetitively converted to service because of employment in an excepted service position. The purpose of these positions is to lead to a competitive appointment and, therefore, should be treated in the same way for suitability purposes as those who are appointed directly into the competitive service.

One commenter wondered what the advantage would be of having an excepted service position if it is covered by the suitability rules. OPM's proposal identified just a limited category of excepted service employees that would be covered by part 731, i.e., those whose excepted service appointment can lead to their noncompetitive conversion to the competitive service. All other excepted service positions are not covered by the suitability rules. However, other excepted service positions are subject to qualification standards which may include disqualifying factors under 5 CFR part 302. At any rate, most persons in excepted service positions already have other employee protections, whether or not they are covered by suitability rules.

OPM proposed to add definitions of *suitability action* and *suitability determination* to § 731.101 to help the reader better understand the coverage of part 731. One commenter suggested that the definition of ''suitability action'' be reworded so that it would be parallel to the definition of ''suitability determination'' and thus clarify the distinction between the two. OPM notes that the construction of the definitions differs because the processes differ. One (suitability actions) concerns the type of actions taken, such as debarment or removal, once a person is determined to be unsuitable and the other (suitability determinations) concerns the process of initially deciding whether a person is suitable. OPM believes that its initial proposed language better draws that distinction and the suggestion is not adopted.

OPM proposed at § 731.104(c) that persons in intermittent, seasonal, per diem and temporary positions, with less than 180 days aggregate service, are not subject to the investigative requirements of part 731. With respect to seasonal employees, one commenter wondered whether the 180 days aggregate service meant 180 days per year or an aggregate of 180 days in all their employment. OPM's response is that the 180 days means 180 days per year. OPM has modified § 731.104(c) accordingly. OPM also has modified the punctuation in this section to clarify that the phrase ''with less than 180 days aggregate service per year'' applies to each of the types of positions noted: intermittent, seasonal, per diem and temporary positions.

Another commenter expressed concern that the rule would allow such persons access to facilities and information without investigation for six months because agencies would not be able to investigate them under the revised rule. That was not the intent. Rather, OPM's intent is to more fully identify those types of positions for which incumbents are not subject to investigation as mandated by part 731. As the proposed rule states, an agency ''must conduct such checks as it deems appropriate to ensure the suitability of the person.'' To accomplish such checks, some agencies may choose to investigate these persons in the same manner as it would those actually covered by part 731, but they are not required to do so. The checks required by § 731.104(c) need not rise to the level required for an investigation under part 731. Likewise, the coverage requirements for suitability purposes of these persons do not prevent agencies from conducting other pre-employment checks, such as an investigation for eligibility for an identity credential under Homeland Security Presidential Directive No.12—a concern expressed by another commenter. Moreover, E.O. 10450 authorizes investigations for all civilian officers and employees, including, under some circumstances, those in intermittent, temporary, or seasonal positions. Finally, as explained in the proposed regulations, OPM believes this change is necessary to maintain consistency between this part, which concerns suitability, and part 732 of this chapter, which governs positions of national security.

OPM also proposed to clarify the definition of *material* in § 731.101 by saying that a statement may be material whether or not OPM or an agency relies upon it. OPM noted that the added language was not intended to change, but rather to reinforce, the meaning of the current definition in that a ''material'' statement does not actually have to influence or affect an official decision by OPM or an agency. This is not a new concept since the former regulations at § 731.105(c) stated: ''A statement may be a material statement even if an agency does not rely upon it.''

Two commenters recommended that the definition be modified. One of these commenters stated that the proposed definition would undercut the commonly accepted legal meaning of ''material'' by setting the threshold for what may be material too low. The other commenter suggested that the definition be modified to state that, in order for it to be material, a statement must ''likely'' influence a decision rather than just be ''capable of'' influencing a decision. OPM believes that in many cases, a statement that is capable of influencing a decision is also likely to be relied on by OPM or an agency. However, as OPM explained in the proposed rule, a ''material'' statement ''does not actually have to influence or affect an official decision by OPM or an agency.'' In some situations, such as those involving false experience or educational claims, whether the experience or education was likely to influence a decision on the person's eligibility for employment may have no relationship to the materiality of the false statement, i.e., whether the false statement is capable of influencing, affects, or has a natural tendency to affect, an official decision even if OPM or an agency does not rely upon it. In such situations, OPM would be concerned with the individual's lack of honesty in the employment process. Accordingly, OPM has not adopted the suggestions.

Another commenter wondered how the definition of ''material'' relates to the statement in the proposed rule's supplementary information discussion that ''Factors not relied upon by OPM or agencies in individual cases may not be considered by MSPB.'' OPM notes that this statement referred to the specific suitability factors provided in § 731.202(b) and the additional considerations provided in § 731.202(c), not statements that may or may not be material under the definition of this part and may or may not be used by the agency or OPM.

While there is no statutory right to appeal actions taken under the procedures set forth in part 731, OPM has provided for such appeals by regulation. This appeal right does not extend to any other employment action that an agency takes outside of the procedures set forth in part 731. In this regard, OPM proposed changes to the regulations that would reaffirm and clarify that there is no right to appeal an agency's decision to object to or request to pass over an employment candidate under part 332 of this chapter, regardless of the basis for the agency's request, including an applicant's fitness or character as discussed in OPM's Delegated Examining Operations Handbook. OPM also proposed changes that would clarify that an agency's reason(s) for not hiring someone is not an appropriate basis to determine whether a person may appeal the agency's action as a suitability action. OPM also proposed a concurrent change

that would remove ''denial of appointment'' as a suitability action under this part. In other words, non-selection for a position is not an appealable suitability action.

While one commenter thought the proposed changes concerning objections and pass overs cleared up much confusion, other commenters thought the changes could be clearer. One commenter noted that objections and pass overs may be different from suitability determinations, but that permitting an agency to ''label'' its action as one or the other elevates ''form over substance.'' The commenter believed this would allow agencies to make *de facto* suitability determinations without following procedural requirements. The commenter recommended that agencies not be allowed to ''label'' their actions. OPM declines to limit agencies' authority in this manner. Agencies typically identify the authority under which they take actions and this in turn informs MSPB of the appropriate review authority, if any, to be used in the event those actions are appealed. A common example occurs when agencies identify the authority for or ''label'' the actions taken under 5 U.S.C. chapters 43 and 75. Performance-based actions may be taken under either authority, but agencies choose which authority to use and MSPB then knows which review standard to apply.

Another commenter recommended that, instead of ''pass over of a preference eligible,'' the regulations refer to ''pass over of an applicant.'' OPM is not adopting this recommendation because it would conflict with statutory and regulatory language describing pass overs. Upon closer examination of the regulation referred to by the commenter (5 CFR 332.406), it is apparent that the proposed rule at part 731 could be modified to refer precisely to pass over requests and objections. That is, part 332 discusses objections to eligibles and pass overs of preference eligibles as two categories of actions. Therefore, OPM has clarified the regulations to refer to ''objections to eligibles'' in §§ 731.101(a) and 731.203(b) rather than simply ''objections.'' The same commenter also recommended that the reference to decisions by OPM concerning pass over requests be changed to reflect agency delegated authority by referring to decisions by OPM and agencies. OPM agrees this change would properly describe who makes these types of decisions and has modified § 731.101(a) accordingly. Finally, another commenter stated it was their understanding that OPM's current position is that ''objections/pass overs may be based either on qualifications or suitability—and that non-selections for suitability reasons are NOT suitability actions and are not covered by Part 731.'' OPM confirms those understandings.

One commenter stated that OPM should eliminate employees and appointees who have successfully completed twelve months of Federal service from coverage of the suitability regulations. The commenter stated that this change would eliminate the ''collision'' between OPM suitability regulations and the statutes that govern employees who have completed their probationary periods. The commenter also argued that this change would preserve agencies' discretion to take adverse actions and avoid the hardship when OPM initiates action to remove a long-term employee for suitability reasons when the agency may want to keep that employee. OPM declines to make these changes to the regulations for a number of reasons. As an initial matter, there is no collision of employee rights upon completion of a probationary period and OPM's suitability regulations. Suitability actions for persons who have become employees as defined by this part can be initiated only by OPM, and the bases for judging a person unsuitable and removing that person after the first year of employment are limited to material intentional false statement, deception or fraud in examination or appointment; refusal to furnish testimony; or a statutory or regulatory bar to employment. The commenter's recommendation would eliminate OPM's ability to take appropriate suitability actions merely because the individual has been employed for 12 months. However, mere completion of 12 months of service cannot shield a person from the consequences of, for example, making material, intentional false statements in order to obtain a position with the Federal Government. This would undermine the integrity of the Federal employment process.

Procedures

A number of commenters expressed support for the proposed additional procedural protections for persons who may be subject to an unfavorable suitability determination or action. One commenter asked what role a representative would have under these protections. OPM expects the role would be similar to that of a representative in other administrative actions, i.e., that a properly-designated representative would have the authority to act on behalf of the person he or she represents, including corresponding on behalf of the person and being responsible for meeting deadlines.

A commenter suggested that representatives designated under the regulations be allowed reasonable official time to review materials and prepare responses to proposed actions. While the regulations do not require the grant of official time, they do not preclude the agency from authorizing official time for a representative. This is consistent with other OPM Governmentwide regulations, at 5 CFR parts 432 and 752, that also do not provide official time for representatives. Therefore, the suggestion to include an official time provision for representatives in the regulations is not adopted.

Authorities

The final rule permits an agency to debar from employment with that agency any person it finds unsuitable for up to three years, as opposed to a period of one year as provided in the current regulations. While OPM changed this rule to give agencies the same flexibility when deciding the appropriate length of debarment as OPM, one commenter suggested that objective criteria be published as to when debarment would be appropriate beyond one year. OPM intends to provide this type of information as part of its guidance issuances referenced in § 731.102(c).

The same commenter also suggested that criteria and examples be given of when it would be appropriate to impose an additional debarment period. An additional debarment period, that is, a new debarment action based on a new suitability determination, may be warranted where there is a strong nexus between the reasons for the suitability determination and the agency mission or position duties. For example, an additional debarment period might be appropriate where a person convicted of embezzlement continues to apply for fiduciary positions and does not report the conviction on the relevant questionnaire; where a person guilty of sexual crimes applies for positions dealing with the public where contact with children reasonably is expected; where an arsonist applies for firefighter positions; and where those with lengthy criminal histories want to work in law enforcement positions. Again, OPM intends to provide such information as part of its guidance referenced in § 731.102(c). Another commenter asked how long an additional debarment period can be. An additional debarment period can be imposed only if an agency makes a new suitability determination.

If it again finds the person unsuitable, the new debarment period could be imposed for up to three years. One commenter expressed concern that an agency may improperly implement its debarment authority; however, the rule at § 731.103(f) calls for the revocation of an agency's delegation of suitability authority if its actions fail to conform to this rule or any of OPM's guidance.

In response to the comments on additional debarment periods, OPM has revised the language in sections 731.204(b) and 731.205(b) of the final rule to state more clearly that upon expiration of a debarment period, if the person formerly debarred again becomes subject to OPM's or an agency's suitability jurisdiction, *e.g.*, by applying for a position in the competitive service, a new suitability determination must be made under 5 CFR part 731 before an additional period of debarment can be imposed.

In § 731.103(g), OPM proposed to eliminate the requirement that agencies with delegated authority seek prior approval from OPM before taking action under other authorities, such as part 315, part 359, or part 752 of this chapter, in cases involving evidence of material, intentional false statement in examination or appointment, or deception or fraud in examination or appointment; or refusal to furnish testimony. While agencies would still be required to notify OPM if they have taken, or plan to take, such action (and could have their delegated authority withdrawn under § 731.103(f) for failure to conform to this part or OPM issuances), one commenter suggested that oversight of agencies' use of this authority should be mandated and that the results of oversight be made public. Under its statutory oversight mandate, OPM will continue to conduct reviews of agency suitability programs and agency use of delegated authority, including whether agencies are properly using their delegated authority under this section. Reports on such reviews are provided to the agency reviewed so that necessary corrective actions may be taken.

One commenter wondered why an agency under § 731.103(g) would be required to notify OPM if it has already taken or plans to take such an action under other authorities. The answer is that OPM may determine it appropriate to debar that person from all Federal employment even though the agency has taken action to remove the person under other authority if the person, for example, provided material, intentional false statements in connection with the employment process. To further clarify the scope of the reporting requirement, OPM is providing at § 731.103(g), that agencies are required to report to OPM only in cases involving material, intentional false statement in examination or appointment, or deception or fraud in examination or appointment; or refusal to furnish testimony as required by § 5.4 of this title. Also, corresponding changes referring back to § 731.103(g) are being inserted into §§ 731.105(e) and 731.203(f) for the same reason.

This commenter also suggested that proposed § 731.103(c) be modified to state more clearly that agencies exercising their delegated authority must do so in accordance with OPM regulations and issuances. The commenter stated that following OPM issuances would ''increase government wide uniformity and consistency in making suitability determinations and taking suitability actions.'' OPM agrees and has modified this section in the final rule accordingly.

OPM proposed modifications to § 731.202 to clarify that OPM or agencies with delegated authority to make suitability determinations and take suitability actions have the authority to rely on the additional suitability considerations contained in paragraph (c) of § 731.202 at their sole discretion. Factors not relied upon by OPM or agencies in individual cases could not be considered by MSPB. One commenter believed that this limitation of MSPB's review ''further erodes the concept of mitigation'' and ''precludes the Board from a full and fair review of OPM and/or agency action.'' OPM strongly disagrees. Under the suitability regulations, MSPB has no authority to mitigate an agency's action in the same way it does not have authority to mitigate performance-based actions taken under chapter 43 of title 5 of the United States Code. In such cases, MSPB can only affirm or reverse the agency's action. With regard to the fullness and fairness of MSPB's review, the regulations are intended to insure a full and fair review by explicitly stating in the final regulations that MSPB must review each specification and each charge in all suitability appeals.

However, OPM has revised section 731.202(c) of the final rule to state that OPM or an agency ''must'' consider ''any'' of the additional considerations to the extent OPM or the relevant agency, in its sole discretion, deems ''any'' of them pertinent to the individual case. This is to state more clearly that an agency need not consider all of the additional considerations, but must consider those that it deems pertinent. As the MSPB's review is limited to the agency's determination, however, the MSPB cannot consider, as aggravating or mitigating factors, additional considerations that the agency did not deem pertinent.

OPM proposed to clarify in paragraph (d) of § 731.103 that agencies may choose to begin preliminary suitability reviews for all applicants at any time during the hiring process. One commenter concurred with the proposal, stating that the ability to begin suitability reviews in the early stages of the recruitment process would facilitate that agency's ability to make timely selections. Another commenter said that this is a change from OPM guidance in 1994 that the suitability process be initiated late in the recruitment process. In more recent guidance, however, OPM stated that agencies may begin the process ''at any time during the hiring process'' (see OPM Memorandum for Chief Human Capital Officers entitled ''Initiating Suitability Determinations'' and dated May 9, 2005). The regulations codify the most recent OPM guidance.

Merit Systems Protection Board Review

In the proposed rule, OPM discussed the basis for concluding that the procedures an agency decides to use to take an action, e.g., objecting to an eligible under 5 CFR part 332 or taking a suitability action under this part, determine whether an agency's action may be appealed. The Board recognized this clear distinction in *Vislisel* v. *OPM*, 29 M.S.P.R. 679 (1986) when it observed that a sustained objection is an agency-initiated procedure separate and apart from a suitability determination under part 731. *Id.* at 682. In *Edwards* v. *Department of Justice*, 87 M.S.P.R. 518 (2001), the Board abandoned its approach in *Vislisel*, holding that, in deciding whether an action was an appealable suitability determination, ''what matters is the substance of the action, not the form.'' *Id.* at 522. OPM noted that this is an incorrect reading of the authority that OPM conferred upon the Board and proposed to adjust the suitability regulations accordingly. Consequently, OPM concluded that, when adjudicating an appeal of an agency action, the Board must assess the agency's action under the procedures elected by the agency and may not hold the agency to standards relating to a legal authority that the agency did not invoke. The Board may not create an appeal right where neither Congress nor OPM has expressly granted it. *King* v. *Jerome*, 42 F.3d 1371, 1374 (Fed. Cir. 1994). OPM proposed changes to the regulations to reflect this conclusion.

One commenter stated that OPM's proposed changes would administratively overrule *Edwards* and

that change would be tampering with what is now settled MSPB precedent. While agreeing that the proposed change would overrule *Edwards*, OPM is not ''tampering'' with MSPB precedent. Rather, OPM is correcting case law that is clearly erroneous and well beyond the intent of Congress—which is that MSPB's jurisdiction is limited to actions appealable under ''any law, rule, or regulation'' as provided by 5 U.S.C. 7701(a). OPM strongly disagrees that this stands on its head the decision in *Lovshin* v. *Navy*, 767 F.2d, 8326 (Fed. Cir. 1985), which provides an agency may choose whether to use 5 U.S.C. chapter 43 or 5 U.S.C. chapter 75 to take a performance-based action. Just as in *Lovshin*, when the choice is between using suitability authority or some other authority, whatever action taken under the chosen authority is subject to review.

Another commenter agreed with the notion that MSPB cannot hold an agency to standards relating to a legal authority the agency did not invoke and concluded that an agency's action ''should rise or fall on how that agency characterizes the action, not how MSPB *could* characterize the agency's action.'' OPM agrees and notes that this is precisely our rationale for clarifying the authority of MSPB.

Finally, OPM strongly disagrees with one commenter's claim that OPM is ''setting up a system that it and agencies will be free to manipulate without a check by MSPB.'' OPM has carefully structured a system that protects the rights of persons by providing for MSPB review of agency actions. Whatever action an agency chooses to take, there is a process for ensuring the rights of those affected are protected.

OPM proposed to eliminate the provision under the current regulations that requires MSPB to remand a case to OPM or an agency if fewer than all the charges in an appeal are sustained. While one commenter concurred, stating that eliminating the remand would be important, several other commenters objected to the proposal, stating, among other things, that the change would be capricious, and that it and other changes proposed would transform MSPB into a ''rubber stamp'' without meaningful review authority. Several commenters were concerned that eliminating the remand and requiring MSPB to sustain only one charge in order to uphold an agency's suitability action might preclude MSPB from considering, or at least not obligate MSPB to consider, all charges and specifications once one charge is sustained and might lead to multiple proceedings. One commenter suggested that the regulations require MSPB to consider all charges and specifications. Another commenter noted that, in 2000, when OPM first proposed that an agency's suitability action must be affirmed by MSPB even if some of the charges are not sustained, OPM ''answered its critics by also providing for remands by MSPB.''

OPM carefully considered these comments and concluded that some changes to the final regulations at § 731.501 are appropriate. For example, while OPM would expect MSPB to review all matters raised in any appeal before it, we have modified the final rule to state explicitly that MSPB must review all charges and all specifications in each appeal. In addition and upon further reflection, OPM concludes that the remand process can be retained in a manner that would help eliminate confusion under the current regulations. Accordingly, OPM has modified the final rule so that remand decisions, as suggested by a commenter, are held in abeyance pending a final decision by MSPB or the courts as appropriate. This should help eliminate the current confusion about when a person can file a petition for review of an initial decision by MSPB and eliminates the current confusion generated when an agency is simultaneously reviewing a case on remand while MSPB is considering a petition for review. The expected reduction in confusion and the assurance that all charges and specifications will be considered should help encourage confidence in the appeal process.

Readability

Commenters supported the changes in the regulations intended to make them more readable, with one commenter stating that the proposed changes do not appear to affect the substance of the regulations. OPM determined however that one proposed change did affect the substance of the regulations with respect to periodic reinvestigations. Specifically, in the proposed regulation, OPM inadvertently deleted section 731.106(d), which provided that agencies relying on authorities such as the Computer Security Act and OMB Circular A–130 Revised may require employees in certain public trust positions to undergo periodic reinvestigation. Accordingly, that section has been reinserted into this final regulation. Sections 731.106(d) and (e) have been redesignated as sections 731.106(e) and (f).

Miscellaneous Comments

One commenter wanted to know how OPM would notify agencies about persons debarred by OPM. In that commenter's experience, the agency had never been notified about any debarment in the last ten years. The process for notifying agencies is beyond the scope of this rule and will not be addressed further.

One commenter believes that, because the proposed regulations state that OPM or an agency with delegated authority cannot take a suitability action against a person who is not covered by the regulations, the regulations imply that an agency may take a suitability action against any person who is covered and may do so at any time. That is an incorrect inference. While OPM can take a suitability action against a person who is an applicant, appointee, or employee, as those terms are defined in this part, an agency may take a suitability action only against an applicant or appointee. An agency may not take a suitability action against an employee. Moreover, the basis on which OPM may take a suitability action against an employee is limited to charges of material, intentional false statement or deception or fraud in examination or appointment; refusal to furnish testimony as required by § 5.4 of this title; or statutory or regulatory bar.

One commenter discussed establishing an internal agency process for interfacing with OPM concerning that agency's actions, particularly debarment actions. Agencies' internal processes are outside the scope of the proposed amendments to the regulations and are not further addressed here.

A commenter stated that a person who is a member of a collective bargaining unit covered by a valid collective bargaining agreement should have the discretion to file a grievance under the parties' negotiated grievance procedure or to appeal to MSPB. This commenter also believes that the scope of review ought to extend to the ''propriety of the agency's action.'' These topics are outside the scope of the proposed regulations and therefore have not been considered.

Another commenter requested a number of revisions to the proposed rule in order to avoid inconsistencies with laws enforced by the Equal Employment Opportunity Commission (EEOC). The commenter believes certain proposed changes to the rules provide agencies with the sole discretion over whether and how to consider a person's misconduct in ways that could conflict with Title VII of the Civil Rights Act of 1964. The commenter also believes that agencies' authority to debar persons for three years at a time as proposed could

conflict with section 501 of the Rehabilitation Act.

With regard to the Title VII concern, the commenter stated that to the extent a suitability determination could be made solely based on a person's conviction or arrest record, it would violate settled law under Title VII disallowing a categorical bar from employment of all individuals with arrest or conviction records, because such a bar has a disparate impact on certain classes of people. OPM notes that the suitability rules do not provide for categorical bars from employment on the basis of a conviction or arrest record. The specific factors listed in the regulations, such as criminal or dishonest conduct, are to be considered in conjunction with any of the additional considerations the agency deems pertinent, and in light of the standard in § 731.201 that the action cannot be taken unless it will ''protect the integrity or promote the efficiency of the service.'' Further, as discussed previously, a negative suitability determination can only be made in accordance with the procedural requirements of the suitability rules, including affording a person the right to answer any charges. Finally, if the person is determined to be unsuitable, he or she may seek administrative review by MSPB and ultimately judicial review. As with any appeal to the Board, the person may raise affirmative defenses, including allegations that the action appealed is discriminatory. OPM disagrees with the suggestion that the Board would be prevented from considering affirmative defenses like these simply because an agency would not be required under the proposed rule to link a determination of unsuitability with a particular position in the Government.

With regard to the Rehabilitation Act (Act), the commenter stated that agencies using alcohol abuse and the illegal use of drugs in making suitability determinations would have to do so in accordance with the Act. For example, if the person has the disability of alcoholism (as opposed to simply abusing alcohol), the Act would have to be followed. The commenter also states that, under the proposed rule, if a person were debarred for a period of three years for alcohol abuse or illegal use of drugs, he or she would be prevented, in violation of the Act, from demonstrating later that he or she can perform the essential duties of a position with or without reasonable accommodation. OPM notes that current alcohol abusers and illegal drug users are not covered by the Rehabilitation Act. See 29 U.S.C. 705(20)(c). OPM also notes that the regulation does not prevent a debarred person from claiming that he or she later has become suitable upon conclusion of the debarment period. To the extent the commenter is suggesting that the Rehabilitation Act requires a shortening of the debarment period for persons who may later become covered individuals, OPM disagrees. The debarment penalty is imposed based on the contemporaneous conduct of the person at the time of the negative suitability determination, not because of any disability of the person.

However, as noted above, OPM has revised the language in sections 731.204(b) and 731.205(b) of the final rule to clarify that upon expiration of a debarment period, if the person formerly debarred again becomes subject to OPM's or an agency's suitability jurisdiction, e.g., by applying for a position in the competitive service, a new suitability determination must be made under 5 CFR part 731 before an additional period of debarment can be imposed. OPM has further revised section 731.202(b)(5) of the final rule to clarify that alcohol abuse of a nature and duration that suggests that the applicant or appointee would be prevented from performing the duties of the position in question, or would constitute a direct threat to the property or safety of the applicant or appointee or others, can only be the basis of a negative suitability determination in the absence of ''evidence of substantial rehabilitation.''

The commenter suggested a number of changes to the suitability factors provided at § 731.202(b) as a means to avoid what the commenter viewed as inconsistencies with laws enforced by EEOC. These factors have been in effect for many years and have resulted in a legally-sound and uniform body of case law governing the application of the factors Governmentwide. OPM does not wish to undermine that case law by changing these factors. Therefore, with the exception of the revision to section 731.202(b)(5) noted above, OPM is not revising the specific factors in section 731.202(b).

Other suggested changes, including the limitation of agency debarment authority to one year, are also not adopted. While not adopting the suggestions, OPM strongly emphasizes to agencies that any actions taken under OPM's suitability rules must be taken in accordance with applicable laws, including those enforced by the EEOC.

Technical Amendments

OPM has made technical amendments to the Authorities for this part by deleting the following citations: ''5 U.S.C. 7701'' and ''E.O. 12731, 3 CFR, 1990 Comp., p. 306.'' These are deleted since they do not provide legal bases for 5 CFR part 731. OPM has also inserted ''as amended'' following the citation to E.O. 10577. OPM also moved the language defining ''covered position'' in section 731.101(a) to ''Definitions'' in section 731.101(b) for easy reference. Finally, in section 731.105(a), OPM deleted the citation to paragraph (a) of section 731.104 because the correct reference is to all of section 731.104.

Executive Order 12866, Regulatory Review

The Office of Management and Budget has reviewed the final rule in accordance with Executive Order 12866.

Regulatory Flexibility Act

I certify that these regulations will not have significant economic impact on a substantial number of small entities because they will affect Federal agencies, employees, and applicants only.

List of Subjects in 5 CFR Part 731

Administrative practices and procedures, Government employees.

Office of Personnel Management.

Linda M. Springer,

Director.

■ Accordingly, OPM is revising 5 CFR part 731 to read as follows:

PART 731—SUITABILITY

Subpart A—Scope

Sec.
731.101 Purpose.
731.102 Implementation.
731.103 Delegation to agencies.
731.104 Appointments subject to investigation.
731.105 Authority to take suitability actions.
731.106 Designation of public trust positions and investigative requirements.

Subpart B—Suitability Determinations and Actions

731.201 Standard.
731.202 Criteria for making suitability determinations.
731.203 Suitability actions by OPM and other agencies.
731.204 Debarment by OPM.
731.205 Debarment by agencies.

Subpart C—OPM Suitability Action Procedures

731.301 Scope.
731.302 Notice of proposed action.
731.303 Answer.
731.304 Decision.

Subpart D—Agency Suitability Action Procedures

731.401 Scope.

731.402 Notice of proposed action.
731.403 Answer.
731.404 Decision.

Subpart E—Appeal to the Merit Systems Protection Board

731.501 Appeal to the Merit Systems Protection Board.

Subpart F—Savings Provision

731.601 Savings provision.

Authority: 5 U.S.C. 1302, 3301, 7301; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218, as amended, 5 CFR, parts 1, 2 and 5.

Subpart A—Scope

§ 731.101 Purpose.

(a) The purpose of this part is to establish criteria and procedures for making determinations of suitability and for taking suitability actions regarding employment in covered positions (as defined in paragraph (b) of this section) pursuant to 5 U.S.C. 3301, E.O. 10577 (3 CFR, 1954–1958 Comp., p. 218), as amended, and 5 CFR 1.1, 2.1(a) and 5.2. Section 3301 of title 5, United States Code, directs consideration of ''age, health, character, knowledge, and ability for the employment sought.'' E.O. 10577 (codified in relevant part at 5 CFR 1.1, 2.1(a) and 5.2) directs OPM to examine ''suitability'' for competitive Federal employment. This part concerns only determinations of ''suitability,'' that is, those determinations based on a person's character or conduct that may have an impact on the integrity or efficiency of the service. Determinations made and actions taken under this part are distinct from objections to eligibles or pass overs of preference eligibles, and OPM's and agencies' decisions on such requests, made under 5 U.S.C. 3318 and 5 CFR 332.406, as well as determinations of eligibility for assignment to, or retention in, sensitive national security positions made under E.O. 10450 (3 CFR, 1949–1953 Comp., p. 936), E.O. 12968, or similar authorities.

(b) *Definitions.* In this part:

Applicant means a person who is being considered or has been considered for employment.

Appointee means a person who has entered on duty and is in the first year of a subject-to-investigation appointment (as defined in § 731.104).

Covered position means a position in the competitive service, a position in the excepted service where the incumbent can be noncompetitively converted to the competitive service, and a career appointment to a position in the Senior Executive Service.

Days means calendar days unless otherwise specified in this part.

Employee means a person who has completed the first year of a subject-to-investigation appointment.

Material means, in reference to a statement, one that is capable of influencing, affects, or has a natural tendency to affect, an official decision even if OPM or an agency does not rely upon it.

Suitability action means an outcome described in § 731.203 and may be taken only by OPM or an agency with delegated authority under the procedures in subparts C and D of this part.

Suitability determination means a decision by OPM or an agency with delegated authority that a person is suitable or is not suitable for employment in covered positions in the Federal Government or a specific Federal agency.

§ 731.102 Implementation.

(a) An investigation conducted for the purpose of determining suitability under this part may not be used for any other purpose except as provided in a Privacy Act system of records notice published by the agency conducting the investigation.

(b) Under OMB Circular No. A–130 Revised, issued November 20, 2000, agencies are to implement and maintain a program to ensure that adequate protection is provided for all automated information systems. Agency personnel screening programs may be based on procedures developed by OPM. The Computer Security Act of 1987 (Pub. L. 100–235) provides additional requirements for Federal automated information systems.

(c) OPM may set forth policies, procedures, criteria, standards, quality control procedures, and supplementary guidance for the implementation of this part in OPM issuances.

§ 731.103 Delegation to agencies.

(a) Subject to the limitations and requirements of paragraphs (f) and (g) of this section, OPM delegates to the heads of agencies authority for making suitability determinations and taking suitability actions (including limited, agency-specific debarments under § 731.205) in cases involving *applicants* for and *appointees* to covered positions in the agency.

(b) When an agency, acting under delegated authority from OPM, determines that a Governmentwide debarment by OPM under § 731.204(a) may be an appropriate action, it must refer the case to OPM for debarment consideration. Agencies must make these referrals prior to any proposed suitability action, but only after sufficient resolution of the suitability issue(s), through subject contact or investigation, to determine if a Governmentwide debarment appears warranted.

(c) Agencies exercising authority under this part by delegation from OPM must adhere to OPM requirements as stated in this part and OPM's issuances described in § 731.102(c). Agencies must also implement policies and maintain records demonstrating that they employ reasonable methods to ensure adherence to these OPM issuances.

(d) Agencies may begin to determine an applicant's suitability at any time during the hiring process. Because suitability issues may not arise until late in the application/appointment process, it is generally more practical and cost-effective to first ensure that the applicant is eligible for the position, deemed by OPM or a Delegated Examining Unit to be among the best qualified, and/or within reach of selection. However, in certain circumstances, such as filling law enforcement positions, an agency may choose to initiate a preliminary suitability review at the time of application. Whether or not a person is likely to be eligible for selection, OPM must be informed in all cases where there is evidence of material, intentional false statements, or deception or fraud in examination or appointment, and OPM will take a suitability action where warranted.

(e) When an agency, exercising authority under this part by delegation from OPM, makes a suitability determination or changes a tentative favorable placement decision to an unfavorable decision, based on an OPM report of investigation or upon an investigation conducted pursuant to OPM-delegated authority, the agency must:

(1) Ensure that the records used in making the determination are accurate, relevant, timely, and complete to the extent reasonably necessary to ensure fairness to the person in any determination;

(2) Ensure that all applicable administrative procedural requirements provided by law, the regulations in this part, and OPM issuances as described in § 731.102(c) have been observed;

(3) Consider all available information in reaching its final decision on a suitability determination or suitability action, except information furnished by a non-corroborated confidential source, which may be used only for limited purposes, such as information used to develop a lead or in interrogatories to a subject, if the identity of the source is not compromised in any way; and

(4) Keep any record of the agency suitability determination or action as

required by OPM issuances as described in § 731.102(c).

(f) OPM may revoke an agency's delegation to make suitability determinations and take suitability actions under this part if an agency fails to conform to this part or OPM issuances as described in § 731.102(c).

(g) OPM retains jurisdiction to make final determinations and take actions in all suitability cases where there is evidence that there has been a material, intentional false statement, or deception or fraud in examination or appointment. OPM also retains jurisdiction over all suitability cases involving a refusal to furnish testimony as required by § 5.4 of this chapter. Agencies must refer these cases to OPM for suitability determinations and suitability actions under this authority. Although no prior approval is needed, notification to OPM is required if the agency wants to take, or has taken, action under its own authority (5 CFR part 315, 5 CFR part 359, or 5 CFR part 752) in cases involving material, intentional false statement in examination or appointment, or deception or fraud in examination or appointment; or refusal to furnish testimony as required by § 5.4 of this title. In addition, paragraph (a) of this section notwithstanding, OPM may, in its discretion, exercise its jurisdiction under this part in any case it deems necessary.

§ 731.104 Appointments subject to investigation.

(a) To establish a person's suitability for employment, appointments to covered positions identified in § 731.101 require the person to undergo an investigation by OPM or by an agency with delegated authority from OPM to conduct investigations. Certain appointments do not require investigation. Except when required because of position risk level (high, moderate, or low) changes, a person in a covered position, who has undergone a suitability investigation, need not undergo another one simply because the person has been:

(1) Promoted;

(2) Demoted;

(3) Reassigned;

(4) Converted from career-conditional to career tenure;

(5) Appointed or converted to an appointment in a covered position if the person has been serving continuously with the agency for at least 1 year in one or more positions under an appointment subject to investigation; or

(6) Transferred, provided the person has served continuously for at least 1 year in a position subject to investigation.

(b)(1) Either OPM or an agency with delegated suitability authority may investigate and take a suitability action against an applicant, appointee, or employee in accordance with § 731.105. There is no time limit on the authority of OPM or an agency with delegated suitability authority to conduct the required investigation of an applicant who has been appointed to a position. An employee does not have to serve a new probationary or trial period merely because his or her appointment is subject to investigation under this section. An employee's probationary or trial period is not extended because his or her appointment is subject to investigation under this section.

(2) The subject to investigation condition also does not eliminate the need to conduct investigations required under § 731.106 for public trust positions when the required investigation commensurate with the risk level of the position has not yet been conducted.

(3) Suitability determinations must be made for all appointments that are subject to investigation.

(c) Positions that are intermittent, seasonal, per diem, or temporary, not to exceed an aggregate of 180 days per year in either a single continuous appointment or series of appointments, do not require a background investigation as described in § 731.106(c)(1). The employing agency, however, must conduct such checks as it deems appropriate to ensure the suitability of the person.

§ 731.105 Authority to take suitability actions.

(a) Neither OPM nor an agency acting under delegated authority may take a suitability action in connection with any application for, or appointment to, a position that is not subject to investigation or check under § 731.104.

(b) OPM may take a suitability action under this part against an *applicant* or *appointee* based on any of the criteria of § 731.202;

(c) Except as limited by § 731.103(g), an agency, exercising delegated authority, may take a suitability action under this part against an *applicant* or *appointee* based on the criteria of § 731.202;

(d) OPM may take a suitability action under this part against an *employee* based on the criteria of § 731.202(b)(3), (4), or (8).

(e) An agency may not take a suitability action against an *employee*. Nothing in this part precludes an agency from taking an adverse action against an employee under the procedures and standards of part 752 of this chapter or terminating a probationary employee under the procedures of part 315 or part 359 of this chapter. An agency must notify OPM to the extent required in § 731.103(g) if it wants to take, or has taken, action under these authorities.

§ 731.106 Designation of public trust positions and investigative requirements.

(a) *Risk designation*. Agency heads must designate every covered position within the agency at a high, moderate, or low risk level as determined by the position's potential for adverse impact to the efficiency or integrity of the service. OPM will provide an example of a risk designation system for agency use in an OPM issuance as described in § 731.102(c).

(b) *Public Trust positions*. Positions at the high or moderate risk levels would normally be designated as ''Public Trust'' positions. Such positions may involve policy making, major program responsibility, public safety and health, law enforcement duties, fiduciary responsibilities or other duties demanding a significant degree of public trust, and positions involving access to or operation or control of financial records, with a significant risk for causing damage or realizing personal gain.

(c) *Investigative requirements*.

(1) Persons receiving an appointment made subject to investigation under this part must undergo a background investigation. OPM is authorized to establish minimum investigative requirements correlating to risk levels. Investigations should be initiated before appointment but no later than 14 calendar days after placement in the position.

(2) All positions subject to investigation under this part must also receive a sensitivity designation of Special-Sensitive, Critical-Sensitive, or Noncritical-Sensitive, when appropriate. This designation is complementary to the risk designation, and may have an effect on the position's investigative requirement. Sections 732.201 and 732.202 of this chapter detail the various sensitivity levels and investigation types. Detailed procedures for determining investigative requirements for all positions based upon risk and sensitivity will be established in an OPM issuance as described in § 731.102(c).

(3) If suitability issues develop prior to the required investigation, OPM or the agency may conduct an investigation sufficient to resolve the issues and support a suitability determination or action, if warranted. If the person is appointed, the minimum level of investigation must be conducted

as required by paragraph (c)(1) of this section.

(d) *Suitability reinvestigations.* Agencies, relying on authorities such as the Computer Security Act of 1987 and OMB Circular No. A–130 Revised (issued November 20, 2000), may require incumbents of certain public trust positions to undergo periodic reinvestigations. The appropriate level of any reinvestigation will be determined by the agency, but may be based on supplemental guidance provided by OPM.

(e) *Risk level changes.* If a person moves to a higher risk level position, or if the risk level of his or her position itself is changed, the person may remain in or encumber the position. Any upgrade in the investigation required for the new risk level should be initiated within 14 calendar days after the move or the new designation is final.

(f) *Completed investigations.* Any suitability investigation completed by an agency under provisions of paragraph (d) of this section must result in a determination by the employing agency. The subject's employment status (i.e., applicant, appointee, or employee as defined in § 731.101) will determine the applicable agency authority and procedures to be followed in any action taken.

Subpart B—Suitability Determinations and Actions

§ 731.201 Standard.

The standard for a suitability action defined in § 731.203 and taken against an applicant, appointee, or employee is that the action will protect the integrity or promote the efficiency of the service.

§ 731.202 Criteria for making suitability determinations.

(a) *General.* OPM, or an agency to which OPM has delegated authority, must base its suitability determination on the presence or absence of one or more of the specific factors (charges) in paragraph (b) of this section.

(b) *Specific factors.* In determining whether a person is suitable for Federal employment, only the following factors will be considered a basis for finding a person unsuitable and taking a suitability action:

(1) Misconduct or negligence in employment;

(2) Criminal or dishonest conduct;

(3) Material, intentional false statement, or deception or fraud in examination or appointment;

(4) Refusal to furnish testimony as required by § 5.4 of this chapter;

(5) Alcohol abuse, without evidence of substantial rehabilitation, of a nature and duration that suggests that the applicant or appointee would be prevented from performing the duties of the position in question, or would constitute a direct threat to the property or safety of the applicant or appointee or others;

(6) Illegal use of narcotics, drugs, or other controlled substances without evidence of substantial rehabilitation;

(7) Knowing and willful engagement in acts or activities designed to overthrow the U.S. Government by force; and

(8) Any statutory or regulatory bar which prevents the lawful employment of the person involved in the position in question.

(c) *Additional considerations.* OPM and agencies must consider any of the following additional considerations to the extent OPM or the relevant agency, in its sole discretion, deems any of them pertinent to the individual case:

(1) The nature of the position for which the person is applying or in which the person is employed;

(2) The nature and seriousness of the conduct;

(3) The circumstances surrounding the conduct;

(4) The recency of the conduct;

(5) The age of the person involved at the time of the conduct;

(6) Contributing societal conditions; and

(7) The absence or presence of rehabilitation or efforts toward rehabilitation.

§ 731.203 Suitability actions by OPM and other agencies.

(a) For purposes of this part, a suitability action is one or more of the following:

(1) Cancellation of eligibility;

(2) Removal;

(3) Cancellation of reinstatement eligibility; and

(4) Debarment.

(b) A non-selection, or cancellation of eligibility for a specific position based on an objection to an eligible or pass over of a preference eligible under 5 CFR 332.406, is *not* a suitability action even if it is based on reasons set forth in § 731.202.

(c) A suitability action may be taken against an applicant or an appointee when OPM or an agency exercising delegated authority under this part finds that the applicant or appointee is unsuitable for the reasons cited in § 731.202, subject to the agency limitations of § 731.103(g).

(d) OPM may require that an appointee or an employee be removed on the basis of a material, intentional false statement, deception or fraud in examination or appointment; refusal to furnish testimony as required by § 5.4 of this chapter; or a statutory or regulatory bar which prevents the person's lawful employment.

(e) OPM may cancel any reinstatement eligibility obtained as a result of a material, intentional false statement, deception or fraud in examination or appointment.

(f) An action to remove an appointee or employee *for suitability reasons* under this part is not an action under part 315, 359, or 752 of this chapter. Where behavior covered by this part may also form the basis for an action under parts 315, 359, or 752 of this chapter, an agency may take the action under part 315, 359, or 752 of this chapter, as appropriate, instead of under this part. An agency must notify OPM to the extent required in § 731.103(g) if it wants to take, or has taken, action under these authorities.

(g) Agencies do not need approval from OPM before taking unfavorable suitability actions. However, they are required to report to OPM all unfavorable suitability actions taken under this part within 30 days after they take the action. Also, all actions based on an OPM investigation must be reported to OPM as soon as possible and in no event later than 90 days after receipt of the final report of investigation.

§ 731.204 Debarment by OPM.

(a) When OPM finds a person unsuitable for any reason listed in § 731.202, OPM, in its discretion, may, for a period of not more than 3 years from the date of the unfavorable suitability determination, deny that person examination for, and appointment to, covered positions.

(b) OPM may impose an additional period of debarment following the expiration of a period of OPM or agency debarment, but only after the person again becomes an applicant, appointee, or employee subject to OPM's suitability jurisdiction, and his or her suitability is determined in accordance with the procedures of this part. An additional debarment period may be based in whole or in part on the same conduct on which the previous suitability action was based, when warranted, or new conduct.

(c) OPM, in its sole discretion, determines the duration of any period of debarment imposed under this section.

§ 731.205 Debarment by agencies.

(a) Subject to the provisions of § 731.103, when an agency finds an applicant or appointee unsuitable based upon reasons listed in § 731.202, the

agency may, for a period of not more than 3 years from the date of the unfavorable suitability determination, deny that person examination for, and appointment to, either all, or specific covered, positions within that agency.

(b) The agency may impose an additional period of debarment following the expiration of a period of OPM or agency debarment, but only after the person again becomes an applicant or appointee subject to the agency's suitability jurisdiction, and his or her suitability is determined in accordance with the procedures of this part. An additional debarment period may be based in whole or in part on the same conduct on which the previous suitability action was based, when warranted, or new conduct.

(c) The agency, in its sole discretion, determines the duration of any period of debarment imposed under this section.

(d) The agency is responsible for enforcing the period of debarment and taking appropriate action if a person applies for, or is inappropriately appointed to, a position at that agency during the debarment period. This responsibility does not limit OPM's authority to exercise jurisdiction itself and take any action OPM deems appropriate.

Subpart C—OPM Suitability Action Procedures

§ 731.301 Scope.

This subpart covers OPM-initiated suitability actions against an *applicant, appointee,* or *employee*.

§ 731.302 Notice of proposed action.

(a) OPM will notify the applicant, appointee, or employee (hereinafter, the ''respondent'') in writing of the proposed action, the charges against the respondent, and the availability of review, upon request, of the materials relied upon. The notice will set forth the specific reasons for the proposed action and state that the respondent has the right to answer the notice in writing. The notice will further inform the respondent of the time limit for the answer as well as the address to which an answer must be made.

(b) The notice will inform the respondent that he or she may be represented by a representative of the respondent's choice and that if the respondent wishes to have such a representative, the respondent must designate the representative in writing.

(c) OPM will serve the notice of proposed action upon the respondent by mail or hand delivery no less than 30 days prior to the effective date of the proposed action to the respondent's last known residence or duty station.

(d) If the respondent encumbers a position covered by this part on the date the notice is served, the respondent is entitled to be retained in a pay status during the notice period.

(e) OPM will send a copy of the notice to any employing agency that is involved.

§ 731.303 Answer.

(a) *Respondent's answer*. A respondent may answer the charges in writing and furnish documentation and/or affidavits in support of the answer. To be timely, a written answer must be submitted no more than 30 days after the date of the notice of proposed action.

(b) *Agency's answer*. An employing agency may also answer the notice of proposed action. The time limit for filing such an answer is 30 days from the date of the notice. In reaching a decision, OPM will consider any answer the agency makes.

§ 731.304 Decision.

The decision regarding the final suitability action will be in writing, be dated, and inform the respondent of the reasons for the decision and that an unfavorable decision may be appealed in accordance with subpart E of this part. OPM will also notify the respondent's employing agency of its decision. If the decision requires removal, the employing agency must remove the appointee or employee from the rolls within 5 work days of receipt of OPM's final decision.

Subpart D—Agency Suitability Action Procedures

§ 731.401 Scope.

This subpart covers agency-initiated suitability actions against an *applicant* or *appointee*.

§ 731.402 Notice of proposed action.

(a) The agency must notify the applicant or appointee (hereinafter, the ''respondent'') in writing of the proposed action, the charges against the respondent, and the availability for review, upon request, of the materials relied upon. The notice must set forth the specific reasons for the proposed action and state that the respondent has the right to answer the notice in writing. The notice must further inform the respondent of the time limit for the answer as well as the address to which such answer must be delivered.

(b) The notice must inform the respondent that he or she may be represented by a representative of the respondent's choice and that if the respondent wishes to have such a representative, the respondent must designate the representative in writing.

(c) The agency must serve the notice of proposed action upon the respondent by mail or hand delivery no less than 30 days prior to the effective date of the proposed action to the respondent's last known residence or duty station.

(d) If the respondent is employed in a position covered by this part on the date the notice is served, the respondent is entitled to be retained in a pay status during the notice period.

§ 731.403 Answer.

A respondent may answer the charges in writing and furnish documentation and/or affidavits in support of the answer. To be timely, a written answer must be submitted no more than 30 days after the date of the notice of proposed action.

§ 731.404 Decision.

The decision regarding the final action must be in writing, be dated, and inform the respondent of the reasons for the decision and that an unfavorable decision may be appealed in accordance with subpart E of this part. If the decision requires removal, the employing agency must remove the appointee from the rolls within 5 work days of the agency's decision.

Subpart E—Appeal to the Merit Systems Protection Board

§ 731.501 Appeal to the Merit Systems Protection Board.

(a) *Appeal to the Merit Systems Protection Board*. When OPM or an agency acting under delegated authority under this part takes a suitability action against a person, that person may appeal the action to the Merit Systems Protection Board (hereinafter ''Board'').

(b) *Decisions by the Merit Systems Protection Board*.

(1) If the Board finds that one or more of the charges brought by OPM or an agency against the person is supported by a preponderance of the evidence, regardless of whether all specifications are sustained, it must affirm the suitability determination. The Board must consider the record as a whole and make a finding on each charge and specification in making its decision.

(2) If the Board sustains fewer than all the charges, the Board must remand the case to OPM or the agency to determine whether the suitability action taken is appropriate based on the sustained charge(s). However, the agency must hold in abeyance a decision on remand until the person has exhausted all rights to seek review of the Board's decision, including court review.

(3) Once review is final, OPM or an agency will determine whether the action taken is appropriate based on the sustained charges and this determination will be final without any further appeal to the Board.

(c) *Appeal procedures.* The procedures for filing an appeal with the Board are found at part 1201 of this title.

Subpart F—Savings Provision

§ 731.601 Savings provision.

No provision of the regulations in this part is to be applied in such a way as to affect any administrative proceeding pending on June 16, 2008. An administrative proceeding is deemed to be pending from the date of the agency or OPM ''notice of proposed action'' described in §§ 731.302 and 731.402.

[FR Doc. E8–7964 Filed 4–14–08; 8:45 am]

BILLING CODE 6326–39–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0304; Directorate Identifier 2008–NE–08–AD; Amendment 39–15470; AD 2008–06–52]

RIN 2120–AA64

Airworthiness Directives; Thielert Aircraft Engines GmbH (TAE) Model TAE 125–02–99 Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting emergency airworthiness directive (AD) 2008–06–52 that was sent previously to all known U.S. owners and operators of certain TAE Model TAE 125–02–99 engines. This AD requires, before further flight, replacing the high-pressure fuel line and installing a high-pressure fuel line support. This AD results from reports of in-flight engine shutdown incidents on airplanes equipped with TAE 125–02–99 engines. We are issuing this AD to prevent an in-flight engine shutdown or engine fire due to a cracked fuel line.

DATES: This AD becomes effective April 30, 2008 to all persons except those persons to whom it was made immediately effective by emergency AD 2008–06–52, issued on March 12, 2008, which contained the requirements of this amendment. The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of April 30, 2008.

We must receive any comments on this AD by June 16, 2008.

ADDRESSES: Use one of the following addresses to comment on this AD.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Contact Thielert Aircraft Engines GmbH, Platanenstrasse 14 D–09350, Lichtenstein, Germany, telephone: +49–37204–696–0; fax: +49–37204–696–55; e-mail: *info@centurion-engines.com*, for the service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail *jason.yang@faa.gov*; telephone (781) 238–7747; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: On March 12, 2008, the FAA issued emergency AD 2008–06–52, that applies to TAE model TAE 125–02–99 engines with a serial number from 02–02–1500 through 02–02–2279. That AD requires, before further flight, replacing the high-pressure fuel line and installing a high-pressure fuel line support. That AD resulted from reports of in-flight engine shutdown incidents on airplanes equipped with TAE 125–02–99 engines. This was found to be the result of a cracked high-pressure fuel line between the high-pressure pump and fuel rail. These cracks were caused by excessive vibration of the fuel line. This condition, if not corrected, could result in an in-flight engine shutdown or engine fire due to a cracked fuel line.

Relevant Service Information

We have reviewed and approved the technical contents of TAE Service Bulletin (SB) No. TM TAE 125–1005 P1, Revision 1, dated February 11, 2008, and SB No. TM TAE 125–1005 P1, Revision 2, dated March 6, 2008. Those SBs describe procedures for installing a new high-pressure fuel line and a high-pressure fuel line bracket.

FAA's Determination and Requirements of This AD

Since the unsafe condition described is likely to exist or develop on other engines of the same type design, we issued emergency AD 2008–06–52 to prevent an in-flight engine shutdown or engine fire due to a cracked fuel line. This AD requires, before further flight, replacing the high-pressure fuel line and installing a high-pressure fuel line support. You must use the service information described previously to perform the actions required by this AD.

FAA's Determination of the Effective Date

Since an unsafe condition exists that requires the immediate adoption of this AD, we have found that notice and opportunity for public comment before issuing this AD are impracticable, and that good cause existed to make the AD effective immediately on March 12, 2008, to all known U.S. owners and operators of certain TAE 125–02–99 engines. These conditions still exist, and we are publishing the AD in the **Federal Register** as an amendment to Section 39.13 of part 39 of the Code of Federal Regulations (14 CFR part 39) to make it effective to all persons.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send us any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include ''AD Docket No. FAA–2008–0304; Directorate Identifier 2008–NE–08–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify it.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2008–06–52 Thielert Aircraft Engines GmbH: Amendment 39–15470. Docket No. FAA–2008–0304; Directorate Identifier 2008–NE–08–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective April 30, 2008, to all persons except those persons to whom it was made immediately effective by emergency AD 2008–06–52, issued March 12, 2008, which contained the requirements of this amendment.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Thielert Aircraft Engines GmbH (TAE) model TAE 125–02–99 engines with a serial number (SN) from 02–02–1500 through 02–02–2279. These engines are installed on, but not limited to, Cessna 172 and (Reims-built) F172 series (STC No. SA01303WI); and Diamond DA42 airplanes.

Unsafe Condition

(d) This AD results from reports of in-flight engine shutdown incidents on airplanes equipped with TAE 125–02–99 engines. This was found to be the result of a cracked high-pressure fuel line between the high-pressure pump and fuel rail. These cracks were caused by excessive vibration of the fuel line. We are issuing this AD to prevent an in-flight engine shutdown or engine fire due to a cracked fuel line.

Compliance

(e) You are responsible for having the actions required by this AD performed before the next flight after the effective date of this AD, unless the actions have already been done.

Corrective Action

(f) Before the next flight, install a new high-pressure fuel line and a high-pressure fuel line bracket using TAE Service Bulletin (SB) No. TM TAE 125–1005 P1, Revision 2, dated March 6, 2008, or TAE SB No. TM TAE 125–1005 P1, Revision 1, dated February 11, 2008.

Alternative Methods of Compliance

(g) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Special Flight Permits

(h) We are limiting special flight permits to relocating the airplane to the next maintenance station, to a maximum flight duration of 2 hours, and to visual flight rules.

Related Information

(i) EASA Emergency Airworthiness Directive (EAD) No. 2008–0056R1–E, dated March 11, 2008, and EASA EAD No. 2008–0027–E, dated February 13, 2008, also address the subject of this AD.

(j) Contact Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *jason.yang@faa.gov*; telephone: (781) 238–7747; fax: (781) 238–7199, for more information about this AD.

Material Incorporated by Reference

(k) You must use the service information specified in Table 1 of this AD to perform the actions required by this AD. The Director of the Federal Register approved the incorporation by reference of the documents listed in Table 1 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You can get a copy from Thielert Aircraft Engines GmbH, Platanenstrasse 14 D–09350, Lichtenstein, Germany, telephone: +49–37204–696–0; fax: +49–37204–696–55; e-mail: *info@centurion-engines.com*. You may review copies at the FAA, New England Region, 12 New England Executive Park, Burlington, MA; 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/cfr/ibr-locations.html*.

TABLE 1.—INCORPORATION BY REFERENCE

Service Bulletin No.	Page	Revision	Date
TM TAE 125–1005 P1, Total Pages—6	ALL	1	February 11, 2008.
TM TAE 125–1005 P1, Total Pages—6	ALL	2	March 6, 2008.

Issued in Burlington, Massachusetts, on April 10, 2008.

Peter A. White,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E8–8118 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–29057; Airspace Docket 07–ASO–20]

Amendment of Class D Airspace; Jacksonville NAS, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D airspace at Jacksonville NAS, FL. An evaluation determined the Class D airspace should be modified and extended to join the Jacksonville Cecil Field Class D airspace area. This rule increases the safety, efficiency and management of the National Airspace System at Jacksonville NAS.

DATES: Effective 0901 UTC, June 05, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Daryl Daniels, System Support, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5581.

SUPPLEMENTARY INFORMATION:

History

On December 10, 2007, the FAA published in the **Federal Register** a NPRM to amend the Class D at Jacksonville NAS, FL (72 FR 69639). The current Class D airspace supporting IFR operations must be extended to contain operations at Jacksonville NAS. This action provides the additional controlled airspace, extending upward from the surface of the Earth to support IFR operations between Jacksonville NAS and Jacksonville Cecil Field. The airspace is also adjusted to allow neighboring Jacksonville Herlong Airport adequate airspace for its operation.

Interested parties were invited to participate in this proposed rulemaking by submitting such written data, views or arguments, as they may have desired on the proposal to the FAA. Minor adjustments were made to the airspace's description to enhance charting. No comments objecting to the proposal were received.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class D airspace at Jacksonville NAS, FL, by providing the additional controlled airspace, extending upward from the surface of the Earth to support IFR operations between Jacksonville NAS and Jacksonville Cecil Field excluding that airspace within a 1.8-mile radius of the Jacksonville Herlong Airport.

Class D airspace designations for airspace areas extending upwards from the surface of the Earth are published in Paragraph 5000 of FAA Order 7400.9R, dated August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designations listed in this document will be published subsequently in the Order.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Class D airspace at Jacksonville NAS.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, Airspace Designations and Reporting Points, dated August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Jacksonville NAS, FL [Revised]

Jacksonville NAS, FL
(Lat. 30°14′09″ N., long. 81°40′50″ W.)
Jacksonville TACAN
(Lat. 30°14′05″ N., long. 81°40′30″ W.)
Herlong Airport
(Lat. 30°16′40″ N., long. 81°48′21″ W.)

That airspace extending upward from the surface of the Earth, to and including 2,600 feet MSL, within a 5.3-mile radius of Jacksonville NAS and within 1 mile north and 2.5 miles south of the Jacksonville TACAN 270 radial, extending from the 5.3-mile radius to 6.5 miles west of the TACAN; excluding that airspace within a 1.8-mile radius of the Herlong Airport.

* * * * *

Issued in College Park, Georgia, on March 27, 2008.

Mark D. Ward,

Manager, System Support Group, Eastern Service Center.

[FR Doc. E8–7671 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–29058; Airspace Docket 07–ASO–21]

Amendment of Class D Airspace; Jacksonville Whitehouse NOLF, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This notice amends the Class D airspace at Jacksonville Whitehouse Naval Out Lying Field (NOLF), FL. An evaluation determined the Class D airspace should be reduced at Jacksonville NOLF. This rule increases the safety and efficiency of the National Airspace System by modifying its dimensions with adjacent Jacksonville Cecil Field Class D airspace and the Herlong Airport.

DATES: Effective 0901 UTC, June 05, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Daryl Daniels, System Support, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5581.

SUPPLEMENTARY INFORMATION:

History

On December 10, 2007, the FAA published in the **Federal Register** a NPRM to amend the Class D airspace at Jacksonville Whitehouse NOLF, FL (72 FR 69638). Airspace evaluation identified the ability to reduce the size of the current Class D airspace while continuing to provide adequate support for the numerous Standard Instrument Approach Procedures (SIAP) at Jacksonville Whitehouse NOLF. The airspace was adjusted to allow neighboring Herlong Airport adequate airspace for its operations and a demarcation line was established between Jacksonville Whitehouse and Jacksonville Cecil's Class D Airspace.

Interested parties were invited to participate in this proposed rulemaking by submitting such written data, views or arguments, as they may have desired on the proposal to the FAA. No comments objecting to the proposal were received.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class D airspace at Jacksonville Whitehouse NOLF, FL by reducing the Class D airspace area from a 5-mile radius to a 4.3-mile radius of Whitehouse NOLF excluding that airspace within a 1.8-mile radius of Herlong Airport and that airspace south of the demarcation line between Jacksonville Whitehouse's and Cecil Field's Class D airspace.

Class D airspace designations are published in Paragraph 5000 of FAA Order 7400.9R, dated August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designations listed in this document will be published subsequently in the Order.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Class D airspace at Jacksonville Whitehouse NOLF.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, Airspace Designations and Reporting Points, dated August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Jacksonville Whitehouse NOLF, FL [Revised]

Whitehouse NOLF, FL
(Lat. 30°21′01″ N., long. 81°52′59″ W.)
Cecil Field
(Lat. 30°13′07″ N., long. 81°52′36″ W.)
Herlong Airport
(Lat. 30°16′40″ N., long. 81°48′21″ W.)

That airspace extending upward from the surface of the Earth, to and including 2,600 feet MSL, within a 4.3-mile radius of Whitehouse NOLF, excluding that airspace within a 1.8-mile radius of Herlong Airport and that airspace south of a line from lat. 30°17′00″ N., long. 81°50′24″ W. to lat. 30°17′00″ N., long. 81°54′47″ W., which abuts the Jacksonville Cecil Field Class D airspace. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in College Park, Georgia, on February 26, 2008.

Mark D. Ward,

Manager, System Support Group, Eastern Service Center.

[FR Doc. E8–7668 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–29055; Airspace Docket 07–ASO–19]

Amendment of Class D and E Airspace; Jacksonville Cecil Field, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D airspace and establishes Class E airspace at Jacksonville Cecil Field, FL. An evaluation determined the Class D airspace should be modified and a required Class E surface airspace extension be established. This rule increases the safety and efficiency of the National Airspace System enhancing operations with adjacent Jacksonville Whitehouse Naval Out Lying Field (NOLF), Jacksonville Naval Air Station (NAS) and the Jacksonville Herlong Airport. This action additionally supports the Standard Instrument Approach Procedures at Cecil Field by the establishment of a Class E4 airspace extension to the Class D.

DATES: Effective 0901 UTC, June 05, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Daryl Daniels, System Support, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5581.

SUPPLEMENTARY INFORMATION:

History

On December 10, 2007, the FAA published in the **Federal Register** a NPRM to amend the Class D and E airspace at Jacksonville Cecil Field, FL (72 FR 69640). Airspace evaluation identified the ability to reduce the size of the current Class D airspace while continuing to provide adequate support for the Standard Instrument Approach Procedures (SIAP) and by the establishment a Class E surface area at Jacksonville Cecil Field. The airspace was also adjusted to allow neighboring Herlong Airport adequate airspace for its operations and a demarcation line was established between Jacksonville Cecil's and Jacksonville Whitehouse NOLF's Class D Airspace. This action will establish permanent geographic dimensions for the Class D airspace which will be independent of the surrounding airports Class D/Tower operation.

Interested parties were invited to participate in this proposed rulemaking by submitting such written data, views or arguments, as they may have desired on the proposal to the FAA. Minor adjustments were made to the description to enhance charting. No comments objecting to the proposal were received.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class D airspace and establishes Class E4 airspace at Jacksonville Cecil Field, FL by reducing the Class D airspace area to a 4.3-mile radius of Cecil Field excluding: (1) That airspace within a 1 .8-mile radius of Herlong Airport, (2) that airspace north of the demarcation line between Jacksonville Cecil Field's and Jacksonville Whitehouse's Class D airspace, and (3) that airspace designated as the Jacksonville NAS Class D airspace. Additionally, this action provides controlled airspace extending upwards for the surface of the Earth to support the VHF Omnidirectional Range (VOR) Runway (RWY) 9 Standard Instrument Approach Procedure (SIAP) at Cecil Field.

Class D and E4 airspace designations for airspace areas extending upwards from the surface of the Earth are published in Paragraph 5000 and 6004 of FAA Order 7400.9R, dated August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class D and E4 airspace designations listed in this document will be published subsequently in the Order.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Class D and establishes Class E4 airspace at Jacksonville Cecil Field.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; ED. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, Airspace Designations and Reporting Points, dated August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Jacksonville Cecil Field, FL [Revised]

Cecil Field, FL
(Lat. 30°13′07″ N., long. 81°52′36″ W.)
Jacksonville NAS, FL

(Lat. 30°14′09″ N., long. 81°40′50″ W.)
Whitehouse NOLF, FL
(Lat. 30°21′01″ N., long. 81°52′59″ W.)
Herlong Airport
(Lat. 30°16′40″ N., long. 81°48′21″ W.)

That airspace extending upward from the surface of the Earth, to and including 2,600 feet MSL, within a 4.3-mile radius of Cecil Field; excluding that airspace within the Jacksonville NAS Class D airspace area, excluding that airspace north of a line from lat. 30°17′00″ N., long. 81°50′24″ W. to lat. 30°17′00″ N., long. 81°54′47″ W., which abuts the Jacksonville Whitehouse NOLF Class D airspace, and excluding that airspace within a 1.8-mile radius of Herlong Airport. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D Surface Area.

* * * * *

ASO FL E4 Jacksonville Cecil Field, FL [New]

Cecil Field, FL
(Lat. 30°13′07″ N., long. 81°52′36″ W.)
Cecil VOR
(Lat. 30°12′47″ N., long. 81°53′27″ W.)

That airspace extending upward from the surface of the Earth within 2.4 miles each side of the Cecil VOR 286 radial extending from the 4.3-mile radius to 7 miles west of the VOR. This Class E airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in College Park, Georgia, on March 27, 2008.

Mark D. Ward,

Manager, System Support Group, Eastern Service Center.

[FR Doc. E8–7669 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 135

Use of Radar in Instrument Approach Procedures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This final rule corrects an inaccurate cross-reference citation in one of the FAA regulations. This correction is necessary to direct the reader to the actual paragraph that addresses the use of radar in instrument approaches.

DATES: This rule is effective April 15, 2008.

FOR FURTHER INFORMATION CONTACT: Dennis Pratte, 135 Air Carrier Operations Branch, AFS–250, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; Telephone No. (202) 493–4971; e-mail *dennis.pratte@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

Section 135.211 was added to Title 14 of the Code of Federal Regulations on October 10, 1978 (43 FR 46783). Paragraph (a)(2) of this section originally contained a cross-reference to paragraph (f) of 14 CFR 91.116, which addressed the use of radar in instrument approach procedures for landings. On August 18, 1989, 14 CFR part 91 was revised (54 FR 34294). As part of the revision, the information previously contained in § 91.116 transferred to § 91.175. The information formerly in § 91.116(f) became § 91.175(i). A second amendment on that same day amended § 135.211(a)(2) to change the cross-reference from § 91.116 to § 91.175 (54 FR 34332). However, the Regional Air Cargo Carriers Association informed the FAA that the reference to paragraph (f) was not changed to paragraph (i), as it should have been. As a result, the current regulations mistakenly refer readers to paragraph (f) of § 91.175, which addresses the minimum weather conditions for takeoffs under instrument flight rules, instead of paragraph (i) of § 91.175, which addresses the use of radar in instrument approach procedures for landings. This inaccurate cross-reference may cause confusion for pilots who are looking for the guidance on the use of radar when landing. Therefore, the FAA is amending § 135.211(a)(2) to correct this cross-reference.

Technical Amendment

This technical amendment will correct the cross-reference in § 135.211(a)(2) to properly refer to § 91.175(i).

Justification for Immediate Adoption

Because this action corrects an incorrect paragraph reference, the FAA finds that notice and public comment under 5 U.S.C. 553(b) is unnecessary. For the same reason, the FAA finds that good cause exists under 5 U.S.C. 553(d) for making this rule effective upon publication.

List of Subjects in 14 CFR Part 135

Aircraft, Airmen, Aviation safety.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations, part 135, as follows:

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 1. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 41706, 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 45101–45105.

§ 135.211 [Amended]

■ 2. Amend § 135.211(a)(2) by removing the citation ''§ 91.175(f)'' and adding in its place the citation ''§ 91.175(i)''.

Issued in Washington, DC, on April 9, 2008.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. E8–7966 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–13–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in May 2008. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: Effective May 1, 2008.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street,

NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

This amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during May 2008, (2) adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during May 2008, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during May 2008.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 5.81 percent for the first 20 years following the valuation date and 4.88 percent thereafter. These interest assumptions represent an increase (from those in effect for April 2008) of 0.17 percent for the first 20 years following the valuation date and 0.17 percent for all years thereafter.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent no change from those in effect for April 2008. For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during May 2008, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

■ In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 175, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_t	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
175	05–1–08	06–1–08	3.25	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 175, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
175	05–1–08	06–1–08	3.25	4.00	4.00	4.00	7	8

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 5. In appendix B to part 4044, a new entry for May 2008, as set forth below, is added to the table.

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
* * *	*		*		*	
May 2008	.0581	1–20	.0488	>20	N/A	N/A

Issued in Washington, DC, on this 7th day of April 2008.

Vincent K. Snowbarger,

Deputy Director, Pension Benefit Guaranty Corporation.

[FR Doc. E8–7939 Filed 4–14–08; 8:45 am]

BILLING CODE 7709–01–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

[Docket ID: MMS–2007–OMM–0060]

RIN 1010–AD48

Incorporate American Petroleum Institute Hurricane Bulletins

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: The direct final rule will incorporate by reference three American Petroleum Institute hurricane bulletins into MMS's regulations. The three bulletins supplement the American Petroleum Institute's Recommended Practice 2A–WSD, *Recommended Practice for Planning, Designing, and Constructing Fixed Offshore Platforms—Working Stress Design*, which contains engineering design principles and good practices for new platforms and assessments of existing platforms. These bulletins are needed to increase survivability during hurricane events by imposing more stringent design and assessment criteria for both new and existing structures located within particular Gulf of Mexico areas. By increasing survivability during hurricane conditions, fewer platforms will be damaged, thereby, protecting critical oil and gas resources and making those resources available after hurricane events.

DATES: *Effective Date:* This rule becomes effective on May 15, 2008. The incorporation by reference of the publication listed in the regulation was approved by the Director of the Federal Register on May 15, 2008.

FOR FURTHER INFORMATION CONTACT: Kirk Malstrom, Office of Offshore Regulatory Programs, Regulations and Standards Branch, at (703) 787–1751.

SUPPLEMENTARY INFORMATION:

Background

After the 2004 and 2005 hurricane seasons, there was significant damage to the oil and gas infrastructure. There were 123 fixed structures destroyed, one floating facility destroyed, and significant damage to dozens of other fixed and floating structures. The offshore oil and gas industry operating in the Gulf of Mexico (GOM) realized that there was a disparity in the metocean criteria in American Petroleum Institute's (API) Recommended Practice (RP) 2A–WSD, *Recommended Practice for Planning, Designing, and Constructing Fixed Offshore Platforms—Working Stress Design*, for the central GOM. The metocean criteria are the standards to which structures are designed and assessed to withstand certain meteorological events involving wind, wave, current, and surge. Following the 2005 hurricane season, MMS, the API, and other industry representatives worked collectively to produce the API hurricane bulletins to increase the survivability of Outer Continental Shelf (OCS) structures during hurricanes.

Each hurricane bulletin updates criteria contained within current MMS incorporated-by-reference API documents. The MMS will incorporate the following API Bulletins in § 250.901:

- BULLETIN 2INT–MET, *Interim Guidance on Hurricane Conditions in the Gulf of Mexico*, updates hurricane metocean conditions (wind, wave, current, and surge) documented in Sections 2.3.4.c and 17.6.2.a of API RP 2A–WSD.
- BULLETIN 2INT–DG, *Interim Guidance for Design of Offshore Structures for Hurricane Conditions,* contains guidance on how to utilize the updated metocean conditions in Bulletin 2INT–MET for designing new offshore structures required in the following API design documents: RP 2A–WSD; RP 2FPS, *Recommended Practice for Planning, Designing and Constructing Floating Production Systems; RP 2RD, Design of Risers for Floating Production Systems and Tension-Leg Platforms; RP 2SK, Design and Analysis of Stationkeeping Systems for Floating Structures; RP 2T, Planning Designing and Constructing Tension Leg Platforms; and* BULLETIN 2TD, *Guidelines for Tie-downs on Offshore Production Facilities for Hurricane Season.*
- BULLETIN 2INT–EX, *Interim Guidance for Assessment of Existing Offshore Structures for Hurricane Conditions*, gives guidance on how to utilize the updated metocean conditions in Bulletin 2INT–MET for the assessment of existing offshore structures required in the following API design documents: RP 2A–WSD; RP 2FPS; RP 2RD; RP 2SK; RP 2T; and BULLETIN 2TD.

You may inspect these bulletins at the Minerals Management Service, 381 Elden Steet, Room 3313, Herndon, Virginia; or at the National Archives and Records Administration. You may obtain these bulletins from API, 1220 L Street, NW., Washington, DC.

The MMS uses standards, specifications, and recommended practices developed by standard-setting organizations and the oil and gas industry as a means of establishing requirements for activities on the OCS. This practice, known as incorporation by reference, allows us to incorporate the provisions of technical standards into the regulations. The legal effect of incorporation by reference is the material is treated as if the entire document were published in the **Federal Register**. This material, like any other properly issued regulation, has the force and effect of law. We hold operators/lessees accountable for complying with the documents

incorporated by reference in our regulations. We currently incorporate by reference 93 private-sector consensus standards into the offshore operating regulations.

The regulations at 1 CFR part 51 govern how we and other Federal agencies incorporate various documents by reference. These regulations implement the Administrative Procedures Act, 5 U.S.C. 552(a), which allows agencies to incorporate by reference material ''reasonably available to the class of persons affected thereby.'' Agencies may only incorporate a document by reference by publishing the document title, date, edition, author, publisher, and publication identification number in the **Federal Register**. Agencies must also gain approval from the Director of the Federal Register for each publication incorporated by reference. Incorporation by reference of a document or publication is limited to the specific edition, supplement, or addendum cited in the regulations.

Under 30 CFR 250.198(a)(2), MMS may update documents incorporated by reference without an opportunity for public comment when we determine that the revisions to a document result in safety improvements, or represent new industry standard technology and do not impose undue cost or burden on the affected parties. The MMS has reviewed these three API bulletins and determined the new editions must be incorporated into the regulations to increase platform survivability and environmental safety. These API bulletins update current MMS incorporated documents and will not impose undue cost or burden on the offshore oil and gas industry. Lessees and operators in the GOM are already using the criteria and guidelines contained in these bulletins to ensure that their new and existing facilities are better designed to meet potential hurricane conditions. Because the regulated community is already using the criteria contained in these bulletins and participated in their development, MMS finds that the incorporation of these bulletins by reference is a minor, technical amendment in which the public is not particularly interested, so that notice and comment on the rulemaking is not necessary under 5 U.S.C. 553(b).

Also, the final rule amends an incorrect citation located in § 250.901(d). The incorrectly referenced standard was superseded by another standard, and the chart in § 250.901(d) was not updated with the correct citation.

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866)

This final rule is not a significant rule as determined by the Office of Management and Budget (OMB) and is not subject to review under E.O. 12866.

(1) This final rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

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

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

(4) This final rule will not raise novel legal or policy issues.

Regulatory Flexibility Act

The Department of the Interior certifies that this final rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

The changes in this final rule will affect lessees and operators of leases and pipeline right-of-way holders in the OCS. This could include about 130 active Federal oil and gas lessees. Small lessees that operate under this rule fall under the Small Business Administration's (SBA) North American Industry Classification System (NAICS) codes 211111, Crude Petroleum and Natural Gas Extraction, and 213111, Drilling Oil and Gas Wells. For these NAICS code classifications, a small company is one with fewer than 500 employees. Based on these criteria, an estimated 70 percent of these companies are considered small.

Nevertheless, changes in this final rule will not have a significant economic effect on a substantial number of small entities because it will not impose undue cost or burden (on the offshore oil and gas industry). Both large and small operators have already begun using and implementing the criteria and guidelines contained in these bulletins. The cost of implementing the standards set forth in these documents is not an undue burden because the resulting assessments and design changes are small when compared to costs of repairing or decommissioning a damaged or destroyed platform.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of MMS, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Disciplinary action for retaliation by an MMS employee may include suspension or termination from employment with the DOI.

Small Business Regulatory Enforcement Fairness Act

The final rule is not a major rule under 5 U.S.C. 804(2) of the Small Business Regulatory Enforcement Fairness Act. This final rule:

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

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

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

Unfunded Mandates Reform Act

This final rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The final rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 et seq.) is not required.

Takings Implication Assessment (E.O. 12630)

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

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this final rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This final rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS

activities, this final rule will not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

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

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

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

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this final rule and determined that it has no potential effects on federally recognized Indian tribes. There are no Indian or tribal lands in the OCS.

Paperwork Reduction Act

The proposed revisions do not contain any information collection subject to the Paperwork Reduction Act (PRA) and does not require a submission to OMB for review and approval under section 3507(d) of the PRA.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. The MMS has analyzed this rule under the criteria of the National Environmental Policy Act and 516 Departmental Manual 2.3A and determined that it falls within the categorical exclusion for ''regulations * * * that are an administrative, financial, legal, technical, or procedural nature and whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis (516 DM 2, App. 1.10). The MMS completed a Categorical Exclusion Review for this action and concluded that none of the exceptional circumstances set forth in 516 DM 2 Appendix 2, exist, therefore, preparation of an environmental analysis or environmental impact statement will not be required.

Data Quality Act

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

Effects on the Energy Supply (E.O. 13211)

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

List of Subjects in 30 CFR 250

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

Dated: March 20, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

■ For the reasons stated in the preamble, Minerals Management Service (MMS) amends 30 CFR part 250 as follows:

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

■ 1. The authority citation for part 250 is revised to read as follows:

Authority: 31 U.S.C. 9701, 43 U.S.C. 1334.

■ 2. In § 250.198, the following changes are made in the table in paragraph (e):

■ A. Add entries in alphanumerical order for API Bulletin 2INT–DG, API Bulletin 2INT–EX, and API Bulletin 2INT–MET as set forth below;

■ B. Revise entries in alphanumerical order for ACI Standard 318–95, ACI 357R–84, ANSI/AISC 360–05, API RP 2A–WSD, API RP 2FPS, API RP 2RD, API RP 2SK, API RP 2SM, API RP 2T, ASTM Standard C 33–99a, ASTM Standard C 94/C 94M–99, ASTM Standard C 150–99, ASTM Standard C 330–99, ASTM Standard C 595–98, AWS D1.1:2000, AWS D1.4–98, AWS D3.6M:1999, NACE Standard MR0175–2003, and NACE Standard RP0176–2003.

§ 250.198 Documents incorporated by reference.

* * * * *

(e) * * *

Title of documents	Incorporated by reference at
ACI Standard 318–95, Building Code Requirements for Reinforced Concrete (ACI 318–95) and Commentary (ACI 318R–95).	§ 250.901(a), (d).
ACI 357R–84, Guide for the Design and Construction of Fixed Offshore Concrete Structures, 1984; reapproved 1997.	§ 250.901(a), (d).
ANSI/AISC 360–05, Specification for Structural Steel Buildings	§ 250.901(a), (d).
* * * * *	* *
API Bulletin 2INT–DG, Interim Guidance for Design of Offshore Structures for Hurricane Conditions, May 2007.	§ 250.901(a), (d).
API Bulletin 2INT–EX, Interim Guidance for Assessment of Existing Offshore Structures for Hurricane Conditions, May 2007.	§ 250.901(a), (d).
API Bulletin 2INT–MET, Interim Guidance on Hurricane Conditions in the Gulf of Mexico, May 2007	§ 250.901(a), (d).
* * * * *	* *
API RP 2A–WSD, Recommended Practice for Planning, Designing and Constructing Fixed Offshore Platforms—Working Stress Design, Twenty-first Edition, December 2000; Errata and Supplement 1, December 2002; Errata and Supplement 2, October 2005, API Stock No. G2AWSD.	§ 250.901(a), (d); § 250.908(a); § 250.920(a), (b), (c), (e).
* * * * *	* *
API RP 2FPS, RP for Planning, Designing, and Constructing, Floating Production Systems	§ 250.901(a), (d).
API RP 2RD, Recommended Practice for Design of Risers for Floating Production Systems (FPSs) and Tension-Leg Platforms (TLPs), First Edition, June 1998; reaffirmed May 2006, API Stock No. G02RD1.	§ 250.800(b)(2); § 250.901(a), (d); § 250.1002(b)(5).
API RP 2SK, Recommended Practice for Design and Analysis of Stationkeeping Systems for Floating Structures, Third Edition, October 2005, API Stock No. G2SK03.	§ 250.800(b)(3); § 250.901(a), (d).
API RP 2SM, Recommended Practice for Design, Manufacture, Installation, and Maintenance of Synthetic Fiber Ropes for Offshore Mooring, First Edition, March 2001, API Stock No. G02SM1.	§ 250.901(a), (d).
API RP 2T, Recommended Practice for Planning, Designing, and Constructing Tension Leg Platforms, Second Edition, August 1997, API Stock No. G02T02.	§ 250.901(a), (d).

Title of documents	Incorporated by reference at
* * * * * * *	
ASTM Standard C 33–99a, Standard Specification for Concrete Aggregates	§ 250.901(a), (d).
ASTM Standard C 94/C 94M–99, Standard Specification for Ready-Mixed Concrete	§ 250.901(a), (d).
ASTM Standard C 150–99, Standard Specification for Portland Cement	§ 250.901(a), (d).
ASTM Standard C 330–99, Standard Specification for Lightweight Aggregates for Structural Concrete	§ 250.901(a), (d).
ASTM Standard C 595–98, Standard Specification for Blended Hydraulic Cements	§ 250.901(a), (d).
AWS D1.1:2000, Structural Welding Code—Steel	§ 250.901(a), (d).
AWS D1.4–98, Structural Welding Code—Reinforcing Steel	§ 250.901(a), (d).
AWS D3.6M:1999, Specification for Underwater Welding	§ 250.901(a), (d).
NACE Standard MR0175–2003, Item No. 21302, Standard Material Requirements, Metals for Sulfide Stress Cracking and Stress Corrosion Cracking Resistance in Sour Oilfield Environments.	§ 250.901(a), § 250.490(p)(2).
NACE Standard RP0176–2003, Item No. 21018, Standard Recommended Practice, Corrosion Control of Steel Fixed Offshore Structures Associated with Petroleum Production.	§ 250.901(a), (d).

■ 3. Amend § 250.901 as follows:

■ A. Redesignate paragraphs (a)(4) through (a)(20) as (a)(7) through (a)(23), respectively,

■ B. Add new paragraphs (a)(4), (5), and (6),

■ C. Revise redesignated paragraphs (a)(7) and (a)(23), and

■ D. Revise paragraph (d)

The additions and revisions read as follows:

§ 250.901 What industry standards must your platform meet?

(a) * * *

(4) American Petroleum Institute (API) Bulletin 2INT–DG, Interim Guidance for Design of Offshore Structures for Hurricane Conditions, (incorporated by reference as specified in § 250.198);

(5) API Bulletin 2INT–EX, Interim Guidance for Assessment of Existing Offshore Structures for Hurricane Conditions, (incorporated by reference as specified in § 250.198);

(6) API Bulletin 2INT–MET, Interim Guidance on Hurricane Conditions in the Gulf of Mexico, (incorporated by reference as specified in § 250.198);

(7) API Recommend Practice (RP) 2A–WSD, RP for Planning, Designing, and Constructing Fixed Offshore Platforms—Working Stress Design (incorporated by reference as specified in § 250.198);

* * * * *

(23) NACE Standard RP0176–2003, Item No. 21018, Standard Recommended Practice, Corrosion Control of Steel Fixed Offshore Structures Associated with Petroleum Production.

* * * * *

(d) The following chart summarizes the applicability of the industry standards listed in this section for fixed and floating platforms:

Industry standard	Applicable to * * *
(1) ACI Standard 318, Building Code Requirements for Reinforced Concrete, Plus Commentary;	Fixed and floating platform, as appropriate.
(2) ANSI/AISC 360–05, Specification for Structural Steel Buildings;	
(3) API Bulletin 2INT–DG, Interim Guidance for Design of Offshore Structures for Hurricane Conditions;	
(4) API Bulletin 2INT–EX, Interim Guidance for Assessment of Existing Offshore Structures for Hurricane Conditions;	
(5) API Bulletin 2INT–MET, Interim Guidance on Hurricane Conditions in the Gulf of Mexico;	
(6) API RP 2A–WSD, RP for Planning, Designing, and Constructing Fixed Offshore Platforms—Working Stress Design;	
(7) ASTM Standard C33–99a, Standard Specification for Concrete Aggregates;	
(8) ASTM Standard C94/C94M–99, Standard Specification for Ready-Mixed Concrete;	
(9) ASTM Standard C150–99, Standard Specification for Portland Cement;	
(10) ASTM Standard C330–99, Standard Specification for Lightweight Aggregates for Structural Concrete;	
(11) ASTM Standard C 595–98, Standard Specification for Blended Hydraulic Cements;	
(12) AWS D1.1, Structural Welding Code—Steel;	
(13) AWS D1.4, Structural Welding Code—Reinforcing Steel;	
(14) AWS D3.6M, Specification for Underwater Welding;	
(15) NACE Standard RP 0176–2003, Standard Recommended Practice (RP), Corrosion Control of Steel Fixed Offshore Platforms Associated with Petroleum Production;	
(16) ACI 357R, Guide for the Design and Construction of Fixed Offshore Concrete Structures;	Fixed platforms.
(17) API RP 14J, RP for Design and Hazards Analysis for Offshore Production Facilities;	Floating platforms.
(18) API RP 2FPS, RP for Planning, Designing, and Constructing, Floating Production Systems;	
(19) API RP 2RD, Design of Risers for Floating Production Systems (FPSs) and Tension-Leg Platforms (TLPs);	
(20) API RP 2SK, RP for Design and Analysis of Station Keeping Systems for Floating Structures;	
(21) API RP 2T, RP for Planning, Designing, and Constructing Tension Leg Platforms;	
(22) API RP 2SM, RP for Design, Manufacture, Installation, and Maintenance of Synthetic Fiber Ropes for Offshore Mooring.	

[FR Doc. E8–7777 Filed 4–14–08; 8:45 am]
BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 250, 270, 281, and 282

[Docket ID: MMS–2007–OMM–0070]

RIN 1010–AD49

Outer Continental Shelf Regulations—Technical Corrections

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This document makes minor technical changes to regulations that were published in various **Federal Register** documents and are codified in the Code of Federal Regulations. These changes will correct various citations and typographical errors in 30 CFR parts 250, 270, 281, and 282.

DATES: Effective on April 15, 2008.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulatory Specialist at (703) 787–1607, fax (703) 787–1555, or e-mail *cheryl.blundon@mms.gov*.

SUPPLEMENTARY INFORMATION:

Background: The technical corrections in this document affect all offshore operators, lessees, pipeline right-of-way holders, and permittees. The corrections are necessary to correct citation and typographical errors, and to add or change a few words for clarification. Obsolete information is being removed, since the grace period that was written into the initial rule is no longer valid. Also, when some rules were previously written in ''plain English,'' words were inadvertently dropped that are now being put back. This will make the regulations easier to read, understand, and follow.

This document corrects regulations in 30 CFR parts 250, 270, 281, and 282 to reflect these changes. Because this rule makes no substantive change in any rule or requirement and has no significant impact on industry or the public, MMS, for good cause, finds that notice and public comment are unnecessary pursuant to 5 U.S.C. 553(b)(B). Furthermore, MMS, for good cause, finds that no period of time is necessary to enable industry or the public to come into compliance with this rule; and therefore provides that the rule is effective upon this publication pursuant to 5 U.S.C. 553(d).

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866)

This final rule is not a significant rule as determined by the Office of Management and Budget (OMB) and is not subject to review under E.O. 12866.

(1) This final rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

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

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

(4) This final rule will not raise novel legal or policy issues.

Regulatory Flexibility Act

The Department of the Interior certifies that this final rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Your comments are important to us. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small business about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of MMS, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Disciplinary action for retaliation by an MMS employee may include suspension or termination from employment with the Department of the Interior.

Small Business Regulatory Enforcement Fairness Act

This final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This final rule:

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

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

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

Unfunded Mandates Reform Act

This final rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. This final rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

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

Federalism (E.O. 13132)

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

Civil Justice Reform (E.O. 12988)

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

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

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

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this final rule and determined that it has no potential effects on federally recognized Indian tribes. There are no Indian or tribal lands in the OCS.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) provides that an agency may not conduct or sponsor a collection of information unless it displays a

currently valid OMB control number. Until OMB approves a collection of information and assigns a control number, you are not required to respond to the collection of information. This final rule does not contain any new information collection requirements subject to the PRA, nor does it affect any previously approved collections; therefore, the rule does not require a submittal to OMB for review and approval under section 3507(d) of the PRA. Any information collection burdens referenced in this rulemaking are already approved under OMB Control Numbers 1010–0114, expiration November 30, 2010; 1010–0151, expiration July 31, 2008; 1010–0059, expiration February 28, 2009; 1010–0149 expiration March 31, 2008; 1010–0128 expiration August 31, 2009; and 1010–0086 expiration December 31, 2010, respectively.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. The MMS has analyzed this rule under the criteria of the National Environmental Policy Act and 516 Departmental Manual 2, Appendix 1.10. and determined that it falls within the categorical exclusion for ''regulations * * * that are of an administrative, financial, legal, technical, or procedural nature and whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis.'' The MMS completed a Categorical Exclusion Review for this action and concluded that the rulemaking does not represent an exception to the established criteria for categorical exclusion; therefore, preparation of an environmental analysis or environmental impact statement will not be required.

Data Quality Act

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

Effects on the Energy Supply (E.O. 13211)

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

Determination To Not Issue a Proposed Rule

The MMS has determined that the good cause exception in 5 U.S.C. 553(b)(3)(B) applies to this rule. The good cause exception allows an agency to dispense with the notice and public procedure when the agency finds for good cause that those requirements are impractical, unnecessary, and contrary to the public interest. Because this rule merely makes technical changes, it makes an administrative change and public comment is unnecessary.

Determination To Make Rule Effective Immediately

Because this rule makes technical changes only, MMS has determined it appropriate to make the rule effective immediately, as allowed under 5 U.S.C. 553(d).

List of Subjects

30 CFR Part 250

Administrative practice and procedures, Continental shelf, Environmental protection, Oil and gas exploration, Public lands—minerals resources, Public lands—rights-of-way.

30 CFR Part 270

Continental shelf, Nondiscrimination, Oil and gas exploration.

30 CFR Part 281

Administrative practice and procedure, Continental shelf, Mineral royalties, Public lands—mineral resources, Reporting and recordkeeping requirements.

30 CFR Part 282

Administrative practice and procedure, Continental shelf, Public lands—mineral resources.

Dated: March 28, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

■ For the reasons stated above, MMS amends 30 CFR parts 250, 270, 281, and 282 as follows:

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

■ 1. The authority citation for part 250 is revised to read as follows:

Authority: 31 U.S.C. 9701, 43 U.S.C. 1334.

§ 250.107 [Amended]

■ 2. In § 250.107(a)(2), after the word ''equipment'' add the words ''and work areas''.

§ 250.260 [Amended]

■ 3. In § 250.260(a), the citation ''15 CFR 930.76(d)'' is revised to read ''15 CFR 930.76(c)''.

§ 250. 803 [Amended]

■ 4. In § 250.803 the following additions are made:

■ A. In § 250.803(b)(8), in the first sentence, after the phrase ''API RP 14G'' add the parenthetical phrase ''(incorporated by reference as specified in § 250.198)''.

■ B. In § 250.803(b)(9)(i), in the last sentence, after the phrase ''API RP 500'' and the phrase ''API RP 505'' add the parenthetical phrase ''(incorporated by reference as specified in § 250.198)''.

■ 5. In § 250.806(c), revise the second sentence to read as follows:

§ 250.806 Safety and pollution prevention equipment quality assurance requirements.

* * * * *

(c) * * * If you want MMS to evaluate other quality assurance programs, submit relevant information about the program and reasons for recognition by MMS to the Chief, Office of Offshore Regulatory Programs; Minerals Management Service; MS–4020; 381 Elden Street, Herndon, Virginia 20170–4817.

§ 250.900 [Amended]

■ 6. In § 250.900(a), in the first sentence, after the word ''You,'' add the word ''must''.

§ 250.1201 [Amended]

■ 7. In § 250.1201, remove the definition of *Calibration*, revise the definition of *Surface commingling*, and add in alphabetical order a new definition of *Verification/Calibration*, to read as follows:

§ 250.1201 Definitions.

* * * * *

Surface commingling—the surface mixing of production from two or more leases and/or unit participating areas prior to royalty measurement.

* * * * *

Verification/Calibration—testing and correcting, if necessary, a measuring device to ensure compliance with industry accepted, manufacturer's recommended, or regulatory required standard of accuracy.

* * * * *

§ 250.1202 [Amended]

■ 8. In § 250.1202(k)(3) and (4), in the first sentence, after the word ''Prove'', add the word ''operating''.

§ 250.1204 [Amended]

■ 9. In § 250.1204(b)(1), after the word ''months'' insert the parenthetical phrase ''(1 time every 60 days)''.

§ 250.1301 [Amended]

■ 10. Amend § 250.1301 by revising paragraphs (b) and (c) to read as follows:

§ 250.1301 What are the requirements for unitization?

* * * * *

(b) *Compulsory unitization.* The Regional Supervisor may require you and other lessees to unitize operations of a reasonably delineated and productive reservoir if unitized operations are necessary to:

(1) Prevent waste;

(2) Conserve natural resources; or

(3) Protect correlative rights, including Federal royalty interests.

(c) *Unit area.* The area that a unit includes is the minimum number of leases that will allow the lessees to minimize the number of platforms, facility installations, and wells necessary for efficient exploration, development, and production of mineral deposits, oil and gas reservoirs, or potential hydrocarbon accumulations common to two or more leases. A unit may include whole leases or portions of leases.

* * * * *

§ 250.1502 [Amended]

■ 11. Remove § 250.1502.

§ 250.1629 [Amended]

■ 12. In §§ 250.1629(b)(1) and (b)(1)(i), after the phrase ''I, IV, and VIII of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code'' add the parenthetical phrase ''(incorporated by reference as specified in 30 CFR 250.198)''.

PART 270—NONDISCRIMINATION IN THE OUTER CONTINENTAL SHELF

■ 13. The authority citation for part 270 is revised to read as follows:

Authority: 43 U.S.C. 1863.

§ 270.6 [Amended]

■ 14. In § 270.6, revise the last sentence to read as follows:

§ 270.6 Process.

* * * If either the complainant or the person(s) alleged to have wrongfully discriminated fail to provide such written notice within a reasonable period of time, the Regional Director must proceed in accordance with the provisions of 30 CFR 250, subpart N.

PART 281—LEASING OF MINERALS OTHER THAN OIL, GAS, AND SULPHUR IN THE OUTER CONTINENTAL SHELF

■ 15. The authority citation for part 281 is revised to read as follows:

Authority: 43 U.S.C. 1334.

§ 281.0 [Amended]

■ 16. In § 281.0, the last sentence is revised to read ''An applicant must respond to obtain or retain a benefit.''

§ 281.26 [Amended]

■ 17. In § 281.26 revise the second sentence of paragraph (e) and revise paragraph (i) to read as follows:

§ 281.26 Payments.

* * * * *

(e) * * * The single responsible person shall be designated as the payor for the lease and shall be so identified on the Solid Minerals Production and Royalty Report (P & R) (MMS–4430) in accordance with § 210.201of this title. * * *

* * * * *

(i) All payors must submit payments and payment forms and maintain auditable records in accordance with 30 CFR Chapter II, Subchapter A—Minerals Revenue Management.

PART 282—OPERATIONS IN THE OUTER CONTINENTAL SHELF FOR MINERALS OTHER THAN OIL, GAS, AND SULPHUR

■ 18. The authority citation for part 282 is revised to read as follows:

Authority: 43 U.S.C 1334.

§ 282.40 [Amended]

■ 19. Revise § 282.40, paragraph (f), to read as follows:

§ 282.40 Bonds.

* * * * *

(f) For the purposes of this section there are three areas:

(1) The Gulf of Mexico and the area offshore the Atlantic Ocean;

(2) The area offshore the Pacific Coast States of California, Oregon, Washington, and Hawaii; and

(3) The area offshore the coast of Alaska.

* * * * *

[FR Doc. E8–7776 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2008–0241]

Drawbridge Operation Regulation; Cape Fear River, Wilmington, NC; Bridge Inspection

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Cape Fear River Memorial Bridge, mile 26.8 at Wilmington, NC. Under this deviation, a one-hour advance notice is required for bridge openings, to allow bridge inspectors time to remove test equipment connected to operating components used in bridge openings.

DATES: This deviation is effective from 6 a.m. on April 28, 2008, to 11:59 p.m. on May 8, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0241 and are available online at *www.regulations.gov*. They are also available for inspection or copying at two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Commander (dpb), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704–5004 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Gary S. Heyer, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398–6629.

SUPPLEMENTARY INFORMATION: North Carolina Department of Transportation, who owns and operates the Cape Fear River Memorial Bridge, requested a deviation from the operating regulations to facilitate inspection of the bridge.

In the closed position to navigation, the drawbridge has a vertical clearance of 65 feet above mean high water. The current operating regulations set out in 33 CFR 117.823 allow the draw need not open for the passage of vessel from 8 a.m. to 10 a.m. on the second Saturday of July of every year, and from 7 a.m. to 11 a.m. on the second Sunday of November of every year; and require the draw to open on signal at all other times in accordance with 33 CFR 117.5.

The Cape Fear River Memorial Bridge is inspected annually on varying dates. During this inspection, vessel operators with mast height lower than 65 feet will continue to be able to transit through the drawbridge. There are not alternate routes for vessels with a mast height greater than 65 feet.

To allow bridge inspectors time to remove test equipment connected to

operating components used in bridge openings, a one-hour advance notice will be required for bridge openings beginning at 6 a.m. on Monday, April 28, 2008, until and including 11:59 p.m. on Thursday, May 8, 2008.

The Coast Guard reviewed the bridge logs provided by NCDOT for April and May in 2007 which revealed that vessel traffic is primarily commercial with a small amount of recreational. The number of bridge openings for commercial traffic averages about 25 openings per month, with about two openings per month for recreational craft.

The Coast Guard will inform the users of the waterway via maritime advisories of the restriction for bridge openings so that vessels can arrange their transits to minimize any impact caused by the temporary deviation. In addition, qualified personnel will be on-site to open the drawbridge for vessels in the event of an emergency.

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

We analyzed this temporary deviation under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The environmental impact that this temporary deviation will have is minimal because the drawbridges being closed to vessels to perform routine maintenance, will not result in a change in functional use, or an impact on a historically significant element or setting.

Dated: April 7, 2008.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch Fifth Coast Guard District.

[FR Doc. E8–7931 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2007–0145]

RIN 1625–AA00

Safety Zone; Colorado River, Parker, AZ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone within in the Lake Moolvalya region on the navigable waters of the Colorado River in Parker, Arizona for the Bluewater Resort and Casino 'Spring Classic' Boat Race. This temporary safety zone is necessary to provide for the safety of the participants, crew, spectators, participating vessels and other vessels and users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 6 a.m. on April 11, 2008, through 6 p.m on April 13, 2008.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CG–2007–0145 and are available for inspection or copying at U.S. Coast Guard Sector San Diego, 2710 N. Harbor Drive, San Diego, CA 92101–1064 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: MST3 Kristen Beer, Waterways Management, U.S. Coast Guard Sector San Diego, CA at (619) 278–7233.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 7, 2008, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Colorado River, Parker, AZ in the **Federal Register** (73 FR 7229). We received no comments on the proposed rule. No public hearing was requested, and none was held.

Under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property.

Background and Purpose

The Southern California Speedboat Club is sponsoring the Bluewater Resort and Casino 'Spring Classic' Boat Race, which is held on the Lake Moolvalya region on the Colorado River in Parker, Arizona. This temporary safety zone is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and other users of the waterway. This event involves powerboats racing along a circular track. The size of the boats varies from 12 to 22 feet. Approximately 85 boats will participate in this event. The sponsor will provide two water rescue and two patrol vessels to patrol this event.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary.

This determination is based on the size and location of the safety zone. Commercial vessels will be hindered by the safety zone. Recreational vessels will not be allowed to transit through the designated safety zone during the specified times.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners and operators of pleasure craft engaged in recreational activities and sightseeing in a portion of the Lower Colorado River from 6 a.m. on April 11, 2008, through 6 p.m. on April 13, 2008. This safety zone will not have a significant economic impact on a substantial number of small entities because the rule will be in effect for only 12 hours for a period of three (3) days. Before the effective period, we will submit an inclusion in the Local Notice to Mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

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

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standard

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards.

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g) of the Instruction, from further environmental documentation. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add new § 165.T11–001 to read as follows:

§ 165.T11–001 Safety Zone; Colorado River, Parker, AZ.

(a) *Location.* The following area is a temporary safety zone: The portion of the Colorado River from Headgate Dam to 0.5 nautical miles north of Bluewater Marina, Parker, Arizona.

(b) *Enforcement Period.* This safety zone will be enforced each day from 6 a.m. to 6 p.m. from April 11, 2008, through April 13, 2008. If the need for the safety zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone.

(c) *Definitions.* The following definition applies to this section: *Designated representative,* means any commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, and local, State, and Federal law enforcement vessels who have been authorized to act on the behalf of the Captain of the Port, New York.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this zone by all vessels is prohibited, unless authorized

by the Captain of the Port, or his designated representative.

(2) Mariners requesting permission to transit through the safety zone may request authorization to do so from the Patrol Commander. The Patrol Commander may be contacted via VHF–FM channel 16.

(3) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated representative.

(4) Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

(5) The Coast Guard may be assisted by other Federal, State, or local agencies.

Dated: March 17, 2008.

C.V. Strangfeld,

Captain, U.S. Coast Guard, Captain of the Port.

[FR Doc. E8–7937 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2007–1139; FRL–8554–6]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Control of Volatile Organic Compound (VOCs) Emissions From the Kraft Foods Global, Inc.—Bakery Located in Henrico County, VA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision pertains to a federally enforceable State operating permit containing terms and conditions for the control of emissions of volatile organic compounds (VOCs) from the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, Virginia. The submittal is for the purpose of meeting the requirements for reasonably available control technology (RACT) in order to implement the maintenance plan for the Richmond 8-hour ozone maintenance area. EPA is approving the revision to the Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: *Effective Date:* This final rule is effective on May 15, 2008.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2007–1139. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and 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 through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814–2166, or by e-mail at *shandruk.irene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2008 (73 FR 5781), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. The NPR proposed approval of Virginia's SIP revision for the purpose of meeting RACT requirements in order to implement the maintenance plan for the Richmond 8-hour ozone maintenance area. The formal SIP revision was submitted by the Virginia Department of Environmental Quality on October 29, 2007. Other specific requirements of RACT and the rationale for EPA's proposed action are explained in the NPR and will not be restated here. No comments were received on the NPR.

II. Summary of SIP Revision

The Virginia Department of Environmental Quality is requesting that a revision to the Commonwealth's SIP concerning a federally enforceable State operating permit containing terms and conditions for the control of emissions of VOCs from the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, Virginia be approved. The purpose of this revision is for meeting the requirements for RACT in order to implement the maintenance plan for the Richmond 8-hour ozone maintenance area.

III. General Information Pertaining to SIP Submittals From the Commonwealth of Virgina

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by Federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. * * *'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the

extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, state audit privilege or immunity law.

Other specific requirements of the SIP revision and the rationale for EPA's proposed action are explained in the NPR and will not be restated here. No public comments were received on the NPR.

IV. Final Action

Virginia has met the requirements concerning a federally enforceable State operating permit containing terms and conditions for the control of emissions of VOCs from the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, Virginia, and EPA is therefore approving Virginia's revision for the purpose of this revision is for meeting the requirements for RACT in order to implement the maintenance plan for the Richmond 8-hour ozone maintenance area.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

B. Submission to Congress and the Comptroller General

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804, however, exempts from section 801 the following types of rules: rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). Because this is a rule of particular applicability, EPA is not required to submit a rule report regarding this action under section 801.

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 16, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action approving Virginia's SIP revision pertaining to a federally enforceable State operating permit containing terms and conditions for the control of emissions of volatile organic compounds (VOCs) from the Kraft Foods Global, Inc.—Richmond Bakery located in Henrico County, Virginia may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 3, 2008.

William T. Wisniewski,

Acting Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (d) is amended by adding the entry for Kraft Food Global, Inc.—Richmond Bakery at the end of the table to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED SOURCE-SPECIFIC REQUIREMENTS

Source name	Permit/order or registration number	State effective date	EPA approval date	40 CFR part 52 citation
*	*	*	*	*
Kraft Foods Global, Inc.—Richmond Bakery.	Registration No. 50703	9/19/07	4/15/08 [Insert page number where the document begins].	52.2420(d)(8)

* * * * *

[FR Doc. E8–7876 Filed 4–14–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2008–0241; FRL–8553–1]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to the Iowa State Implementation Plan submitted on January 16, 2008. The revision includes changes to the definition of ''permitting authority'' in each of Iowa's rules used for compliance with EPA's Clean Air Interstate Rule. Iowa's SIP revision is in response to EPA's request of Iowa to revise the definitions to ensure that all allowances issued in the EPA Budget Trading Programs can be traded and used for compliance with the allowance-holding requirement in any State in the program.

DATES: This direct final rule will be effective June 16, 2008, without further notice, unless EPA receives adverse comment by May 15, 2008. If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2008–0241, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: jay.michael@epa.gov.*
3. *Mail:* Michael Jay, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.
4. *Hand Delivery or Courier:* Deliver your comments to Michael Jay, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2008–0241. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov* or e-mail information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *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, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. The Regional Office's official hours of business are Monday through Friday, 8 a.m. to 4:30 p.m. excluding Federal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Michael Jay at (913) 551–7460, or by e-mail at *jay.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This section provides additional information by addressing the following questions:

What is a SIP?
What is the Federal approval process for a SIP?
What does Federal approval of a state regulation mean to me?
What is being addressed in this document?

Have the requirements for approval of a SIP revision been met?
What action is EPA taking?

What is a SIP?

Section 110 of the Clean Air Act (CAA) requires states to develop air pollution regulations and control strategies to ensure that state air quality meets the national ambient air quality standards established by EPA. These ambient standards are established under section 109 of the CAA, and they currently address six criteria pollutants. These pollutants are: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must submit these regulations and control strategies to us for approval and incorporation into the Federally-enforceable SIP.

Each Federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

What is the Federal approval process for a SIP?

In order for state regulations to be incorporated into the Federally-enforceable SIP, states must formally adopt the regulations and control strategies consistent with state and Federal requirements. This process generally includes a public notice, public hearing, public comment period, and a formal adoption by a state-authorized rulemaking body.

Once a state rule, regulation, or control strategy is adopted, the state submits it to us for inclusion into the SIP. We must provide public notice and seek additional public comment regarding the proposed Federal action on the state submission. If adverse comments are received, they must be addressed prior to any final Federal action by us.

All state regulations and supporting information approved by EPA under section 110 of the CAA are incorporated into the Federally-approved SIP. Records of such SIP actions are maintained in the Code of Federal Regulations (CFR) at title 40, part 52, entitled ''Approval and Promulgation of Implementation Plans.'' The actual state regulations which are approved are not reproduced in their entirety in the CFR outright but are ''incorporated by reference,'' which means that we have approved a given state regulation with a specific effective date.

What does Federal approval of a state regulation mean to me?

Enforcement of the state regulation before and after it is incorporated into the Federally-approved SIP is primarily a state responsibility. However, after the regulation is Federally approved, we are authorized to take enforcement action against violators. Citizens are also offered legal recourse to address violations as described in section 304 of the CAA.

What is being addressed in this document?

The SIP revision addresses changes to the definition of ''permitting authority'' in each of Iowa's rules for compliance with the Clean Air Interstate Rule (CAIR), that include the following: 567–34.201 for the annual NO_X trading program, 567–34.210 for the annual SO_2 trading program, and 567–34.221 for the ozone season trading program. Each rule has been revised to specify that the definition of ''permitting authority'' shall mean the definition contained in the corresponding EPA CAIR model rule for purposes of its use in the definitions of ''allocate or allocation'' and in all other references it shall mean the Iowa Department of Natural Resources (IDNR). Iowa has made these revisions to its State rules in response to an EPA letter request sent to the IDNR on February 17, 2007. This SIP revision is necessary to ensure that all allowances issued in the EPA Budget Trading Programs are fungible and can be traded and used for compliance with the allowance-holding requirement in any State in the program. By revising the definition of ''permitting authority'' to be consistent with the EPA CAIR model rules when used in the definitions of ''allocate or allocation,'' the IDNR ensures that allowances issued by permitting authorities other than the IDNR, such as States other than Iowa, can be used for compliance with Iowa's CAIR rules. EPA has reviewed Iowa's revised definitions and has found that Iowa has successfully incorporated EPA's recommended changes.

Have the requirements for approval of a SIP revision been met?

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of this docket, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

What action is EPA taking?

EPA is taking direct final action to approve a revision to the Iowa SIP submitted on January 16, 2008. We are processing this action as a direct final action because the revisions make changes to the existing rules which are noncontroversial. Therefore, we do not anticipate any adverse comments. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because

application of those requirements would be inconsistent with the 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 rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 16, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 3, 2008.

William Rice,

Acting Regional Administrator, Region 7.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart Q—Iowa

■ 2. In § 52.820(c) the table is amended by revising the entries for 567–34.201, 567–34.210, and 567–34.221 to read as follows:

§ 52.820 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED IOWA REGULATIONS

Iowa citation	Title	State effective date	EPA approval date	Explanation
Iowa Department of Natural Resources Environmental Protection Commission [567]				
*	*	*	*	*
Chapter 34—Provisions for Air Quality Emissions Trading Programs				
*	*	*	*	*
567–34.201	CAIR NO_X annual trading program provisions.	11/28/2007	4/15/2008 [*insert FR page number where the document begins*].	
*	*	*	*	*
567–34.210	CAIR SO_2 trading program	11/28/2007	4/15/2008 [*insert FR page number where the document begins.*	
*	*	*	*	*
567–34.221	CAIR NO_X ozone season trading program general provisions.	11/28/2007	4/15/2008 [*insert FR page number where the document begins.*	
*	*	*	*	*

* * * * *

[FR Doc. E8–7815 Filed 4–14–08; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 73, No. 73
Tuesday, April 15, 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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 351

RIN 3206–AL64

Competitive Area

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing proposed regulations that provide agencies with the option of establishing a reduction in force (RIF) competitive area comprised only of pay band positions. An agency would have this option only when the competitive area would otherwise include pay band positions and other positions not covered by a pay band system.

DATES: We will consider comments received on or before May 15, 2008.

ADDRESSES: You may submit comments, identified by RIN 3206–AL64, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *employ@opm.gov.* Include ''RIN 3206–AL64'' in the subject line of the message.
- Fax: (202) 606–2329.
- Mail: Angela Bailey, Deputy Associate Director for Talent and Capacity Policy, U.S. Office of Personnel Management, Room 6551, 1900 E Street, NW., Washington, DC 20415–9700.
- Hand Delivery/Courier: OPM, Room 6551, 1900 E Street, NW., Washington, DC, 20415.

FOR FURTHER INFORMATION CONTACT: Michael J. Mahoney by telephone on 202–606–0960, by FAX on 202–606–2329, by TDD on 202–418–3134, or by e-mail at *employ@opm.gov.*

SUPPLEMENTARY INFORMATION: Section 351.402(b) of OPM's regulations presently provides that an agency must define a RIF competitive area solely on the basis of the agency's organizational unit(s) and geographical location. Once defined, the competitive area includes all employees covered by that definition.

OPM is adding new section 351.402(e) to provide that when a competitive area defined under section 351.402(b) includes both pay band positions and positions not covered by a pay band, the agency may, at its discretion, define a competitive area, that is otherwise consistent with section 351.402(b), to include either only pay band positions or only positions not covered by a pay band system. In a related change, OPM is revising section 351.403(a)(2) to clarify how an agency establishes RIF competitive levels for pay band positions and for other positions.

Explanation

OPM's regulations cover RIF competition involving positions under different pay schedules. For example, section 351.203 includes the RIF definition of ''Representative Rate'' for traditional General Schedule (GS) and Federal Wage System (FWS) positions, and for alternative pay schedule positions (e.g., pay band, unclassified, and negotiated rate positions). The RIF regulations also cover how an agency determines the retention standing of employees in GS/FWS positions and in positions with an alternative pay schedule.

In a recent review of the RIF regulations, and as more and more agencies move portions of their workforces into alternative systems, OPM found that significant inconsistencies may result when a RIF competitive area includes pay band positions and positions covered by the General Schedule (GS) or Federal Wage System (FWS). For example, a pay band personnel system may also include specific staffing, classification, pay, and performance management provisions that differ significantly from the GS and/or FWS system. These distinctions between pay band and other positions could be magnified when all of the positions are included in the same RIF competitive area.

To establish a RIF competitive level to determine which employee is released from the present position, section 351.403(a)(2) provides that the agency use the official position description that documents the duties, responsibilities, and qualifications tied to each competing employee's official position of record. Consistent with the regulations, a RIF competitive level for GS or FWS employees only includes interchangeable positions having the same grade, classification series, work schedule, type of service (e.g., competitive or excepted), and additional criteria covered in section 5 CFR 351.403. However, in a pay band system a single pay band may combine multiple grades and classification series that are documented on a single generic official position description. In operation, the agency may, and in some cases does, supplement this position description with other documentation to distinguish actual work assignments among the pay band positions. A separate competitive area for pay band positions eliminates the requirement to create position descriptions that must conform to those in another personnel system (*e.g.,* GS and/or FWS).

Sections 351.701(b) and (c) provide that a GS or FWS competitive service employee has potential ''bump'' and ''retreat'' rights to positions in the competitive area that are no more than three grades or grade-intervals below the employee's official position of record. Section 351.701(c) also provides a preference eligible with a compensable service-connected disability of 30% or more with a potential retreat right of up to five grades or grade-intervals from the employee's official position of record. However, the compensation architecture of a pay band system does not equate efficiently to the grade/grade-interval structure used to determine the assignment rights of GS or FWS employees. These differences may make it difficult for an agency to determine equivalent assignment rights from pay band to GS/FWS positions or vice versa. A separate competitive area for pay band positions eliminates these difficulties in determining the potential assignment rights of pay band and GS/FWS employees who are released from a retention register by RIF and makes it easier to make comparisons.

Revisions to Competitive Level

Section 351.403(a)(2) is renumbered as section 351.403(a)(2)(i) and revised to clarify that, except as provided in new section 351.403(a)(2)(ii) for pay band positions, competitive level determinations are based on each employee's official position of record

(including the official position description), not the employee's personal qualifications.

New section 351.403(a)(2)(ii) provides that to establish a competitive level comprised of pay band positions, an agency may supplement an employee's official position description with other applicable records that document the employee's actual duties and responsibilities.

Revisions to Competitive Area

New section 351.402(e) provides that when a competitive area defined under section 351.402(b) includes pay band positions and positions not covered by a pay band, the agency may, at its discretion, define a competitive area otherwise consistent with section 351.402 to include only pay band positions. Section 351.402(b) is revised to include a reference to new section 351.402(e).

Examples of Separate Competitive Area for Pay Band Positions

Example 1

Under section 351.402(b) an agency defines its activities in Memphis and Vicksburg to be in the same competitive area. At present this competitive area would include GS, FWS, and pay band positions.

At its option the agency may apply new section 351.402(e) and define a separate competitive area that includes only its pay band positions in Memphis and Vicksburg. Under section 351.402(e), the competitive area for pay band positions must otherwise conform to section 351.402(b), that is, be based on the same organizational unit and geographical location as the remaining positions (i.e., the GS and FWS positions in the original competitive area).

Example 2

Under current regulations, an agency defines its headquarters to be one competitive area that includes GS, FWS, and pay band positions.

At its option the agency may apply new section 351.402(e) and define a separate competitive area that includes only its pay band positions in the headquarters. Under section 351.402(e) the competitive area for pay band positions must still be based on the same organizational unit and geographical location as the remaining positions, that is the GS and FWS positions that were in the original competitive area (the entire headquarters).

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only certain Federal employees.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 5 CFR Part 351

Administrative practice and procedure, Government employees.

Office of Personnel Management.

Linda M. Springer,

Director.

Accordingly, OPM proposes to amend part 351 of title 5, Code of Federal Regulations, as follows:

PART 351—REDUCTION IN FORCE

1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 1302, 3502, 3503; sec. 351.801 also issued under E.O. 12828, 58 FR 2965.

2. In § 351.402, paragraph (b) is revised, and paragraph (e) is added, to read as follows:

§ 351.402 Competitive area.

* * * * *

(b) A competitive area must be defined solely in terms of the agency's organizational unit(s) and geographical location and, except as provided in paragraph (e) of this section, it must include all employees within the competitive area so defined. A competitive area may consist of all or part of an agency. The minimum competitive area is a subdivision of the agency under separate administration within the local commuting area.

* * * * *

(e) When a competitive area defined under paragraph (b) of this section includes pay band positions and positions not covered by a pay band, the agency may, at its discretion, define a separate (and additional) competitive area, otherwise consistent with paragraph (b) of this section, to include only pay band positions. The original competitive area would then include only the remaining positions, i.e., those positions not covered by a pay band.

3. In § 351.403, paragraph (a)(2) is revised to read as follows:

§ 351.403 Competitive level.

(a) * * *

(2)(i) Except as provided in paragraph (a)(2)(ii) of this section for pay band positions, competitive level determinations are based on each employee's official position of record (including the official position description), not the employee's personal qualifications.

(ii) To establish a competitive level comprised of pay band positions, an agency may supplement an employee's official position of record with other applicable records that document the employee's actual duties and responsibilities.

* * * * *

[FR Doc. E8–7968 Filed 4–14–08; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 43, 61, 91, and 141

[Docket No. FAA–2007–29015; Notice No. 08–03]

RIN 2120–AJ10

Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft; Modifications to Rules for Sport Pilots and Flight Instructors With a Sport Pilot Rating

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to amend its rules for sport pilots and flight instructors with a sport pilot rating. The FAA believes these changes are necessary to address airman certification issues that have arisen since regulations for the operation of light-sport aircraft were implemented. These changes would align the certification requirements for sport pilots and flight instructors with a sport pilot rating with those requirements currently applicable to other airmen certificates.

DATES: Send your comments on or before August 13, 2008.

ADDRESSES: You may send comments identified by docket number FAA 2007–29015 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the electronic form of all comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://DocketsInfo.dot.gov*.

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time and follow the online instructions for accessing the docket. Or, go to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this proposed rule, contact Larry L. Buchanan, Light-Sport Aviation Branch, AFS–610, Regulatory Support Division, Flight Standards Service, Federal Aviation Administration, 6500 South MacArthur Blvd., Oklahoma City, OK 73169; telephone (405) 954–6400; Mailing address: Light-Sport Aviation Branch, AFS–610; P.O. Box 25082; Oklahoma City, OK 73125.

For legal questions concerning this proposed rule, contact Paul Greer, Regulations Division, AGC–200, Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; telephone (202) 267–3073.

SUPPLEMENTARY INFORMATION: Later in this preamble under ''VI. Additional Information,'' we discuss how you can comment on this proposal and how we will handle your comments. Included in this discussion is related information about the docket, privacy, and the handling of proprietary or confidential business information. We also discuss how you can get a copy of this proposal and related rulemaking documents.

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator, including the authority to issue, rescind, and revise regulations. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Chapter 447—Safety Regulation. Under section 44701, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations necessary for safety. Under section 44703, the FAA issues an airman certificate to an individual when we find, after investigation, that the individual is qualified for, and physically able to perform the duties related to, the position authorized by the certificate. In this NPRM, the FAA is proposing to amend the training, qualification, certification, and operating requirements for sport pilots and flight instructors with a sport pilot rating.

These changes are intended to ensure that these airmen have the training and qualifications necessary to enable them to operate light-sport aircraft safely. For this reason, the proposed changes are within the scope of the FAA's authority and are a reasonable and necessary exercise of our statutory obligations.

Guide to Terms and Acronyms Frequently Used in This Document

AGL—Above Ground Level
ATC—Air Traffic Control
CAS—Calibrated Airspeed
DPE—Designated Pilot Examiner
MSL—Mean Sea Level
NDPER—National Designated Pilot Examiner Registry
PTS—Practical Test Standards
VFR—Visual Flight Rules
V_H—Maximum airspeed in level flight with maximum continuous power

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4. Place all requirements for flight instructors under a single subpart (subpart H) of part 61
5. Require 1 hour of flight training on the control and maneuvering of an airplane solely by reference to instruments for student pilots seeking a sport pilot certificate to operate an airplane with a maximum airspeed in level flight with maximum continuous power (V_H) greater than 87 knots calibrated airspeed (CAS) and sport pilots operating airplanes with a V_H greater than 87 knots CAS
6. Remove the requirement for persons exercising sport pilot privileges and flight instructors with a sport pilot rating to carry their logbooks while in flight
7. Remove the requirement that persons exercising sport pilot privileges have an aircraft make-and-model endorsement to operate a specific set of aircraft while adding provisions for endorsements for the operation of powered parachutes with elliptical wings and aircraft with a V_H less than or equal to 87 knots CAS
8. Remove the requirement for all flight instructors to log at least 5 hours of flight time in a make and model of light-sport aircraft before providing training in any aircraft from the same set of aircraft in which that training is given
9. Permit persons exercising sport pilot privileges and the privileges of a student pilot seeking a sport pilot certificate to fly up to an altitude of not more than 10,000 feet mean sea level (MSL) or 2,000 feet above ground level (AGL), whichever is higher
10. Permit private pilots to receive compensation for production flight testing of powered parachutes and weight-shift-control aircraft intended for certification in the light-sport category under § 21.190
11. Revise student sport pilot solo cross-country navigation and communication flight training requirements
12. Clarify cross-country distance requirements for private pilots seeking to operate weight-shift-control aircraft
13. Revise aeronautical experience requirements at towered airports for persons seeking to operate a powered parachute or weight-shift-control aircraft as a private pilot
14. Remove the requirement for pilots with only a powered parachute or a weight-shift-control aircraft rating to take a knowledge test for an additional rating at the same certificate level
15. Revise the amount of hours of flight training an applicant for a sport pilot certificate must log within 60 days prior to taking the practical test
16. Remove expired ultralight transition provisions and limit the use of aeronautical experience obtained in ultralight vehicles
17. Add a requirement for student pilots to obtain endorsements identical to those proposed for sport pilots in §§ 61.324 and 61.327
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22. Revise the minimum safe-altitude requirements for powered parachutes and weight-shift-control aircraft
III. Paperwork Reduction Act
IV. International Compatibility
V. Regulatory Notices and Analyses
A. Economic Assessment
B. Regulatory Flexibility Determination
C. International Trade Impact Assessment
D. Unfunded Mandates Assessment
E. Executive Order 13132, Federalism
F. Environmental Analysis
G. Regulations That Significantly Affect Energy Supply, Distribution, or Use
VI. Additional Information

I. Background

On July 27, 2004, the FAA issued the ''Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft'' final rule (69 FR 44772). That rule established the certification and qualification requirements for sport pilots and flight instructors with a sport pilot rating in part 61. The rule also established requirements for the certification, operation, maintenance, and manufacture of light-sport aircraft. Since the adoption of that rule, the FAA has been evaluating the process for certificating pilots and flight instructors conducting operations in light-sport aircraft and has determined that changes to these certification requirements are necessary to align the certification requirements for sport pilots and flight instructors with a sport pilot rating with those requirements currently applicable to other airmen certificates and to better serve the sport pilot and light-sport aircraft community. Through experience gained by the FAA inspector workforce and information provided by organizations and individual aircraft owners in the light-sport community, the agency believes it has a critical understanding of where the 2004 rule may not adequately reflect the needs of the flying community or may not provide sufficient regulatory oversight.

II. Discussion of the Proposed Regulatory Requirements

II. A. Overview

As stated in the preamble of the 2004 final rule, the FAA adopted the regulations ''to allow individuals to experience sport and recreational aviation in a manner that is safe for the intended operations, but not overly burdensome'' (69 FR 44774; July 27, 2004). The FAA remains committed to this philosophy.

Since the implementation of the 2004 final rule, the FAA's Light-Sport Aviation Branch inspector workforce has had informal discussions with organizations and individuals in the light-sport community about the rule's effectiveness. As a result of these discussions, and through experience gained in administering the 2004 final rule, the FAA has reviewed the current regulations and believes that some provisions are unnecessary or redundant and should be modified. The agency has identified a number of areas where it believes it can provide relief to the light-sport community without compromising safety. These include—

- Removing all requirements applicable to ''sets of aircraft,'' to include all requirements for specific endorsements to operate an aircraft within a particular set of aircraft;
- Removing the requirement for all sport pilot flight instructors to log at least 5 hours of flight time in a particular make and model of light-sport aircraft before providing training in the same set of aircraft;
- Eliminating the current requirement for flight training at an airport with an operating control tower to be in a powered parachute or weight-shift-control aircraft for those persons seeking privileges to operate those aircraft;
- Eliminating the requirement for sport pilots to be trained in the use of radios for VFR navigation and communication when the aircraft intended to be used by the pilot is not equipped with such instruments;
- Lowering of the amount of hours of flight training that an applicant for a sport pilot certificate must log within 60 days prior to taking the practical test;
- Eliminating provisions that would require a person exercising sport pilot privileges and flight instructors with a sport rating to carry his or her logbook while in flight;
- Permitting a person exercising sport pilot privileges to fly above 10,000 feet MSL when that altitude is less than 2,000 feet above the surface and proposing less restrictive requirements for the operation of powered parachutes and weight-shift-control aircraft in other than congested areas;
- Permitting private pilots to receive compensation for production flight testing of powered parachutes or weight-shift-control aircraft;
- Removing the current requirement for experimental aircraft certificated in the light-sport category to comply with the applicable maintenance and preventive maintenance requirements of part 43 when those aircraft have been previously issued a special airworthiness certificate in the light-sport category; and
- Providing for the use of aircraft with a special airworthiness certificate in the light-sport category in training courses approved under part 141.

In addition, the FAA's inspector workforce has observed an apparent lack of standardization in the administration of practical tests leading to the issuance of category and class privileges for sport pilot applicants. This lack of standardization has resulted in the FAA's experiencing difficulties in obtaining documentation that those practical tests were successfully completed. When documentation that a person has been awarded privileges to operate a specific category and class of aircraft is not on file with the FAA, it may be difficult for that person to demonstrate that those privileges have been awarded, especially if that person's logbook is lost, destroyed, or unavailable. The agency, therefore, is proposing to—

- Replace sport pilot privileges with aircraft category and class ratings on all pilot certificates;
- Replace flight instructor privileges with aircraft category ratings on all flight instructor certificates; and
- Remove current provisions for the conduct of proficiency checks by flight instructors and include provisions for the issuance of category and class ratings by designated pilot examiners.

By placing privileges to operate a category and class of aircraft as a rating on a person's sport pilot certificate, the FAA would provide sport pilots with enhanced recognition of their skills and better integrate them into the wider aviation community. This action may not only facilitate further growth in the light-sport industry but may also lead to broader international recognition of these certificates.

Lastly, after review of the current regulations, the FAA is proposing the following changes, which the agency believes are necessary to enhance safety—

- Require one hour of flight training on the control and maneuvering of an aircraft solely by reference to

instruments for sport pilots operating airplanes with a V_H greater than 87 knots CAS and also for student pilots seeking a sport pilot certificate to operate an airplane with a V_H greater than 87 knots CAS because operators of these aircraft are more likely to encounter instrument meteorological conditions than operators of other categories of aircraft;

• Require a specific endorsement for sport pilots and student pilots seeking a sport pilot certificate for the operation of a powered parachute with an elliptical wing and for an aircraft with a V_H less than or equal to 87 knots CAS in order to retain current safety requirements that would be deleted if the FAA adopts the proposal to remove the requirement that persons exercising sport pilot privileges have an aircraft make-and-model endorsement to operate a specific set of aircraft; and

• Require that aircraft owners/operators retain a record of the current status of applicable safety directives for special light-sport aircraft, which, upon further consideration, the FAA believes would close a gap in the 2004 rule.

These and other proposed amendments are discussed in further detail below.

The FAA notes that some sections the FAA is proposing to be amended in this NPRM were also proposed to be amended in a separate rulemaking action, ''Pilot, Flight Instructor, and Pilot School Certification,'' published in the **Federal Register** on February 7, 2007. That February 7, 2007, NPRM, however, did not address sport pilot issues. The specific sections proposed to be revised by this NPRM may therefore be further revised in the final rule if the amendments proposed by the February 7, 2007 rulemaking action become final prior to the proposals contained in this NPRM.

II.B. Discussion of Specific Proposals

This proposed rule would—

1. Replace sport pilot privileges with aircraft category and class ratings on all pilot certificates.

2. Replace sport pilot flight instructor privileges with aircraft category ratings on all flight instructor certificates.

3. Remove current provisions for the conduct of proficiency checks by flight instructors and include provisions for the issuance of category and class ratings by designated pilot examiners.

4. Place all requirements for flight instructors under a single subpart (subpart H) of part 61.

5. Require 1 hour of flight training on the control and maneuvering of an airplane solely by reference to instruments for student pilots seeking a sport pilot certificate to operate an airplane with a V_H greater than 87 knots CAS and sport pilots operating airplanes with a V_H greater than 87 knots CAS.

6. Remove the requirement for persons exercising sport pilot privileges and flight instructors with a sport pilot rating to carry their logbooks while in flight.

7. Remove the requirement that persons exercising sport pilot privileges have an aircraft make-and-model endorsement to operate a specific set of aircraft while adding specific regulatory provisions for endorsements for the operation of powered parachutes with elliptical wings and aircraft with a V_H less than or equal to 87 knots CAS.

8. Remove the requirement for all flight instructors to log at least 5 hours of flight time in a make and model of light-sport aircraft before providing training in any aircraft from the same set of aircraft in which that training is given.

9. Permit persons exercising sport pilot privileges and the privileges of a student pilot seeking a sport pilot certificate to fly up to an altitude of not more than 10,000 feet mean sea level (MSL) or 2,000 feet above ground level (AGL), whichever is higher.

10. Permit private pilots to receive compensation for production flight testing powered parachutes and weight-shift-control aircraft intended for certification in the light-sport category under § 21.190.

11. Revise student sport pilot solo cross-country navigation and communication flight training requirements.

12. Clarify cross-country distance requirements for private pilots seeking to operate weight-shift-control aircraft.

13. Revise aeronautical experience requirements at towered airports for persons seeking to operate a powered parachute or weight-shift-control aircraft as a private pilot.

14. Remove the requirement for pilots with only a powered parachute or a weight-shift-control aircraft rating to take a knowledge test for an additional rating at the same certificate level.

15. Revise the amount of hours of flight training an applicant for a sport pilot certificate must log within 60 days prior to taking the practical test.

16. Remove expired ultralight transition provisions and limit the use of aeronautical experience obtained in ultralight vehicles.

17. Add a requirement for student pilots to obtain endorsements identical to those proposed for sport pilots in §§ 61.324 and 61.327.

18. Clarify that an authorized instructor must be in a powered parachute when providing flight instruction to a student pilot.

19. Remove the requirement for aircraft certificated as experimental aircraft in the light-sport category to comply with the applicable maintenance and preventive maintenance requirements of part 43 when those aircraft have been previously issued a special airworthiness certificate in the light-sport category.

20. Require aircraft owners or operators to retain a record of the current status of applicable safety directives for special light-sport aircraft.

21. Provide for the use of aircraft with a special airworthiness certificate in the light-sport category in training courses approved under part 141.

22. Revise the minimum safe-altitude requirements for powered parachutes and weight-shift-control aircraft.

II.B.1. Replace sport pilot privileges with aircraft category and class ratings on all pilot certificates (§§ 61.1, 61.3, 61.5, 61.7, 61.23, 61.31, 61.51, 61.52, 61.63, 61.87, 61.303, 61.309, 61.311, 61.313, 61.317, and 61.321)

Currently, to obtain additional aircraft category and class privileges at the sport pilot level, the holder of a pilot certificate must complete a proficiency check administered by an authorized instructor. Upon successful completion of that proficiency check, that person receives a logbook endorsement from the instructor who administered the proficiency check. That endorsement permits the person completing the proficiency check to exercise sport pilot privileges in the category and class of aircraft in which the proficiency check was administered.

Consistent with the FAA's system for issuing all other pilot certificates and ratings, the FAA is proposing to require a person seeking privileges to operate an additional category and class of light-sport aircraft as a sport pilot to obtain the appropriate category and class rating. These ratings would be issued after the completion of a practical test typically administered by an FAA-designated pilot examiner (DPE). The practice of obtaining privileges to operate a light-sport aircraft after completion of a proficiency check by an authorized instructor would be discontinued. Privileges to operate light-sport aircraft would be indicated as ratings on a person's pilot certificate rather than by an endorsement in a person's logbook.

As a result of experience gained in administering the July 2004 final rule, the FAA recognizes that authorized instructors are generally not trained to

administer tests leading to the issuance of certificate privileges, and that the FAA does not have procedures in place (such as those used for DPEs) to oversee that activity. Currently, authorized instructors are not required to receive training in the administration of proficiency checks or practical tests; however, DPEs tasked with administering practical tests normally complete a course consisting of 40 hours of initial training prior to receiving their designation as pilot examiners. These examiners are directly supervised by an aviation safety inspector and must complete recurrent training consisting of a 10-hour online course and 4 hours of individual training in addition to completing a flight evaluation from an aviation safety inspector every year prior to renewal of their designation. A DPE's designation can be terminated if the FAA determines that person cannot administer a practical test in accordance with the Practical Test Standards (PTS).

Under the current system of administering proficiency checks, authorized instructors are not directly supervised by any FAA personnel. The FAA cannot (absent certificate action) restrict the ability of an authorized instructor to administer a proficiency check leading to the issuance of additional sport pilot privileges, even if the performance of the authorized instructor in administering proficiency checks is substandard. Additionally, the FAA is experiencing difficulties in obtaining documentation from authorized instructors indicating that proficiency checks have been successfully completed. These difficulties significantly hinder the ability of a person to demonstrate that privileges to operate a specific category and class of aircraft have been awarded if that person's logbook containing the appropriate endorsements for the operation of that category and class of aircraft is lost, destroyed, or otherwise unavailable.

Issuance of sport pilot certificates with category and class ratings would conform to the procedures for the issuance of other pilot certificates and standardizes the manner in which additional privileges are granted. The proposal would place no additional burden on current holders of sport pilot (or other) certificates with category and class privileges obtained through instructor endorsements, provided that the FAA has a record of those endorsements. To facilitate compliance with the rule, the FAA would reissue pilot certificates with the category and class ratings corresponding to the privileges previously granted through instructor endorsements. Persons receiving these certificates would have to take no action to accomplish the exchange of their pilot certificates.

If the FAA does not have a record that a pilot has been granted privileges through an instructor endorsement, that pilot would have to complete an airman certificate and/or rating application (FAA Form 8710–11) and present it, along with evidence of the endorsement, to a designated pilot examiner or FAA inspector, and the FAA would then issue that person a certificate with corresponding category and class ratings. For some individuals, this may result in travel time and transportation cost if there is no closely located DPE or Flight Standards District Office (FSDO). Persons intending to exercise the privileges of their current pilot certificates granted through an endorsement would be required to obtain a new pilot certificate with corresponding category and class ratings within 2 years of the effective date of the final rule.

In addition, the PTS for the sport pilot certificate would not be revised to introduce any requirements as a result of this proposed change. The proposal would place no burden on current holders of these certificates, as the FAA would adopt a procedure for certificate replacement.

II.B.2. Replace sport pilot flight instructor privileges with aircraft category ratings on all flight instructor certificates (§§ 61.181, 61.183, 61.185, 61.187, 61.191, 61.195, and part 61 subpart K)

For reasons similar to those discussed immediately above, the FAA is proposing to require a person holding a flight instructor certificate with a sport pilot rating to obtain sport pilot instructor ratings indicating appropriate category and class privileges. These new ratings would be specifically listed on that person's flight instructor certificate. This change would also apply to flight instructors with other than a sport pilot rating who have privileges to provide instruction in light-sport aircraft obtained through an instructor endorsement. Currently, for a flight instructor to obtain privileges to provide instruction leading to the issuance of a sport pilot certificate in an additional category or class of light-sport aircraft, or to the issuance of a private pilot certificate in a powered parachute or a weight-shift-control aircraft, the holder of that certificate must complete a proficiency check administered by an authorized instructor. Upon successful completion of that proficiency check, that person receives a logbook endorsement from the instructor who administered the proficiency check. That endorsement permits the person completing the proficiency check to provide instruction as a flight instructor with a sport pilot rating in the category and class of aircraft in which the proficiency check was administered.

Consistent with the FAA's system for issuing ratings for other flight instructor certificates, the FAA proposes that a flight instructor seeking to provide training to operate an additional category and class of a light-sport aircraft obtain appropriate category and class ratings. Those ratings would be specifically listed on that person's flight instructor certificate. These ratings would be issued after the completion of a practical test administered by a DPE. The practice of obtaining privileges to provide training in a light-sport aircraft after completion of a proficiency check by an authorized instructor would be discontinued. Privileges to provide training in these light-sport aircraft would be indicated as ratings on that person's flight instructor certificate rather than as an endorsement in that person's logbook.

As stated in II.B.1., authorized instructors are neither trained to administer tests leading to the issuance of certificate privileges nor directly supervised by FAA personnel. The FAA is also experiencing difficulties in obtaining documentation from authorized instructors when administering proficiency checks to flight instructors seeking additional privileges.

Issuance of flight instructor certificates with sport pilot category and class ratings would generally conform to the procedures for the issuance of other ratings on the flight instructor certificate and standardize the manner in which additional flight instructor privileges are granted. The proposal would place no additional burden on current holders of flight instructor certificates with a sport pilot rating or other instructors with flight instructor privileges issued through an instructor endorsement, provided that the FAA has a record of these endorsements. To facilitate compliance with the rule, the FAA would reissue flight instructor certificates with the category and class ratings corresponding to the privileges previously granted through instructor endorsements. This action would occur at the time the flight instructor applies for renewal or reinstatement of his or her flight instructor certificate, which may occur as much as 27 calendar months after the effective date of the rule. If the FAA does not have a record that a flight instructor with a sport pilot rating has been granted privileges

through an instructor endorsement, that flight instructor would have to complete an airman certificate and/or rating application (FAA Form 8710–11) and present it, along with evidence of the endorsement, to a designated pilot examiner or FAA inspector. The FAA would then issue that person a flight instructor certificate with corresponding sport pilot category and class ratings. For some individuals, this may result in travel time and transportation cost if there is no closely located DPE or FSDO.

To limit the burden placed on future applicants for a flight instructor certificate with a sport pilot rating, the FAA would retain the provisions of current § 61.419, which do not require an applicant who seeks to obtain privileges to provide training in an additional category or class of light-sport aircraft to take an additional knowledge test. These provisions would be codified in proposed § 61.191(c), which would not require a person who applies for an additional sport pilot rating on a flight instructor certificate to pass a knowledge test on the areas listed in proposed § 61.185(a)(2)(ii).

II.B.3. Remove current provisions for the conduct of proficiency checks by authorized flight instructors and include provisions for the issuance of category and class ratings by designated pilot examiners (§ 61.413)

At this time, flight instructors with a sport pilot rating may perform proficiency checks leading to the issuance of privileges equivalent to those of ratings. These checks are performed without any additional training, and the FAA has observed that there is little standardization in the administration of these checks and the completion of the documentation necessary for the issuance of additional sport pilot privileges. Flight instructors receive no training in the administration of proficiency checks and their actions in conducting these tests are not supervised or reviewed by the FAA.

To correct these deficiencies, the FAA is proposing to remove § 61.413(i) to no longer permit flight instructors to administer proficiency checks leading to the issuance of sport pilot privileges. Privileges currently obtained in this manner would be replaced with privileges obtained through the issuance of a rating issued by a DPE specifically trained to administer practical tests.

II.B.4. Place all requirements for flight instructors under a single subpart (subpart H) of part 61 (Part 61 subpart H heading, §§ 61.5, 61.181, 61.183, 61.185, 61.186, 61.187, 61.189, 61.191, 61.193, 61.195, 61.197, 61.199, and §§ 61.401 through 61.431)

The FAA is proposing to move the requirements for flight instructors with a sport pilot rating currently found in part 61 subpart K (§§ 61.401 through 61.431) to current part 61 subpart H. All flight instructor requirements would be located in one subpart. This action would standardize certification requirements for all flight instructors. The FAA recognizes that many of the requirements contained in subpart K for flight instructors with a sport pilot rating are identical to those contained in subpart H for flight instructors with other ratings. If the proposed changes for flight instructors currently certificated under subpart K are adopted, the privileges and limitations of those flight instructors and the methods by which they are certificated would be so similar to those of flight instructors currently certificated under subpart H that separate subparts for the certification of all flight instructors would no longer be necessary. The FAA believes that eliminating redundancies caused by the retention of two separate subparts would clarify requirements applicable to all flight instructors. This change would significantly reduce confusion experienced by the flight instructor community, especially among those flight instructors currently certificated under subpart H who intend to provide training to persons seeking sport pilot certificates. In addition, the change would provide all flight instructors with a single source of information for their certification requirements and the privileges and limitations applicable to their certificates.

The following table shows the proposed relocation of the subpart K requirements to subpart H.

Subpart K—Flight instructors with a sport pilot rating	Subpart H—Flight instructors other than flight instructors with a sport pilot rating
Subpart heading—Removed	Subpart heading revised.
§ 61.401 What is the purpose of this subpart?	§ 61.181 Applicability.
§ 61.403 What are the age, language, and pilot certificate requirements for a flight instructor certificate with a sport pilot rating?	§ 61.183 Eligibility requirements.
§ 61.405 What tests do I have to take to obtain a flight instructor certificate with a sport pilot rating?	§ 61.183(f) Eligibility requirements.
§ 61.407 What aeronautical knowledge must I have to apply for a flight instructor certificate with a sport pilot rating?	§ 61.185 Aeronautical knowledge.
§ 61.409 What flight proficiency requirements must I meet to apply for a flight instructor certificate with a sport pilot rating?	§ 61.187 Flight proficiency.
§ 61.411 What aeronautical experience must I have to apply for a flight instructor certificate with a sport pilot rating?	§ 61.186 Aeronautical experience requirements for persons applying for a flight instructor certificate with a sport pilot rating.
§ 61.413 What are the privileges of my flight instructor certificate with a sport pilot rating?	§ 61.193 Flight instructor privileges.
§ 61.415 What are the limits of my flight instructor certificate with a sport pilot rating?	§ 61.195 Flight instructor limitations and qualifications.
§ 61.417 Will my flight instructor certificate with a sport pilot rating list aircraft category and class ratings?	§ 61.5 Certificates and ratings issued under this part.
§ 61.419 How do I obtain privileges to provide training in an additional category or class of light-sport aircraft?	§ 61.191 Additional flight instructor ratings.
§ 61.421 May I give myself an endorsement?	§ 61.195 Flight instructor limitations and qualifications.
§ 61.423 What are the recordkeeping requirements for a flight instructor certificate with a sport pilot rating?	§ 61.189 Flight instructor records.
§ 61.425 How do I renew my flight instructor certificate?	§ 61.197 Renewal of flight instructor certificates.
§ 61.427 What must I do if my flight instructor certificate with a sport pilot rating expires?	§ 61.199 Expired flight instructor certificates and ratings.
§ 61.429 May I exercise the privileges of a flight instructor certificate with a sport pilot rating if I hold a flight instructor certificate with another rating?	§§ 61.189 Flight instructor records, 61.193 Flight instructor privileges, and 61.195 Flight instructor limitations and qualifications.

Subpart K—Flight instructors with a sport pilot rating	Subpart H—Flight instructors other than flight instructors with a sport pilot rating
§ 61.431 Are there special provisions for obtaining a flight instructor certificate with a sport pilot rating for persons who are registered ultralight instructors with an FAA-recognized ultralight organization?	Removed.

II.B.5. Require 1 hour of flight training on the control and maneuvering of an airplane solely by reference to instruments for student pilots seeking a sport pilot certificate to operate an airplane with a V_H greater than 87 knots CAS and sport pilots operating airplanes with a V_H greater than 87 knots CAS (§§ 61.89, 61.93, and 61.327)

Current regulations require student pilots seeking a sport pilot certificate to receive and log flight training in the control and maneuvering of an aircraft solely by reference to flight instruments. This training must be received before conducting a solo cross-country flight or any flight greater than 25 nautical miles from the airport from where the flight originated. It also must be received prior to making a solo flight and landing at any location other than the airport of origination. These requirements are detailed in § 61.93 and are applicable to persons seeking a student pilot certificate to operate any category and class of aircraft. That section, however, does not specify any minimum flight training time to meet these requirements. In addition, current regulations for the issuance of a sport pilot certificate do not require an applicant to receive flight training on the control and maneuvering of any aircraft solely by reference to instruments.

The FAA is concerned that persons exercising student or sport pilot privileges in airplanes with a maximum airspeed in level flight with maximum continuous power (V_H) greater than 87 knots calibrated airspeed (CAS) may inadvertently encounter conditions less than those specified for VFR operations due to their greater speed and range. Operators of these aircraft are more likely to encounter instrument meteorological conditions than operators of other categories of aircraft. In order to enhance the ability of these pilots to appropriately react to the possibility of encountering instrument meteorological conditions and the potential consequences of attempting continued visual flight rule (VFR) flight in instrument meteorological conditions, the FAA is proposing to require persons operating an airplane with a V_H greater than 87 knots CAS to receive and log 1 hour of flight training on the control and maneuvering of an aircraft solely by reference to instruments.

The FAA recognizes that persons may currently be authorized to operate aircraft with a V_H greater than 87 knots CAS. To provide those persons with a reasonable period of time to obtain this training, the agency is proposing that the training be completed by 1 year after the effective date of the final rule. This training would include straight and level flight, climbs and descents, turns to a heading, and recovery from unusual flight attitudes. Due to the slower speeds and limited capabilities of categories and classes of aircraft other than airplanes, the FAA is not proposing that this requirement be extended to operators of those categories and classes of aircraft and airplanes with a V_H less than or equal to 87 knots CAS. The FAA notes that for training to be conducted solely by reference to instruments in visual meteorological conditions, it must be conducted with a view-limiting device.

II.B.6. Remove the requirement for persons exercising sport pilot privileges and flight instructors with a sport pilot rating to carry their logbooks while in flight (§ 61.51)

The FAA is proposing to remove the requirements in § 61.51(i)(3) and (i)(5) for persons exercising sport pilot privileges and flight instructors with a sport pilot rating to carry their logbooks while in flight. Because the FAA is proposing to issue category and class ratings for sport pilots, the requirement for a sport pilot to carry a logbook or other evidence of required authorized instructor endorsements would no longer be necessary. Similarly, because the FAA is also proposing to issue sport pilot ratings for flight instructors, the requirement for a flight instructor to carry a logbook or other evidence of required endorsements would no longer be necessary.

All pilots and flight instructors are required to have their certificates in their physical possession or readily accessible in the aircraft when exercising the privileges of that certificate. Because ratings are listed on pilot and flight instructor certificates, the proposal, if adopted, would enable the FAA to determine that a pilot or flight instructor was properly rated to operate or provide instruction in an aircraft without the need to examine that person's logbook or other documentation. Any additional endorsements required for a person to exercise sport pilot privileges need not be in that person's physical possession or readily accessible in the aircraft; however, a person must present those required records for inspection upon a reasonable request, as required by § 61.51(i).

Because all pilots and flight instructors will not have certificates reflecting the new ratings until 27 months after the effective date of the proposed provisions, the FAA would not implement the provisions of this section until after that time.

II.B.7. Remove the requirement that persons exercising sport pilot privileges have an aircraft make-and-model endorsement to operate a specific set of aircraft while adding specific regulatory provisions for endorsements for the operation of powered parachutes with elliptical wings and aircraft with a V_H less than or equal to 87 knots CAS (§§ 61.315, 61.319, 61.324, and 61.327)

To operate any aircraft within a set of aircraft, a person exercising sport pilot privileges must have a logbook endorsement from an authorized flight instructor for a specific category, class, and make and model of aircraft within that set of light-sport aircraft. This requirement is specified in current § 61.319, and the procedure for obtaining the endorsement is found in § 61.323. At the time the rules were adopted, the FAA believed that grouping makes and models of light-sport aircraft that have similar performance and operating characteristics as a set of aircraft was an effective means to permit persons exercising sport pilot privileges to operate any aircraft within that set once an endorsement to operate any aircraft within that set had been received.

In implementing the 2004 final rule, the FAA developed standards for defining and establishing sets of aircraft. Sets of aircraft were developed for airplanes, weight-shift-control aircraft, powered parachutes, gyroplanes, and lighter-than-air aircraft. Airplanes, for example, were grouped into eight specific sets, with four specific sets for airplanes with a V_H less than or equal to 87 knots (tricycle gear, tailwheel, ski-

equipped, and float-equipped), and four identical sets for airplanes with a V_H greater than 87 knots. The FAA has used this concept of grouping aircraft having similar operating characteristics successfully in the National Designated Pilot Examiner Registry (NDPER) program for training and checking pilots operating warbirds and other vintage aircraft. The FAA believed that incorporating a requirement for a specific endorsement based on a set of aircraft would ensure that any person exercising sport pilot privileges would receive additional flight training appropriate to the aircraft in which operations would be conducted.

When the various sets of aircraft were being developed to implement the 2004 rule, the FAA required specific endorsements for a person to operate an aircraft within a set. For example, for a sport pilot to operate a powered parachute with an elliptical wing or an aircraft with a V_H at or below 87 knots, that person must obtain a make-and-model endorsement for that set of aircraft. In addition, a specific endorsement is currently required to operate aircraft with a V_H greater than 87 knots. A specific endorsement is also required to operate an aircraft equipped with a tailwheel. A proficiency check also is required to operate an airplane—single-engine land or airplane—single-engine sea. Due to the duplicative nature of currently required endorsements and proficiency checks, the FAA has determined that a specific requirement for a make-and-model endorsement to operate any aircraft within a set of aircraft is redundant, and that safety concerns can be adequately addressed using existing endorsements and the additional endorsements set forth in this NPRM.

The FAA is therefore proposing to add § 61.315(c)(20) to specify that the holder of a sport pilot certificate with a powered parachute rating may not act as pilot in command of a light-sport aircraft that is a powered parachute with an elliptical wing unless that holder has met the endorsement requirements proposed in § 61.324. Additionally, the FAA is also proposing to revise § 61.315(c)(14) to require the holder of a sport pilot certificate with any category and class rating to meet the endorsement requirements proposed in § 61.327. That section would require the holder of a sport pilot certificate seeking to operate a light-sport aircraft that has a V_H less than or equal to 87 knots CAS to receive and log ground and flight training from an authorized instructor. A person receiving that training would also be required to receive a logbook endorsement from the authorized instructor who provided that training certifying that he or she is proficient in the operation of those aircraft. The current endorsement to operate a light-sport aircraft with a V_H greater than 87 knots CAS would be retained.

The FAA believes that deleting the requirement for set-of-aircraft endorsements while having specific regulatory provisions for sport pilots to obtain endorsements to operate powered parachutes with an elliptical wing, aircraft with a V_H less than or equal to 87 knots CAS, and aircraft with a V_H greater than 87 knots CAS would eliminate redundant endorsement requirements and provide a level of safety equivalent to that found in the current regulation. The FAA recognizes that pilots may currently be authorized to operate powered parachutes with an elliptical wing and aircraft with a V_H less than or equal to 87 knots without the endorsements specified in the proposal. The proposal would not require persons with pilot-in-command time in these aircraft prior to the effective date of the final rule to obtain these endorsements.

II.B.8. Remove the requirement for all flight instructors to log at least 5 hours of flight time in a make and model of light-sport aircraft before providing training in any aircraft from the same set in which that training is given (§ 61.415)

The FAA is proposing to eliminate the requirement in § 61.415(e) for flight instructors exercising the privileges of a sport pilot rating to have logged 5 hours of flight time in order to provide flight instruction in a make and model aircraft within a specific set of aircraft. The FAA has determined that the aeronautical experience requirements for the issuance of a flight instructor certificate with a sport pilot rating and the endorsements necessary to exercise those privileges are sufficient for an instructor to safely provide flight instruction in any aircraft for which that instructor has privileges. If an appropriately rated flight instructor has the required endorsements to operate a specific aircraft, the FAA believes that an additional requirement to obtain 5 hours of aeronautical experience imposes an unnecessary burden on the flight instructor and should not be required to safely provide instruction in that aircraft. The requirement for a flight instructor to log additional aeronautical experience based on the specific set of aircraft in which the person intends to provide instruction would also no longer be necessary if the proposal to eliminate the requirement in § 61.319 for a person exercising sport pilot privileges to have a make and model endorsement to operate any aircraft within a specific set of aircraft is adopted.

II.B.9. Permit persons exercising sport pilot privileges and the privileges of a student pilot seeking a sport pilot certificate to fly up to an altitude of not more than 10,000 feet MSL or 2,000 feet AGL, whichever is higher (§§ 61.89 and 61.315)

Section 61.89 describes the general limitations for student pilots. Paragraph (c)(3) of that section states that a student pilot seeking a sport pilot certificate may not act as pilot in command of an aircraft at an altitude of more than 10,000 feet mean sea level (MSL). Section 61.315(c)(11) places the same limitation on sport pilots. The FAA is proposing to revise §§ 61.89(c)(3) and 61.315(c)(11) by adding the words ''or 2,000 feet AGL [above ground level], whichever is higher.'' This revision would allow sport pilots and student pilots seeking a sport pilot certificate to operate in mountainous areas higher than 10,000 feet MSL when such operations are less than 2,000 feet AGL. The FAA believes that the current regulations unnecessarily burden sport pilots and students seeking sport pilot certificates who operate light-sport aircraft in areas of high elevation. These operations can be performed safely because student pilots seeking a sport pilot certificate and sport pilots are currently trained in proper preflight preparation procedures, which include training in aeromedical factors, such as the effects of hypoxia. In addition, these pilots receive training in reduced aircraft performance at high-density altitudes and in the effect of operations at higher altitudes. These pilots are required to demonstrate knowledge of these factors during the practical test.

Additionally, many of the new light-sport aircraft are capable of operating above 10,000 feet MSL. By providing sport pilots with the ability to better utilize the capabilities of these aircraft and operate at higher altitudes in mountainous terrain, the proposed revision should assist in reducing the risks associated with mountain flying. By restricting operations above 10,000 feet MSL to no more than 2,000 feet AGL, sport pilots operating light-sport aircraft should not impose a hazard to high-performance aircraft that routinely operate at higher altitudes.

II.B.10. Permit private pilots to receive compensation for production flight testing of powered parachutes and weight-shift-control aircraft intended for certification in the light-sport category in § 21.190 (§ 61.113)

The FAA is proposing to add § 61.113(h) to allow a private pilot to act as pilot in command for compensation or hire when conducting a production flight test in a powered parachute or a weight-shift-control aircraft intended for certification in the light-sport category under § 21.190.

The 2004 final rule created two new categories of aircraft-powered parachutes and weight-shift-control aircraft. The final rule also permitted the manufacture of these aircraft for certification in the light-sport category under § 21.190. During the manufacturing process, these aircraft must undergo a production flight test. For other categories of aircraft, these production flight tests are carried out by persons with at least a commercial pilot certificate who can receive compensation for the conduct of this activity. The final rule, however, did not create ratings at the commercial pilot level for these two new categories of aircraft. Since private pilots under the current rule cannot receive compensation when conducting production flight tests, the regulations currently do not provide a means for a pilot conducting production flight tests of powered parachutes or weight-shift-control aircraft to be compensated for that activity. The FAA recognizes both the need for production flight tests of these aircraft and the fact that persons conducting these flight tests may be compensated. The proposal therefore would provide a means for appropriately rated pilots with sufficient experience to conduct these flight tests for compensation or hire. The FAA maintains that these operations should be conducted by a person who holds at least a private pilot certificate with the appropriate category and class rating. As reflected in current operating limitations for special light-sport aircraft, the FAA believes that pilots conducting a production flight test should have a minimum of 100 hours pilot-in-command time in the same category of aircraft as that undergoing a production flight test.

The provisions of this rule would only apply to powered parachutes and weight-shift-control aircraft intended for certification under § 21.190. It would not permit private pilots to be compensated for conducting test flights of other aircraft that are not intended for certification under § 21.190 (e.g., experimental amateur-built aircraft that meet the definition of ''light-sport aircraft'' or aircraft intended for certification as experimental light-sport aircraft under § 21.191(i)).

II.B.11. Revise student sport pilot solo cross-country navigation and communication flight training requirements (§ 61.93)

The FAA is proposing to amend § 61.93(e)(9), (e)(12), (h)(9), (k)(9), and (k)(11) regarding maneuvers and procedures for cross-country flight training in a single-engine airplane, a gyroplane, and an airship. The amendment would except student pilots seeking a sport pilot certificate from the requirement to receive and log flight training on the use of radios for VFR navigation and two-way communications, unless this equipment is installed in the aircraft used for the solo cross-country flight. In addition, the amendment would except student pilots seeking a sport pilot certificate from the requirement to receive and log flight training on control and maneuvering solely by reference to flight instruments, unless operating an airplane with a V_H greater than 87 knots CAS. Since sport pilots are not required to be trained in the use of radios for VFR navigation, two-way communications, and flight by reference to instruments, the FAA has determined that student pilots seeking a sport pilot certificate should not be required to receive training in those maneuvers and procedures unless operating an airplane with a V_H greater than 87 knots CAS.

II.B.12. Clarify cross-country distance requirements for private pilots seeking to operate weight-shift-control aircraft (§ 61.109)

Currently § 61.109(j)(2)(i) specifies that a person applying for a private pilot certificate with a weight-shift-control rating must log ''one cross-country flight over 75 nautical miles total distance'' at night with an authorized instructor. Although paragraph (j)(2)(i) uses the term ''cross-country flight,'' persons applying for this rating frequently have overlooked the provisions of § 61.1(b)(3)(ii)(B), which states that for purposes of meeting the aeronautical experience requirements for a private pilot certificate with a weight-shift-control rating, cross-country time includes a point of landing at least a straight-line distance of more than 50 nautical miles from the original point of departure. To ensure that persons applying for a private pilot certificate with a weight-shift-control rating complete a cross-country flight that meets the requirements of both §§ 61.1 and 61.109(j), the FAA is proposing to add language in § 61.109(j), consistent with § 61.1, to indicate that the cross-country flight must include a point of landing that is a straight-line distance of more than 50 nautical miles from the original point of departure. The proposal merely clarifies the existing regulation and would not add any new requirement.

II.B.13. Revise the aeronautical experience requirements at towered airports for persons seeking to operate a powered parachute or weight-shift-control aircraft as a private pilot (§ 61.109)

The FAA is proposing to revise the aeronautical experience requirements for a private pilot certificate with a powered parachute rating in § 61.109(i)(4)(ii) and for a weight-shift-control aircraft rating in § 61.109(j)(4)(iii). These paragraphs currently state that training for powered parachute and weight-shift-control aircraft ratings must include at least 3 takeoffs and landings (with each landing involving a flight in a traffic pattern) at an airport with an operating control tower. These paragraphs also require that the takeoffs and landings be performed in the specific category of aircraft for which a rating is sought while in solo flight. The FAA is proposing to permit these takeoffs and landings to be performed in any category of aircraft and in either solo or dual flight.

Currently, many persons seeking to obtain ratings in powered parachutes or weight-shift-control aircraft experience difficulty in conducting operations at tower-controlled airports. These aircraft frequently experience difficulty operating in the traffic pattern with other categories and classes of aircraft due to their slower speeds, flight characteristics, and operating limitations. This proposal would allow persons seeking these ratings to conduct operations at tower-controlled airports without the burden of having to conduct these operations in a powered parachute or weight-shift-control aircraft while in solo flight. This proposal would provide applicants with additional flexibility in obtaining the aeronautical experience necessary to conduct operations at tower-controlled airports. An applicant would not only be permitted to obtain the necessary aeronautical experience in the category of aircraft for which a rating is sought while in solo flight, but also in dual flight in any category of aircraft.

II.B.14. Remove the requirement for pilots with only powered parachute and weight-shift-control aircraft ratings to take a knowledge test for an additional rating at the same certificate level (§ 61.63)

The FAA is proposing to amend § 61.63(b)(5) and (c)(5) to permit persons who hold powered parachute and weight-shift-control aircraft category ratings to apply for a pilot certificate with an additional category or class rating without taking an additional knowledge test. Knowledge tests for applicants for category or class ratings for powered aircraft at the same certificate level address identical aeronautical knowledge areas. Persons who hold a category rating for a powered aircraft (other than powered parachutes and weight-shift-control aircraft) are not currently required to take a knowledge test when applying for an additional category or class rating for a powered aircraft at their certificate level.

The 2004 final rule created two additional categories and classes of powered aircraft. In that rule, applicants who hold category ratings for powered parachutes or weight-shift-control aircraft seeking additional category and class ratings were not provided the same relief as that provided to persons who hold category and class ratings for other powered aircraft. The FAA is therefore proposing to amend § 61.63 to provide applicants who hold category ratings for powered parachutes or weight-shift-control aircraft with this relief.

II.B.15. Revise the amount of hours of flight training an applicant for a sport pilot certificate must log within 60 days prior to taking the practical test (§ 61.313)

Current § 61.313 requires an applicant for a sport pilot certificate to log at least ''3 hours of flight training on those areas of operation specified in § 61.311 preparing for the practical test, within 60 days before the date of the test.'' In developing the aeronautical experience requirements for the issuance of the sport pilot certificate, the FAA based this requirement on the corresponding aeronautical experience requirements for the issuance of higher-level pilot certificates. Those certificates, however, require applicants to log more flight time than is required for the issuance of a sport pilot certificate and to prepare for testing on a higher number of tasks. Due to the lower number of hours required for a person to apply for a sport pilot certificate and the lower number of tasks for which preparation is necessary, the number of hours currently required to be logged within 60 days before the date of the practical test is proportionately higher than that required for other certificates. Accordingly, the FAA is proposing to reduce the number of hours that must be logged in preparation for the practical test within 60 days of that test from 3 hours to 2 hours, for aircraft other than gliders. For gliders, the FAA is proposing to reduce the aeronautical experience that must be logged in preparation for the practical test from 3 hours to 3 training flights. The FAA believes that these proposed changes would better correspond to the time required to prepare for the practical test and recognize the unique characteristics of gliders. The FAA, however, is not reducing the total number of hours required for the issuance of any category and class of sport pilot certificate.

II.B.16. Remove expired ultralight transition provisions and limit the use of aeronautical experience obtained in ultralight vehicles (§§ 61.52, 61.301, 61.309, 61.311, 61.313, 61.329, and 61.431)

Current §§ 61.329 and 61.431 describe special provisions for obtaining sport pilot certificates and flight instructor certificates with a sport pilot rating for persons who are registered with FAA-recognized ultralight organizations. These sections were intended to provide a means for pilots and flight instructors who received training from an FAA-recognized ultralight organization to transition to sport pilot certificates and flight instructor certificates with a sport pilot rating. As provided in the rules, the transition period for obtaining a sport pilot certificate expired on January 31, 2007, and the transition period for obtaining a flight instructor certificate with a sport pilot rating expired on January 31, 2008. Because January 31, 2007, and January 31, 2008, have passed, the FAA is proposing to remove § 61.329 (except for the ultralight pilot record provisions of paragraph (a)(2)(iv), which will be transferred to § 61.52) and § 61.431. In addition, the FAA intends to amend §§ 61.309, 61.311, and 61.313 to remove references to § 61.329. The reference to the expired transition provisions in § 61.301(a)(7) would also be removed.

Additionally, the proposal would revise § 61.52(a) and (b) to permit persons to use aeronautical experience obtained in ultralight vehicles to meet the requirements for certain airman certificates and ratings and also to meet the provisions of § 61.69 until January 31, 2012. The FAA originally adopted the provisions of current § 61.52 to facilitate the process for operators of ultralight vehicles to obtain airman certificates established by the 2004 rule and to meet the requirements of § 61.69. The FAA did not intend for these transition provisions to be indefinite in duration. Since operators of ultralight vehicles should have transitioned to the new airman certificates prior to the date of this proposal, or have used their aeronautical experience to meet the provisions of § 61.69, the FAA believes that retaining the provisions for the use of aeronautical experience in § 61.52 is no longer warranted. The FAA recognizes, however, that operators of ultralight vehicles may have acquired aeronautical experience in ultralight vehicles with the intent of obtaining airman certificates established by the 2004 rule, or to meet the experience requirements of § 61.69. To provide these persons with a sufficient amount of time to use this aeronautical experience to obtain the new certificates, or meet the requirements of § 61.69, the FAA is proposing a date of January 31, 2012, after which the provisions of § 61.52 may no longer be used.

II.B.17. Add a requirement for student pilots to obtain endorsements identical to those proposed for sport pilots in proposed §§ 61.324 and 61.327 (§ 61.89)

In § 61.89, the FAA is proposing to add paragraphs (c)(5) and (c)(6) to require student pilots seeking sport pilot certificates to obtain endorsements identical to those specified in proposed §§ 61.327 (to operate a light-sport aircraft based on V_H) and 61.324 (to operate a powered parachute with an elliptical wing), respectively. Currently, sport pilots are required to obtain specific endorsements for the operation of particular light-sport aircraft. These endorsements have not been required for student pilots seeking a sport pilot certificate because these student pilots are required to have a specific make-and-model endorsement for each aircraft they operate. If a student pilot does not obtain the endorsements required for holders of sport pilot certificates, the student pilot is precluded from operating the corresponding light-sport aircraft upon issuance of the sport pilot certificate. By requiring student pilots seeking a sport pilot certificate to receive these identical endorsements while exercising student pilot privileges, the FAA would ensure that newly certificated sport pilots would be able to continue to operate those aircraft in which they have exercised pilot-in-command privileges as student pilots.

II.B.18. Clarify that an authorized instructor must be in a powered parachute when providing flight instruction to a student pilot (§ 61.313)

In § 61.313(g)(1), which describes the requirements for logging aeronautical experience to obtain powered parachute category land or sea class ratings, the FAA is proposing to add the words ''from an authorized instructor in a powered parachute aircraft'' to clarify that an authorized instructor must be in the aircraft for a student pilot to log flight training time. The FAA is concerned that there is confusion in the sport pilot community whether paragraph (g)(1) allows for ''radio flight training'' (i.e., flight training when an authorized instructor is not in the aircraft), which was not the FAA's intent. The proposed change would be consistent with other provisions for logging the aeronautical experience necessary to apply for a sport pilot certificate and would clarify that all flight training must be received from an authorized instructor in flight in an aircraft, as specified in § 61.1(b)(6).

Also in § 61.313(g)(1), the FAA is changing the words ''at least 2 hours of solo flight training'' to ''at least 2 hours of solo flight time.'' The word ''training'' implies that an instructor should be in the aircraft, which is not appropriate in a solo flight time requirement.

II.B.19. Remove the requirement for aircraft certificated as experimental aircraft in the light-sport category to comply with the applicable maintenance and preventive maintenance requirements of part 43 when those aircraft have been previously issued a special airworthiness certificate in the light-sport category (§ 43.1)

Currently, aircraft that have been issued a special airworthiness certificate in the light-sport category must continue to meet the applicable maintenance and preventive maintenance requirements of part 43 when those aircraft are subsequently certificated as experimental light-sport aircraft under § 21.191(i)(3).

A manufacturer may produce a special light-sport aircraft for certification under the provisions of § 21.190 and the maintenance provisions of part 43 will apply to that aircraft. The manufacturer may continue to produce that same aircraft as an aircraft kit under the provisions of § 21.191(i)(2), and part 43 will not apply to the maintenance of that aircraft. However, that same aircraft, when originally certificated under § 21.190 and subsequently re-certificated as an experimental light-sport aircraft under the provisions of § 21.191(i)(3) must continue to comply with the provisions of part 43. Additionally, these rules preclude non-certificated persons from performing maintenance on aircraft originally certificated under § 21.190 and subsequently re-certificated under § 21.191(i)(3), even though these experimental aircraft are restricted to personal use. When originally proposing these rules, the FAA's intent was to have identical maintenance requirements for all aircraft certificated under § 21.191(i) regardless of whether they were previously certificated in another category. The current maintenance rules for these aircraft, however, negate the underlying rationale for originally adopting the provisions of § 21.191(i)(3). The FAA is therefore proposing to amend § 43.1 to remove the requirement for aircraft certificated as experimental aircraft in the light-sport category to comply with the requirements of part 43 when those aircraft have been previously issued a special airworthiness certificate in the light-sport category. The proposal would conform maintenance requirements for aircraft certificated under § 21.191(i) to the original intent of the 2004 final rule.

II.B.20. Require aircraft owners or operators to retain a record of the current status of applicable safety directives for special light-sport aircraft (§ 91.417)

Currently § 91.327(b)(4) specifies that no person may operate an aircraft that has a special airworthiness certificate in the light-sport category unless the owner or operator complies with each safety directive applicable to the aircraft that corrects an existing unsafe condition. Although owners and operators must comply with these safety directives, there currently is no requirement to retain a record of the current status of applicable safety directives or transfer of that information at the time of sale of the aircraft.

Without a requirement to retain and transfer this information, owners, operators, and FAA safety inspectors are not able to easily determine whether maintenance actions critical to flight safety have been accomplished on special light-sport aircraft. This requirement should have been included in the 2004 final rule. The FAA is therefore proposing to revise § 91.417(a)(2)(v) to require owners or operators to retain these records. These records must be transferred in accordance with the provisions of § 91.419.

II.B.21. Provide for use of aircraft with a special airworthiness certificate in the light-sport category in training courses approved under part 141 (§ 141.39)

When the 2004 final rule was issued, the FAA did not revise part 141 to provide for the use of light-sport aircraft in courses approved under that part. Since that time, the FAA has received requests for special light-sport aircraft to be used in courses approved under part 141. Although special light-sport aircraft are not type-certificated aircraft, they are designed, manufactured, and certificated in accordance with consensus standards that have been accepted by the FAA. When part 141 was originally adopted, the FAA did not contemplate the use of aircraft manufactured in accordance with consensus standards. Since these aircraft are manufactured in accordance with FAA-accepted consensus standards, the FAA believes that these aircraft provide an acceptable level of safety for use in part 141 training courses. To be used in a course approved under part 141, the aircraft also would have to be properly equipped for performing the tasks specified in the training course in which the aircraft would be used. The FAA is therefore proposing to revise § 141.39(b) to permit the use of special light-sport aircraft in training courses that are approved under part 141.

II.B.22. Revise minimum safe-altitude requirements for powered parachutes and weight-shift-control aircraft, and balloons (§ 91.119)

Currently pilots of powered parachutes and weight-shift-control aircraft must remain at least 1,000 feet above the highest obstacle within a horizontal radius of 2,000 feet when operating over any congested area of a city, town, or settlement, or over any open-air assembly of persons. When operating over other than congested areas, powered parachutes and weight-shift-control aircraft must be operated at an altitude of 500 feet above the surface, except when operating over open water or sparsely populated areas. When operating over these areas, these aircraft may not be operated closer than 500 feet to any person, vessel, vehicle, or structure. The restrictions specified for operations over congested areas and other than congested areas are not applicable when necessary for the takeoff or landing of the aircraft.

While the FAA believes that current operating restrictions for powered parachutes and weight-shift-control aircraft over congested areas are appropriate, the agency believes that

current restrictions on the operation of powered parachutes and weight-shift-control aircraft over other than congested areas are overly restrictive.

The FAA recognizes that the operational characteristics (lower maximum gross weights, slower speeds, and lower climb rates) of powered parachutes and weight-shift control aircraft enable them to safely operate over other than congested areas at altitudes lower than those at which other aircraft are routinely operated. Additionally, many of these aircraft have been designed with the intent of conducting operations at altitudes below those permitted by the current regulation. Requiring these aircraft to operate at altitudes more appropriate to other categories and classes of aircraft significantly decreases their utility to owners and operators. In the event of a forced landing, the slower speeds, lower weights, and greater maneuverability of these aircraft allow for shorter landing distances and lower impact forces. The FAA is therefore proposing to amend § 91.119 to allow powered parachutes and weight-shift-control aircraft to be operated over other than congested areas at less than 500 feet above the surface, provided the operation is conducted without hazard to persons or property on the surface.

III. Paperwork Reduction Act

Information collection requirements associated with the proposed amendments to part 61 to replace sport pilot privileges with aircraft category and class ratings on all pilot certificates and to replace sport pilot flight instructor privileges with aircraft category ratings on all flight instructor certificates have been approved previously by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and assigned OMB Control Number 2120–0690. This rulemaking action would ensure that sport pilots and flight instructors with a sport pilot rating are in compliance with the FAA's existing requirement that a record of their logbook endorsements are on file with the FAA.

Information collection requirements associated with the proposed amendment to § 91.419 to require owners and operators of special light-sport aircraft (SLSAs) to retain a record of the current status of applicable safety directives and transfer that information at the time of the sale of that aircraft would be a new information collection requirement. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has submitted the information requirements associated with this proposal to the Office of Management and Budget for its review. A summary of those requirements is as follows.

Use: The information will be used to enable safety inspectors, in situations such as accident investigations, to determine whether required maintenance actions were accomplished on SLSAs.

Respondents: There are currently 927 registered SLSAs (expected to increase by 75 aircraft every 2 years). However, the FAA does not know the exact numbers of owners and operators. The FAA expects the number of owners and operators would be fewer than 927.

Frequency: Owners and operators of SLSAs would retain and transfer records on the status of safety directives only when safety directives have been issued on their SLSAs. The FAA estimates that it would take an owner operator 2 hours per year to comply with the requirement.

Annual Burden Estimate

There would be no annualized cost to the Federal government. For owners and operators, the total hour burden would be 21,540 hours over a 10-year period. The average number of hours each year would be 2,154, computed as follows:

Year	Number of SLSA aircraft	Hours per aircraft	Total hour burden
2008	927	2	1,854
2009	927	2	1,854
2010	1002	2	2,004
2011	1002	2	2,004
2012	1077	2	2,154
2013	1077	2	2,154
2014	1152	2	2,304
2015	1152	2	2,304
2016	1227	2	2,454
2017	1227	2	2,454
Total			21,540
Average			2,154

The total cost burden, assuming the value of an owner or operator's time is $31.50 per hour, would be $678,510 ($467,646 discounted). The annualized cost would be $66,584 per year ($467,646 multiplied by 0.14238 (the capital recovery factor)).

The agency is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of collecting information on those who are to respond, including by using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Individuals and organizations may send comments on the information collection requirement by June 16, 2008, and should direct them to the address listed in the Addresses section at the end of this preamble. Comments also should be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for FAA, New Executive Building, Room 10202, 725 17th Street, NW., Washington, DC 20053.

According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number. The OMB control number for this information collection will be published in the **Federal**

Register, after the Office of Management and Budget approves it.

IV. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

V. Regulatory Notices and Analyses

V.A. Economic Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule. We suggest readers seeking greater detail read the full regulatory evaluation, a copy of which we have placed in the docket for this rulemaking.

In conducting these analyses, FAA has determined that this proposed rule: (1) Has benefits that justify its costs, (2) is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, (3) is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (4) would not have a significant economic impact on a substantial number of small entities; (5) would not create unnecessary obstacles to the foreign commerce of the United States; and (6) would not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

Costs and Benefits: The total cost of this rule would be approximately $8.2 million ($5.8 million, discounted). Much of this cost ($4.3 million) is attributed to new training requirements for sport pilots who fly aircraft with a V_H greater than 87 knots CAS. Another substantial portion of the cost ($3.0 million) is attributed to changes to the way in which sport pilot practical exams are administered. Benefits include increased safety for sport pilots flying in conditions requiring navigation by reference to instruments, the ability for pilots of powered parachutes and weight-shift-control aircraft to fly at lower altitudes in other-than-congested areas, and the ability for sport pilots to possess certificates with ratings similar to those of other pilots.

V.B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354)(RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This proposed rule would impose minimal costs on individuals who are or are in the process of becoming sport pilots. Most of these individuals fly for sport or recreation, and therefore the Regulatory Flexibility Act does not apply to them. However, the rule would impose costs on flight instructors with sport pilot ratings who provide instruction as a business endeavor, and in this case the Regulatory Flexibility Act does apply. The estimated 390 current instructors who have already filed the correct paperwork with the FAA would pay nothing. The estimated 210 instructors who have not filed the proper paperwork would incur a one-time cost of approximately $130 each, which the FAA does not consider a significant cost. Therefore, the FAA certifies that this proposed rule would not have a significant economic impact on a substantial number of flight instructors with a sport pilot rating engaged in a business endeavor. The FAA requests comments from affected entities on this finding and determination.

V.C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and has determined that it would have no significant impact on international trade.

V.D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $128.1 million in lieu of $100 million. This proposed rule does not contain such a mandate.

V.E. Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have federalism implications.

V.F. Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this proposed rulemaking action qualifies for the categorical exclusion identified in paragraph 307(k) and involves no extraordinary circumstances.

V.G. Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this NPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a ''significant energy action'' under the executive order because it is not a ''significant regulatory action'' under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VI. Additional Information

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, please send only one copy of written comments, or if you are filing comments electronically, please submit your comments only one time.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents using the Internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);
2. Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/*; or
3. Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html*.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Be sure to identify the docket number, notice number, or amendment number of this rulemaking.

You may access all documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, from the Internet through the Federal eRulemaking Portal referenced in paragraph (1).

List of Subjects

14 CFR Part 43

Aircraft, Aviation safety.

14 CFR Part 61

Aircraft, Airmen, Recreation and recreation areas, Teachers.

14 CFR Part 91

Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 141

Airmen, Educational facilities, Schools.

The Proposed Amendments

In consideration of the foregoing, the FAA proposes to amend parts 43, 61, 91, and 141 of title 14 Code of Federal Regulations (14 CFR parts 43, 61, 91, and 141) as follows:

PART 43—MAINTENANCE, PREVENTIVE MAINTENANCE, REBUILDING, AND ALTERATION

1. The authority citation for part 43 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44703, 44705, 44707, 44711, 44713, 44717, 44725.

2. Amend § 43.1 by revising paragraph (b) to read as follows:

§ 43.1 Applicability.

* * * * *

(b) This part does not apply to any aircraft for which the FAA has issued an experimental certificate, unless the FAA has previously issued a different kind of airworthiness certificate, other than a special airworthiness certificate in the light-sport category, for that aircraft.

* * * * *

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

3. The authority citation for part 61 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

4. Amend § 61.1 by revising paragraphs (b)(3)(iii) introductory text and (b)(3)(iv) introductory text to read as follows:

§ 61.1 Applicability and definitions.

* * * * *

(b) * * *

(3) * * *

(iii) For the purpose of meeting the aeronautical experience requirements for a sport pilot certificate (except for a powered parachute rating), time acquired during a flight conducted in an appropriate aircraft that—

* * * * *

(iv) For the purpose of meeting the aeronautical experience requirements for a sport pilot certificate with a powered parachute rating or a private pilot certificate with a powered parachute category rating, time acquired during a flight conducted in an appropriate aircraft that—

* * * * *

5. Amend § 61.3 by revising paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iv), and (c)(2)(v) introductory text to read as follows:

§ 61.3 Requirement for certificates, ratings, and authorizations.

* * * * *

(c) * * *

(2) * * *

(i) Is exercising the privileges of a student pilot certificate while seeking a pilot certificate with a glider category rating or a balloon class rating;

(ii) Is exercising the privileges of a student pilot certificate while seeking a sport pilot certificate with other than

glider or balloon ratings and holds a current and valid U.S. driver's license;

* * * * *

(iv) Is exercising the privileges of a sport pilot certificate with glider or balloon ratings;

(v) Is exercising the privileges of a sport pilot certificate with other than glider or balloon ratings and holds a current and valid U.S. driver's license. A person who has applied for or held a medical certificate may exercise the privileges of a sport pilot certificate using a current and valid U.S. driver's license only if that person—

* * * * *

6. Amend § 61.5 by revising paragraph (c)(5) to read as follows:

§ 61.5 Certificates and ratings issued under this part.

* * * * *

(c) * * *

(5) Sport pilot ratings—

(i) Sport pilot—airplane single-engine.

(ii) Sport pilot—weight-shift control aircraft.

(iii) Sport pilot—powered parachute.

(iv) Sport pilot—rotorcraft-gyroplane.

(v) Sport pilot—glider.

(vi) Sport pilot—lighter-than-air airship.

(vii) Sport pilot—lighter-than-air balloon.

* * * * *

7. Amend § 61.7 by adding paragraphs (c), (d), and (e) to read as follows:

§ 61.7 Obsolete certificates and ratings.

* * * * *

(c) Prior to [*TWO YEARS FROM EFFECTIVE DATE OF FINAL RULE*], the holder of a sport pilot certificate without a category and class rating whose logbook has been endorsed for sport pilot privileges in a specific category and class of aircraft may—

(1) Exercise the privileges of a sport pilot certificate with a corresponding category and class rating; and

(2) Exchange that certificate for a sport pilot certificate with a category and class rating corresponding to the privileges previously held.

(d) Prior to [*TWO YEARS FROM EFFECTIVE DATE OF FINAL RULE*], the holder of a recreational pilot certificate or higher whose logbook has been endorsed for sport pilot privileges in a specific category and class of aircraft may—

(1) Exercise the privileges of a sport pilot with a category and class rating in an aircraft corresponding to the category and class of aircraft specified in that pilot's logbook endorsement; and

(2) Exchange that certificate for a recreational pilot certificate or higher with a category and class rating corresponding to the sport pilot privileges previously held.

(e) A flight instructor certificate with a sport pilot rating issued before [*EFFECTIVE DATE OF FINAL RULE*] is equivalent to a flight instructor certificate with a sport pilot rating and the appropriate aircraft category and class rating. A flight instructor certificate with other than a sport pilot rating held by a person who has the privileges of a flight instructor certificate with a sport pilot rating is equivalent to a flight instructor certificate with the corresponding flight instructor ratings and sport pilot category and class ratings. The holder of a flight instructor certificate who has sport pilot privileges not listed on that certificate may not exercise those privileges after [*TWENTY SEVEN CALENDAR MONTHS FROM EFFECTIVE DATE OF FINAL RULE*].

8. Amend § 61.23 by:

a. Revising paragraph (b)(1);

b. Removing paragraph (b)(2);

c. Redesignating paragraphs (b)(3) through (b)(8) as paragraphs (b)(2) through (b)(7) respectively; and

d. Revising newly redesignated paragraph (b)(3)(i).

The revisions read as follows:

§ 61.23 Medical certificates: Requirement and duration.

* * * * *

(b) * * *

(1) When exercising the privileges of a student pilot certificate while seeking a pilot certificate with a glider category rating or balloon class rating;

* * * * *

(3) * * *

(i) A sport pilot-glider rating or sport pilot-lighter-than air balloon rating; or

* * * * *

§ 61.31 [Amended]

9. Amend § 61.31 by:

a. Adding the word ''or'' after the semicolon at the end of paragraph (k)(2)(iv);

b. Removing the semicolon and the word ''or'' at the end of paragraph (k)(2)(v) and adding a period in their place; and

c. Removing paragraph (k)(2)(vi).

10. Amend § 61.51 by:

a. Revising paragraphs (c)(1) and (e)(1)(i);

b. Removing paragraphs (i)(3) and (i)(5); and

c. Redesignating paragraph (i)(4) as (i)(3).

The revision reads as follows:

§ 61.51 Pilot logbooks.

* * * * *

(c) * * *

(1) Apply for a certificate or rating issued under this part; or

* * * * *

(e) * * *

(1) * * *

(i) Is the sole manipulator of the controls of an aircraft for which the pilot is rated;

* * * * *

11. Amend § 61.52 by revising paragraphs (a) introductory text, (b), (c)(2) and (c)(3), and adding paragraph (c)(4) to read as follows:

§ 61.52 Use of aeronautical experience obtained in ultralight vehicles.

(a) Before January 31, 2012, a person may use aeronautical experience obtained in an ultralight vehicle to meet the requirements for the following certificates and ratings issued under this part:

* * * * *

(b) Before January 31, 2012, a person may use aeronautical experience obtained in an ultralight vehicle to meet the provisions of § 61.69.

(c) * * *

(2) Document and log that aeronautical experience in accordance with the provisions for logging aeronautical experience specified by an FAA-recognized organization and in accordance with the provisions for logging pilot time in aircraft as specified in § 61.51;

(3) Obtain the aeronautical experience in a category and class of vehicle that is appropriate to the rating sought; and

(4) Provide the FAA with a certified copy of his or her ultralight pilot records from an FAA-recognized ultralight organization, that—

(i) Document that he or she is a registered ultralight pilot with that FAA-recognized ultralight organization; and

(ii) Indicate that he or she is recognized to operate the category and class of aircraft for which sport pilot privileges are sought.

12. Amend § 61.63 by revising paragraphs (b)(5) and (c)(5) to read as follows:

§ 61.63 Additional aircraft ratings (other than on an airline transport pilot certificate).

* * * * *

(b) * * *

(5) Need not take an additional knowledge test, provided the applicant holds an airplane, rotorcraft, powered-lift, weight-shift-control aircraft, powered parachute, or airship rating at that pilot certificate level.

(c) * * *

(5) Need not take an additional knowledge test, provided the applicant holds an airplane, rotorcraft, powered-

lift, weight-shift-control aircraft, powered parachute, or airship rating at that pilot certificate level.

* * * * *

13. Amend § 61.87 by revising the introductory text of paragraphs (d), (g), (i), (j), (l), and (m) to read as follows:

§ 61.87 Solo requirements for student pilots.

* * * * *

(d) *Maneuvers and procedures for pre-solo flight training in a single-engine airplane.* A student pilot who is receiving training for a single-engine airplane rating must receive and log flight training for the following maneuvers and procedures:

* * * * *

(g) *Maneuvers and procedures for pre-solo flight training in a gyroplane.* A student pilot who is receiving training for a gyroplane rating must receive and log flight training for the following maneuvers and procedures:

* * * * *

(i) *Maneuvers and procedures for pre-solo flight training in a glider.* A student pilot who is receiving training for a glider rating must receive and log flight training for the following maneuvers and procedures:

* * * * *

(j) *Maneuvers and procedures for pre-solo flight training in an airship.* A student pilot who is receiving training for an airship rating must receive and log flight training for the following maneuvers and procedures:

* * * * *

(l) *Maneuvers and procedures for pre-solo flight training in a powered parachute.* A student pilot who is receiving training for a powered parachute rating must receive and log flight training for the following maneuvers and procedures:

* * * * *

(m) *Maneuvers and procedures for pre-solo flight training in a weight-shift-control aircraft.* A student pilot who is receiving training for a weight-shift-control aircraft rating must receive and log flight training for the following maneuvers and procedures:

* * * * *

14. Amend § 61.89 by:

a. Revising paragraph (c)(3);

b. Removing the period from the end of paragraph (c)(4) and adding a semicolon; and

c. Adding paragraphs (c)(5), (c)(6), and (c)(7).

The revision and additions read as follows:

§ 61.89 General limitations.

* * * * *

(c) * * *

(3) At an altitude of more than 10,000 feet MSL or 2,000 feet AGL, whichever is higher;

* * * * *

(5) Of a light-sport aircraft without having received the applicable ground training, flight training, and instructor endorsements specified in § 61.327 (a) and (b);

(6) Prior to conducting a cross-country flight in a light-sport aircraft without having received the applicable ground training, flight training, and instructor endorsements specified in § 61.327 (c); and

(7) Of a powered parachute with an elliptical wing without having received the ground training, flight training, and instructor endorsement specified in § 61.324.

15. Amend § 61.93 by revising paragraphs (e)(9), (e)(12), (h)(9), (k)(9), and (k)(11) to read as follows:

§ 61.93 Solo cross-country flight requirements.

* * * * *

(e) * * *

(9) Use of radios for VFR navigation and two-way communication, except that a student pilot seeking a sport pilot certificate must only receive and log flight training on the use of radios installed in the aircraft to be flown;

* * * * *

(12) Control and maneuvering solely by reference to flight instruments, including straight and level flight, turns, descents, climbs, use of radio aids, and ATC directives. For student pilots seeking a sport pilot certificate, the provisions of this paragraph only apply when receiving training for cross-country flight in an airplane that has a V_H greater than 87 knots CAS.

* * * * *

(h) * * *

(9) Use of radios for VFR navigation and two-way communication, except that a student pilot seeking a sport pilot certificate must only receive and log flight training on the use of radios installed in the aircraft to be flown; and

* * * * *

(k) * * *

(9) Use of radios for VFR navigation and two-way communication, except that a student pilot seeking a sport pilot certificate must only receive and log flight training on the use of radios installed in the aircraft to be flown;

* * * * *

(11) Control of the airship solely by reference to flight instruments, except for a student pilot seeking a sport pilot certificate; and

* * * * *

16. Amend § 61.109 by:

a. Removing the word ''and'' at the end of paragraphs (i)(3) and (j)(3);

b. Revising paragraphs (i)(4)(ii) and (j)(2)(i);

c. Adding the word ''and'' to the end of paragraph (j)(4)(i);

d. Removing paragraph (j)(4)(iii); and

e. Adding paragraphs (i)(5) and (j)(5).

The revisions and additions read as follows:

§ 61.109 Aeronautical experience.

* * * * *

(i) * * *

(4) * * *

(ii) Twenty solo takeoffs and landings to a full stop (with each landing involving a flight in a traffic pattern) at an airport; and

(5) Three takeoffs and landings (with each landing involving a flight in the traffic pattern) in an aircraft at an airport with an operating control tower.

(j) * * *

(2) * * *

(i) One cross-country flight of over 75 nautical miles total distance that includes a point of landing that is a straight-line distance of more than 50 nautical miles from the original point of departure; and

* * * * *

(5) Three takeoffs and landings (with each landing involving a flight in the traffic pattern) in an aircraft at an airport with an operating control tower.

* * * * *

17. Amend § 61.113 by:

a. Amending paragraph (a) by removing the words ''paragraphs (b) through (g)'' and adding in their place the words ''paragraphs (b) through (h)''; and

b. Adding paragraph (h) to read as follows:

§ 61.113 Private pilot privileges and limitations: Pilot in command.

* * * * *

(h) A private pilot may act as pilot in command for the purpose of conducting a production flight test in a light-sport aircraft intended for certification in the light-sport category under § 21.190 of this chapter, provided that—

(1) The aircraft is a powered parachute or a weight-shift-control aircraft; and

(2) The person has at least 100 hours of pilot-in-command time in the category and class of aircraft flown.

Subpart H—Flight Instructors

18. Revise the heading of subpart H of part 61 to read as set forth above.

§ 61.181 [Amended]

19. Amend § 61.181 by removing the words ''(except for flight instructor certificates with a sport pilot rating).''

20. Amend § 61.183 by revising paragraphs (c) and (j) to read as follows:

§ 61.183 Eligibility requirements.

* * * * *

(c) Hold—

(1) Either a commercial pilot certificate or airline transport pilot certificate with:

(i) An aircraft category and class rating that is appropriate to the flight instructor rating sought; and

(ii) An instrument rating, or privileges on that person's pilot certificate that are appropriate to the flight instructor rating sought, if applying for—

(A) A flight instructor certificate with an airplane category and single-engine class rating;

(B) A flight instructor certificate with an airplane category and multiengine class rating;

(C) A flight instructor certificate with a powered-lift rating; or

(D) A flight instructor certificate with an instrument rating; or

(2) At least a sport pilot certificate with a category and class rating appropriate to the flight instructor rating sought, if seeking a flight instructor certificate with a sport pilot rating.

* * * * *

(j) Log—

(1) At least 15 hours as pilot in command in the category and class of aircraft that is appropriate to the flight instructor rating sought, if applying for a flight instructor certificate with other than a sport pilot rating; or

(2) The aeronautical experience specified in § 61.186, if applying for a flight instructor certificate with a sport pilot rating; and

* * * * *

21. Amend § 61.185 by revising paragraph (a)(2) to read as follows:

§ 61.185 Aeronautical knowledge.

(a) * * *

(2) The aeronautical knowledge areas for—

(i) A recreational, private, and commercial pilot certificate applicable to the aircraft category for which flight instructor privileges are sought, if applying for a flight instructor certificate with other than a sport pilot rating; or

(ii) A sport pilot certificate applicable to the aircraft category for which flight instructor privileges are sought, if applying for a flight instructor certificate with a sport pilot rating; and

* * * * *

22. Add § 61.186 to read as follows:

§ 61.186 Aeronautical experience requirements for persons applying for a flight instructor certificate with a sport pilot rating.

A person applying for a flight instructor certificate with a sport pilot rating must meet the aeronautical experience requirements specified in the following table:

A person applying for a flight instructor certificate with a sport pilot rating for . . .	Must log at least . . .	Which must include at least . . .
(a) Airplane category with a single-engine class rating,	(1) 150 hours of flight time as a pilot,	(i) 100 hours of flight time as pilot in command in a powered aircraft, (ii) 50 hours of flight time in a single-engine airplane, (iii) 25 hours of cross-country flight time, (iv) 10 hours of cross-country flight time in a single-engine airplane, and (v) 15 hours of flight time as pilot in command in a single-engine airplane that is a light-sport aircraft.
	(2) [Reserved].	
(b) Glider category rating, ...	(1) 25 hours of flight time as pilot in command of a glider, 100 flights in a glider, and 15 flights as pilot in command in a glider that is a light-sport aircraft; or (2) 100 hours in heavier-than-air aircraft, 20 flights in a glider, and 15 flights as pilot in command in a glider that is a light-sport aircraft.	
(c) Rotorcraft category with a gyroplane class rating,	(1) 125 hours of flight time as a pilot,	(i) 100 hours of flight time as pilot in command in a powered aircraft, (ii) 50 hours of flight time in a gyroplane, (iii) 10 hours of cross-country flight time, (iv) 3 hours of cross-country flight time in a gyroplane, and (v) 15 hours of flight time as pilot in command in a gyroplane that is a light-sport aircraft.
	(2) [Reserved].	
(d) Lighter-than-air category with an airship class rating,	(1) 100 hours of flight time as a pilot, ...	(i) 40 hours of flight time in an airship, (ii) 20 hours of flight time as pilot in command in an airship, (iii) 10 hours of cross-country flight time, (iv) 5 hours of cross-country flight time in an airship, and (v) 15 hours of flight time as pilot in command in an airship that is a light-sport aircraft.
	(2) [Reserved].	
(e) Lighter-than-air category with a balloon class rating,	(1) 35 hours of flight time as pilot in command,	(i) 20 hours of flight time in a balloon, (ii) 10 flights in a balloon, and

A person applying for a flight instructor certificate with a sport pilot rating for . . .	Must log at least . . .	Which must include at least . . .
		(iii) 5 flights as pilot in command in a balloon that is a light-sport aircraft.
	(2) [Reserved].	
(f) Weight-shift-control aircraft category rating,	(1) 150 hours of flight time as a pilot,	(i) 100 hours of flight time as a pilot in command in a powered aircraft, (ii) 50 hours of flight time in a weight-shift-control aircraft, (iii) 25 hours of cross-country flight time, (iv) 10 hours of cross-country flight time in a weight-shift-control aircraft, and (v) 15 hours of flight time as a pilot in command in a weight-shift-control aircraft that is a light-sport aircraft.
	(2) [Reserved].	
(g) Powered-parachute category rating,	(1) 100 hours of flight time as a pilot,	(i) 75 hours of flight time as a pilot in command in a powered aircraft, (ii) 50 hours of flight time in a powered parachute, (iii) 15 hours of cross-country flight time, (iv) 5 hours of cross-country flight time in a powered parachute, and (v) 15 hours of flight time as pilot in command in a powered parachute that is a light-sport aircraft.
	(2) [Reserved].	

23. Amend § 61.187 by adding paragraph (b)(8) to read as follows:

§ 61.187 Flight proficiency.

* * * * *

(b) * * *

(8) For a sport pilot rating with the appropriate aircraft category and class rating:

(i) Fundamentals of instructing;

(ii) Technical subject areas;

(iii) Preflight preparation;

(iv) Preflight lesson on a maneuver to be performed in flight;

(v) Preflight procedures;

(vi) Airport, seaplane base, and gliderport operations, as applicable;

(vii) Takeoffs (or launches), landings, and go-arounds;

(viii) Fundamentals of flight;

(ix) Performance maneuvers, and for gliders, performance speeds;

(x) Ground reference maneuvers (except for gliders and lighter-than-air);

(xi) Soaring techniques;

(xii) Slow flight (not applicable to lighter-than-air and powered parachutes)

(xiii) Stalls (not applicable to lighter-than-air, powered parachutes, and gyroplanes);

(xiv) Spins (applicable to airplanes and gliders);

(xv) Emergency operations;

(xvi) Tumble entry and avoidance techniques (applicable to weight-shift-control aircraft); and

(xvii) Post-flight procedures.

* * * * *

24. Amend § 61.191 by adding paragraph (c) to read as follows:

§ 61.191 Additional flight instructor ratings.

* * * * *

(c) A person who applies for an additional sport pilot rating on a flight instructor certificate is not required to pass the knowledge test on the areas listed in § 61.185 (a)(2)(ii).

25. Revise § 61.193 to read as follows:

61.193 Flight instructor privileges.

(a) A person who holds a flight instructor certificate with other than a sport pilot rating is authorized, within the limits of that person's flight instructor certificate and ratings, to provide training and endorsements that are required for and relate to—

(1) A student pilot certificate;

(2) A pilot certificate;

(3) A flight instructor certificate;

(4) A ground instructor certificate;

(5) An aircraft rating;

(6) A flight review, an operating privilege, or recency-of-experience requirement of this part;

(7) A practical test; and

(8) A knowledge test.

(b) A person who holds a flight instructor certificate with a sport pilot rating is authorized, within the limits of that person's flight instructor certificate and rating, to provide training and endorsements that are required for, and relate to—

(1) A student pilot certificate seeking a sport pilot certificate;

(2) A sport pilot certificate;

(3) A flight instructor certificate with a sport pilot rating;

(4) An aircraft rating for a sport pilot;

(5) A flight review;

(6) An operating privilege or recency-of-experience requirement of this part for a person exercising the privileges of a sport pilot;

(7) A practical test for a sport pilot certificate, a private pilot certificate with a powered parachute or weight-shift-control aircraft rating, or a flight instructor certificate with a sport pilot rating; and

(8) A knowledge test for a sport pilot certificate, a private pilot certificate with a powered parachute or weight-shift-control aircraft rating, or a flight instructor certificate with a sport pilot rating.

26. Amend § 61.195 by adding paragraphs (d)(7) and (k) to read as follows:

§ 61.195 Flight instructor limitations and qualifications.

* * * * *

(d) * * *

(7) Student pilot's certificate and logbook of a student pilot seeking a sport pilot certificate for solo flight in Class B, C and D airspace areas, at an airport within Class B, C, or D airspace and to, from, through or on an airport having an operational control tower, unless that flight instructor has—

(i) Given that student ground and flight training in that airspace or at that airport; and

(ii) Determined that the student is proficient to operate the aircraft safely.

* * * * *

(k) *Additional limitations for a flight instructor with a sport pilot rating.* A

flight instructor with a sport pilot rating may only provide flight instruction in a light-sport aircraft and must have—

(1) At least a private pilot certificate with the applicable category and class ratings at any certificate level to provide training for a private pilot certificate with a powered parachute or weight-shift-control aircraft rating;

(2) The endorsement specified in § 61.324 or be otherwise authorized to operate a powered parachute with an elliptical wing to provide training in a powered parachute with an elliptical wing;

(3) The endorsement specified in § 61.327(a) or be otherwise authorized to operate a light-sport aircraft with a V_H greater than 87 knots CAS to provide training in a light-sport aircraft with a V_H greater than 87 knots CAS;

(4) The endorsement specified in § 61.327(b) or be otherwise authorized to operate a light-sport aircraft with a V_H less than or equal to 87 knots CAS to provide training in a light-sport aircraft with a V_H less than or equal to 87 knots CAS; and

(5) The endorsement specified in § 61.325 or be otherwise authorized to conduct operations in Class B, C, and D airspace, at an airport located in Class B, C, or D airspace, and to, from, through, or at an airport having an operational control tower to provide training in this airspace and at these airports.

§ 61.301 [Amended]

27. Amend § 61.301 by removing paragraph (a)(7).

28. Amend § 61.303 by:

a. Removing the words ''light sport'' adding the words ''light-sport'' in their place in paragraphs (a)(1)(ii)(A) introductory text and (a)(2)(ii)(A) introductory text; and

b. Revising the introductory text of paragraphs (a)(1)(i)(A), (a)(1)(ii), (a)(1)(iii)(A), (a)(2)(i)(A), (a)(2)(ii), (a)(2)(iii)(A), (a)(3)(i)(A), (a)(3)(ii)(A), and (a)(3)(iii)(A), and paragraph (a)(3)(ii)(A)(*1*) to read as follows:

§ 61.303 If I want to operate a light-sport aircraft, what operating limits and endorsement requirements in this subpart must I comply with?

(a) * * *

If you hold	And you hold	Then you may operate	And
(1) * * *	(i) * * *	(A) Any light-sport aircraft for which you hold the appropriate category and class rating,	(*1*) * * *
	(ii) At least a recreational pilot certificate with a category and class rating at that certificate level or higher,	(A) * * *	(*1*) * * *
	(iii) * * *	(A) That light-sport aircraft, only if you hold the appropriate category and class rating,	(*1*) * * *
(2) * * *	(i) * * *	(A) Any light-sport aircraft for which you hold the appropriate category and class rating,	(*1*) * * *
	(ii) At least a recreational pilot certificate with a category and class rating at that certificate level or higher,	(A) * * *	(*1*) * * *
	(iii) * * *	(A) That light-sport aircraft, only if you hold the appropriate category and class ratings,	(*1*) * * *
(3) * * *	(i) * * *	(A) Any light-sport glider or balloon for which you hold the appropriate category and class rating,	(*1*) * * *
	(ii) * * *	(A) Any light-sport glider or balloon in that category and class,	(*1*) You do not have to hold any of the endorsements required by this subpart, nor do you have to balloon in comply with the limitations in § 61.315.
	(iii) * * *	(A) Any light-sport glider or balloon, only if you hold the glider category or balloon class rating,	(*1*) * * *

* * * * *

§ 61.309 [Amended]

29. Amend § 61.309 introductory text by removing the words ''Except as specified in § 61.329, to'' and adding the word ''To'' to the beginning of the sentence.

30. Amend § 61.311 by revising the introductory text to read as follows:

§ 61.311 What flight proficiency requirements must I meet to apply for a sport pilot certificate?

To apply for a sport pilot certificate you must receive and log ground and flight training from an authorized instructor on the following areas of operation, as appropriate, for airplane single-engine land or sea, glider, gyroplane, airship, balloon, powered parachute land or sea, and weight-shift-control aircraft land or sea ratings:

* * * * *

31. Amend § 61.313 by:

a. Removing the words ''Except as specified in § 61.329, use'' from the introductory text and adding the word ''Use'' to the beginning of the sentence;

b. Removing the numeral ''3'' and adding in its place the numeral ''2'' in paragraphs (a)(1)(iv), (d)(1)(iv), (e)(1)(iv), (f)(1)(ii), (g)(1)(v) and (h)(1)(iv);

c. Revising the introductory text of paragraphs (a) through (h);

d. Revising paragraph (g)(1) introductory text; and

e. Revising paragraphs (b)(1)(ii) and (c)(1)(ii).

The revisions read as follows:

§ 61.313 What aeronautical experience must I have to apply for a sport pilot certificate?

* * * * *

If you are applying for a sport pilot certificate with . . .	Then you must log at least . . .	Which must include at least . . .
(a) Airplane category and single-engine land or sea class ratings,	(1) * * *	* * *
(b) Glider category rating, and you have not logged at least 20 hours of flight time in heavier-than-air aircraft,	(1) * * *	* * * (ii) at least 3 training flights on those areas of operation specified in § 61.311 preparing for the practical test within 60 days before the date of the test.
(c) Glider category rating, and you have logged at least 20 hours of flight time in heavier-than-air craft,	(1) * * *	* * * (ii) at least 3 training flights on those areas of operation specified in § 61.311 preparing for the practical test within 60 days before the date of the test.
(d) Rotorcraft category and gyroplane class ratings,	(1) * * *	* * *
(e) Lighter-than-air category and airship class ratings,	(1) * * *	* * *
(f) Lighter-than-air category and balloon class ratings,	(1) * * *	* * *
(g) Powered parachute category land or sea class ratings,	(1) 12 hours of flight time in a powered parachute, including 10 hours of flight training in a powered parachute from an authorized instructor, and at least 2 hours of solo flight time in a powered parachute on the areas of operation listed in § 61.311,	* * *
(h) Weight-shift-control aircraft category land or sea class ratings,	(1) * * *	* * *

32. Amend § 61.315 by revising paragraphs (c)(11), (c)(14), and (c)(16) and adding paragraph (c)(20) to read as follows:

§ 61.315 What are the privileges and limits of my sport pilot certificate?

* * * * *

(c) * * *

(11) At an altitude of more than 10,000 feet MSL, or 2,000 feet AGL, whichever is higher.

* * * * *

(14) If the aircraft has:

(i) A V_H greater than 87 knots CAS, unless you have met the requirements of § 61.327(a).

(ii) A V_H less than or equal to 87 knots CAS, unless you have met the requirements of § 61.327(b) or have logged pilot-in-command time in an aircraft with a V_H less than or equal to 87 knots CAS before (insert effective date of final rule).

* * * * *

(16) Contrary to any limit on your pilot certificate or airman medical certificate, or any other limit or endorsement from an authorized instructor.

* * * * *

(20) That is a powered parachute with an elliptical wing, unless you have met the requirements specified in § 61.324.

33. Revise § 61.317 to read as follows:

§ 61.317 Is my sport pilot certificate issued with aircraft category and class ratings?

Your sport pilot certificate will list aircraft category and class ratings. When you successfully pass the practical test for a sport pilot certificate, regardless of the light-sport aircraft rating you seek, the FAA will issue a sport pilot certificate with the appropriate aircraft category and class rating.

§ 61.319 [Removed and reserved]

34. Remove and reserve § 61.319.

§ 61.321 [Removed and reserved]

35. Remove and reserve § 61.321.

§ 61.323 [Removed and reserved]

36. Remove and reserve § 61.323.

37. Add § 61.324 to read as follows:

§ 61.324 How do I obtain privileges to operate a powered parachute with an elliptical wing?

(a) Except as specified in paragraph (b) of this section, if you hold a sport pilot certificate with a powered parachute rating and you seek to operate a powered parachute with an elliptical wing you must—

(1) Receive and log ground and flight training from an authorized instructor in a powered parachute with an elliptical wing; and

(2) Receive a logbook endorsement from the authorized instructor who provided you with the training specified in paragraph (a) of this section certifying that you are proficient to operate a powered parachute with an elliptical wing.

(b) The training and endorsements required by paragraph (a) of this section are not required if you have logged flight time as pilot in command of a powered parachute with an elliptical wing prior to [*EFFECTIVE DATE OF THE FINAL RULE*].

38. Revise § 61.327 to read as follows:

§ 61.327 Are there specific endorsement requirements to operate light-sport aircraft based on V_H?

(a) If you hold a sport pilot certificate and you seek to operate a light-sport aircraft that has a V_H greater than 87 knots CAS you must—

(1) Receive and log ground and flight training from an authorized instructor in an aircraft that has a V_H greater than 87 knots CAS; and

(2) Receive a logbook endorsement from the authorized instructor who provided the training specified in paragraph (a)(1) of this section certifying that you are proficient in the operation of light-sport aircraft with a V_H greater than 87 knots CAS.

(b) Except as specified in paragraph (d) of this section, if you hold a sport pilot certificate and you seek to operate a light-sport aircraft that has a V_H less than or equal to 87 knots CAS you must—

(1) Receive and log ground and flight training from an authorized instructor in

an aircraft that has a V_H less than or equal to 87 knots CAS; and

(2) Receive a logbook endorsement from the authorized instructor who provided the training specified in paragraph (b)(1) of this section certifying that you are proficient in the operation of light-sport aircraft with a V_H less than or equal to 87 knots CAS.

(c) If you hold a sport pilot certificate and you seek to operate a light-sport aircraft that is an airplane and has a V_H greater than 87 knots CAS after [*ONE YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE*], you must receive and log 1 hour of flight training in a single-engine airplane that has a V_H greater than 87 knots CAS on the control and maneuvering of an airplane solely by reference to instruments, including straight and level flight, climbs and descents, turns to a heading, and recovery from unusual flight attitudes.

(d) The training and endorsements required by paragraph (b) of this section are not required if you have logged flight time as pilot in command of an aircraft with a V_H less than or equal to 87 knots CAS prior to [*EFFECTIVE DATE OF THE FINAL RULE*].

§ 61.329 [Removed]

39. Remove § 61.329.

§§ 61.401 through 61.431 (Subpart K) [Removed]

40. Remove subpart K consisting of §§ 61.401 through 61.431.

PART 91—GENERAL OPERATING AND FLIGHT RULES

41. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180).

42. Amend § 91.119 by revising paragraph (d) to read as follows:

§ 91.119 Minimum safe altitudes: General.

* * * * *

(d) *Helicopters, powered parachutes, and weight-shift-control aircraft.* If the operation is conducted without hazard to persons or property on the surface—

(1) A helicopter may be operated at less than the minimums prescribed in paragraph (b) or (c) of this section, provided each person operating the helicopter complies with any routes or altitudes specifically prescribed for helicopters by the FAA; and

(2) A powered parachute or weight-shift-control aircraft may be operated at less than the minimums prescribed in paragraph (c) of this section.

43. Amend § 91.417 by revising paragraph (a)(2)(v) to read as follows:

§ 91.417 Maintenance records.

(a) * * *

(2) * * *

(v) The current status of applicable airworthiness directives (AD) and safety directives including, for each, the method of compliance, the AD or safety directive number and revision date. If the AD or safety directive involves recurring action, the time and date when the next action is required.

* * * * *

PART 141—PILOT SCHOOLS

44. The authority citation for part 141 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709, 44711, 45102–45103, 45301–45302.

45. Amend § 141.39 by revising paragraph (b) to read as follows:

§ 141.39 Aircraft.

* * * * *

(b) Each aircraft must be certificated with a standard airworthiness certificate, a primary airworthiness certificate, or a special airworthiness certificate in the light-sport category unless the Administrator determines that due to the nature of the approved course, an aircraft not having a standard airworthiness certificate, a primary airworthiness certificate, or a special airworthiness certificate in the light-sport category may be used;

* * * * *

Issued in Washington, DC on April 9, 2008.

James J. Ballough,

Director, Flight Standards Service.

[FR Doc. 08–1127 Filed 4–11–08; 8:45am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–124590–07]

RIN 1545–BG11

Guidance Regarding Foreign Base Company Sales Income; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a notice of proposed rulemaking.

SUMMARY: This document contains corrections to a notice of proposed rulemaking (REG–124590–07) that was published in the **Federal Register** on Thursday, February 28, 2008 (73 FR 10716) providing guidance relating to foreign base company sales income, as defined in section 954(d), in cases in which personal property sold by a controlled foreign corporation (CFC) is manufactured, produced, or constructed pursuant to a contract manufacturing arrangement or by one or more branches of the CFC.

FOR FURTHER INFORMATION CONTACT: Ethan Atticks at (202) 622–3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 954 of the Internal Revenue Code.

Need for Correction

As published, a notice of proposed rulemaking (REG–124590–07) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of a notice of proposed rulemaking (REG–124590–07), which was the subject of FR Doc. E8–3557, is corrected as follows:

1. On page 10717, column 1, in the preamble, under the paragraph heading ''B. The Branch Rule'', line 7 from the bottom of the paragraph, the language ''CFC and constitutes FBCSI of the CFC.'' is corrected to read ''CFC and constitutes FBCSI of the CFC. See section 954(d)(2).''.

2. On page 10718, column 1, in the preamble, under the paragraph heading ''*C. Legal Developments*'', line 4 from the bottom of the first paragraph, the language ''considered the activities of a separate'' is corrected to read ''treated as the activities of a separate''.

3. On page 10718, column 2, in the preamble, under the paragraph heading ''Explanation of Provisions'', line 11 from the bottom of the column, the language ''and/or a branch of the CFC, is involved'' is corrected to read ''and/or a branch of the CFC, is otherwise involved''.

4. On page 10718, column 3, in the preamble, under the paragraph heading ''*A. Application of the Manufacturing Exception Where the Physical Manufacturing Test Is Not Satisfied by the CFC but the CFC Is Involved in the Manufacturing Process—Substantial Contribution to Manufacturing*'', lines 2 and 3 of the first paragraph, the language ''income from the purchase of personal property from any person and

''its'' sale'' is corrected to read ''income derived in connection with the purchase of personal property from a related person and ''its'' sale to any person, and income derived in connection with the purchase of personal property from any person and ''its'' sale''.

5. On page 10718, column 3, in the preamble, under the paragraph heading ''*A. Application of the Manufacturing Exception Where the Physical Manufacturing Test Is Not Satisfied by the CFC but the CFC Is Involved in the Manufacturing Process—Substantial Contribution to Manufacturing*'', line 4 from the bottom of the second paragraph, the language ''purchase or sales and manufacturing'' is corrected to read ''purchasing or selling and manufacturing''.

6. On page 10719, column 2, in the preamble, under the paragraph heading ''*A. Application of the Manufacturing Exception Where the Physical Manufacturing Test Is Not Satisfied by the CFC but the CFC Is Involved in the Manufacturing Process—Substantial Contribution to Manufacturing*'', first paragraph of the column, lines 6 and 7, the language ''for the manufacturing exception from FBCSI only if the CFC, acting through'' is corrected to read ''for the manufacturing exception only if the CFC, acting through''.

7. On page 10719, column 2, in the preamble, under the paragraph heading ''*A. Application of the Manufacturing Exception Where the Physical Manufacturing Test Is Not Satisfied by the CFC but the CFC Is Involved in the Manufacturing Process—Substantial Contribution to Manufacturing*'', line 9 from the bottom of the second paragraph of the column, the language ''proposed § 1.954–3(a)(4)(iv)(*b*), a CFC'' is corrected to read ''proposed § 1.954–3(a)(4)(iv)(*a*), a CFC''.

8. On page 10719, column 3, in the preamble, under the paragraph heading ''*A. Application of the Manufacturing Exception Where the Physical Manufacturing Test Is Not Satisfied by the CFC but the CFC Is Involved in the Manufacturing Process—Substantial Contribution to Manufacturing*'', first paragraph of the column, lines 4 through 8, the language ''principles of § 1.954–3(a)(4)(ii) and (iii); (2) performance of manufacturing activities that are considered in, but insufficient to satisfy the tests provided in § 1.954–3(a)(4)(ii) or (iii); (3) control'' is corrected to read ''principles of § 1.954–3(a)(4)(ii) or (iii); (2) performance of activities that are considered in applying, but insufficient to satisfy, the tests provided in § 1.954–3(a)(4)(ii) and (iii); (3) control''.

9. On page 10721, column 2, in the preamble, under the paragraph heading ''2. Modification of § 1.954–3(b)(2)(ii)(*e*)'', second paragraph of the column, lines 1 through 4, the language ''In addition, consistent with the clarification regarding the scope of the branch rule contained in proposed § 1.954–3(b)(1), § 1.954–3(b)(2)(ii)(*e*) is'' is corrected to read ''In addition, consistent with § 1.954–3(b)(2)(ii)(*f*), § 1.954–3(b)(2)(ii)(*e*) is''.

10. On page 10722, column 1, in the preamble, under the paragraph heading ''3. Modification of § 1.954–3(b)(2)(i)(*b*), (b)(2)(ii)(*b*) and (b)(4), Example 3'', first paragraph of the column, last line, the language ''the branch's country is FBCSI.'' is corrected to read ''the branch's country result in FBCSI.''.

§ 1.954–3 [Corrected]

11. On page 10723, column 3, § 1.954–3(a)(4)(i), lines 16 and 17, the language ''provisions of paragraphs (a)(ii), (a)(iii), or (a)(iv) of this section through the'' is corrected to read ''provisions of paragraphs (a)(4)(ii), (a)(4)(iii), or (a)(4)(iv) of this section through the''.

12. On page 10724, column 1, § 1.954–3(a)(4)(iv)(*a*), line 16, the language ''respect to the property prior to sale were'' is corrected to read ''respect to that property prior to sale were''.

13. On page 10724, column 2, § 1.954–3(a)(4)(iv)(*c*), first line, the language ''The rules of this paragraph (a)(iv)'' is corrected to read ''The rules of this paragraph (a)(4)(iv)''.

14. On page 10724, column 2, § 1.954–3(a)(4)(iv)(*c*) *Example 1.* (i), line 6 of the paragraph, the language ''paragraph (a)(4)(iii)) of this section into'' is corrected to read ''paragraph (a)(4)(iii) of this section) into''.

15. On page 10724, column 3, § 1.954–3(a)(4)(iv)(*c*) *Example 3.* (ii), lines 2 through 4, the language ''undertaken with respect to Product X between the time the raw materials were purchased and the time Product X was sold'' is corrected to read ''undertaken with respect to Product X prior to sale''.

16. On page 10725, column 2, § 1.954–3(b)(1)(ii)(*c*)(*2*), line 12 from the bottom of the paragraph, the language ''corporation and as if any such other'' is corrected to read ''corporation and as if any other''.

17. On page 10725, column 3, § 1.954–3(b)(1)(ii)(*c*)(*2*) *Example.* (i), line 9, the language ''property (Product X and Y respectively)'' is corrected to read '' property (Product X and Product Y respectively)''.

18. On page 10725, column 3, § 1.954–3(b)(1)(ii)(*c*)(*3*), line 6, the language ''*construct, grow, or extract the same*'' is corrected to read ''*construct, grow, or extract the same item of personal*''.

19. On page 10726, column 2, § 1.954–3(b)(1)(ii)(*c*)(*3*)(*c*), last sentence of the paragraph, the language ''The location of any particular activity (that is, for purposes of deciding whether that activity is conducted in a particular branch or in the remainder of the controlled foreign corporation) will be determined by applying the principles of paragraph (b)(1)(ii)(*c*)(*3*)(*d*) of this section.'' is removed.

20. On page 10727, column 1, § 1.954–3(b)(1)(ii)(*c*)(*3*)(*f*) *Example 1.*(i), first line of the column, the language ''Branch A and B do not satisfy either'' is corrected to read ''Branch A and Branch B do not satisfy either''.

21. On page 10727, column 2, § 1.954–3(b)(1)(ii)(*c*)(*3*)(*f*) *Example 3.*(i), line 11 from the bottom of the paragraph, the language ''country M but who regularly travel to'' is corrected to read ''Country M but who regularly travel to''.

22. On page 10728, column 1, § 1.954–3(b)(1)(ii)(*c*)(*3*)(*f*) *Example 4.*(ii), lines 1 through 8 from the bottom of the paragraph, the language ''The remainder of FS does not qualify for the manufacturing exception from foreign base company sales income contained in paragraph (a)(4)(iv) of this section. Because Product X is sold for use, consumption, or disposition outside of Country M, the income from the sale of Product X is foreign base company sales income.'' is corrected to read ''The remainder of FS must therefore independently qualify for the manufacturing exception contained in paragraph (a)(4) of this section or income from the sale of Product X will be foreign base company sales income.''

23. On page 10728, column 2, § 1.954–3(b)(1)(ii)(*c*)(*3*)(*f*) *Example 5.*(ii), lines 8 through 25, the language ''Accordingly, paragraph (b)(1)(ii)(b) of this section is applied by comparing the effective rate of tax imposed on the income from the sales of Product X against the effective rate of tax that would apply to the sales income in Branch A, which is located in the jurisdiction that would impose the highest effective rate of tax on the sales income (30%). Because the effective rate of tax in Country B with respect to the sales income (0%) is less than 90% of, and at least 5 percentage points less than, the effective rate of tax that would apply to such income in Country A (30%), the seller, Branch B, is treated as selling on behalf of Branch A, which is treated as the remainder of FS pursuant to paragraph (b)(1)(ii)(*c*) of this section.

Further, for purposes of determining'' is corrected to read ''Accordingly, pursuant to paragraph (b)(2)(ii)(*c*)(*3*)(*e*), Branch A is treated as the location of manufacturing for purposes of applying paragraph (b)(1)(ii)(*b*) of this section. Therefore, the effective rate of tax imposed on the income from the sales of Product X is compared against the effective rate of tax that would apply to that income if it were earned in Country A, which would impose the highest effective rate of tax on the sales income (30%). Because the effective rate of tax in Country B with respect to the sales income (0%) is less than 90% of, and at least 5 percentage points less than, the effective rate of tax that would apply to such income in Country A (30%), Branch B, treated as the remainder of FS pursuant to paragraph (b)(1)(ii)(*c*) of this section, is treated as selling on behalf of Branch A. Further, for purposes of determining''.

24. On page 10728, column 2, § 1.954–3(b)(1)(ii)(*c*)(*3*)(*f*) *Example 5*.(ii), lines 1 through 12 from the bottom of the paragraph, the language ''company sales income. Since the location of manufacturing of Product X is considered to be the location of Branch A rather than Branch B, Branch B, treated as the remainder of FS, does not qualify for the manufacturing exception from foreign base company sales income contained in paragraph (a)(4) of this section. Since the sale of Product X is for use, consumption, or disposition outside of Country B, the income from the sale of Product X is foreign base company sales income.'' is corrected to read ''company sales income. Branch B, treated as the remainder of FS, must therefore independently qualify for the manufacturing exception from foreign base company sales income contained in paragraph (a)(4) of this section or the income from the sale of Product X will be foreign base company sales income.''.

25. On page 10729, column 1, § 1.954–3(b)(2)(ii)(*a*), lines 1 through 7 from the bottom of the paragraph, the language ''tested against the effective rate of tax that would apply to such income if it were earned in the jurisdiction of such other branch or similar establishment or the remainder of the controlled foreign corporation under § 1.954–3(b)(1)(i)(*b*) or (ii)(*b*) of this section.'' is corrected to read ''tested under the principles of § 1.954–3(b)(1)(i)(*b*) or (ii)(*b*) of this section against the effective rate of tax that would apply to such income if it were earned in the jurisdiction of such other branch or similar establishment or the remainder of the controlled foreign corporation.''.

26. On page 10729, column 2, § 1.954–3(b)(2)(ii)(*c*)(*2*) *Example 1*.(ii), line 6, the language ''Branch A (30%), the seller, the remainder of'' is corrected to read ''Branch A (30%), the remainder of''.

27. On page 10729, column 3, § 1.954–3(b)(2)(ii)(*c*)(*2*) *Example 3*.(i), line 7 from the bottom of the column, the language ''persons. 100 percent of the articles sold'' is corrected to read ''persons. One hundred percent of the articles sold''.

28. On page 10730, column 1, § 1.954–3(b)(2)(ii)(*c*)(*2*) *Example 3*.(i), first paragraph of the column, line 10, the language ''Country, but the income of Branch B for 1964'' is corrected to read ''country, but the income of Branch B for 1964''.

29. On page 10730, column 1, § 1.954–3(b)(2)(ii)(*d*), line 10, the language ''the last sentence of paragraph (a)(6), the'' is corrected to read ''paragraph (a)(6)(i), the''.

LaNita Van Dyke,

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

[FR Doc. E8–8031 Filed 4–14–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 54

[REG–108508–08]

RIN 1545–BH71

Determination of Minimum Required Pension Contributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations providing guidance on the determination of minimum required contributions for purposes of the funding rules that apply to single employer defined benefit plans. These regulations would affect sponsors, administrators, participants, and beneficiaries of single employer defined benefit plans. This document also provides a notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by July 14, 2008. Outlines of topics to be discussed at the public hearing scheduled for August 4, 2008, at 10 a.m. must be received by July 15, 2008.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–108508–08), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–108508–08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS–REG–108508–08). The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Lauson C. Green or Linda S. F. Marshall at (202) 622–6090; concerning submissions of comments, the hearing, and/or being placed on the building access list to attend the hearing, Richard A. Hurst, at *Richard.A.Hurst@irscounsel.treas.gov* or (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed Income Tax Regulations (26 CFR part 1) under sections 430(a), 430(c), 430(e), and 430(j), as added to the Internal Revenue Code (Code) by the Pension Protection Act of 2006 (PPA '06), Public Law 109–280 (120 Stat. 780). In addition, this document contains proposed Excise Tax Regulations (26 CFR part 54) under section 4971.

Section 412 provides minimum funding requirements that generally apply for pension plans (including both defined benefit pension plans and money purchase pension plans). PPA '06 makes extensive changes to those minimum funding requirements that generally apply for plan years beginning on or after January 1, 2008. Section 430, which was added by PPA '06, specifies the minimum funding requirements that apply to single employer defined benefit pension plans (including multiple employer plans) pursuant to section 412.[1]

[1] Section 302 of the Employee Retirement Income Security Act of 1974, as amended (ERISA), sets forth funding rules that are parallel to those in Code section 412, and section 303 of ERISA sets forth additional funding rules for single employer plans that are parallel to those in section 430 of the Code. Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713) and section 302 of ERISA, the Secretary of the Treasury has interpretive jurisdiction over the subject matter addressed in these proposed regulations for purposes of ERISA, as well as the Code. Thus, these proposed Treasury regulations issued under section 430 of the Code would apply as well for purposes of section 303 of ERISA.

Section 430(a) provides that a plan's minimum required contribution for a plan year is determined under one of two rules, depending on whether the value of plan assets is less than, or is equal to or greater than, the plan's funding target. If the value of plan assets is less than the funding target, the minimum required contribution is the sum of: (1) Target normal cost; (2) any shortfall amortization charge; and (3) any waiver amortization charge. If the value of plan assets equals or exceeds the funding target, the minimum required contribution is the plan's target normal cost, reduced (but not below zero) by the excess of the value of plan assets over the plan's funding target. For purposes of section 430(a), the value of plan assets is determined after reduction for certain funding balances as provided under section 430(f)(4)(B).

Section 430(c) provides that a shortfall amortization charge is the total (not less than zero) of the shortfall amortization installments for the plan year with respect to any shortfall amortization base established for that plan year and the 6 preceding plan years. Section 430(c)(2)(A) provides that the shortfall amortization installments with respect to a shortfall amortization base established for a plan year are the amounts necessary to amortize the shortfall amortization base in level annual installments over the 7-plan-year period beginning with that plan year.

Section 430(c)(3) provides that a shortfall amortization base is determined for a plan year based on the plan's funding shortfall for the plan year. Under section 430(c)(4), the funding shortfall is the amount (if any) by which the plan's funding target for the year exceeds the value of the plan's assets (as reduced by the funding standard carryover balance and prefunding balance under section 430(f)(4)(B)). The shortfall amortization base for a plan year is the plan's funding shortfall, minus the present value (determined using the interest rates under section 430(h)(2)) of the total of the shortfall amortization installments and waiver amortization installments that have been determined for the plan year and any succeeding plan year with respect to any shortfall amortization bases and waiver amortization bases for preceding plan years.

Under section 430(c)(5), a shortfall amortization base is not established for a plan year if the value of a plan's assets is at least equal to the plan's funding target for the plan year. For this purpose, the prefunding balance is subtracted from the value of plan assets, but only if an election to use that prefunding balance to offset the minimum required contribution is in effect for the plan year. A transition rule applies for plan years beginning after 2007 and before 2011 under which only a specified percentage of the plan's funding target is taken into account for purposes of section 430(c)(5). The transition rule does not apply to a plan that is not in effect for 2007 or to a plan that is subject to the pre-PPA '06 deficit reduction contribution rules for 2007 (that is, a plan covering more than 100 participants and with a funded current liability below the applicable threshold).

Under section 430(e), the waiver amortization charge for a plan year is the total of the waiver amortization installments for the plan year with respect to any waiver amortization bases for the 5 preceding plan years. Under section 430(e)(2), the waiver amortization installments with respect to a waiver amortization base established for a plan year are the amounts necessary to amortize the waiver amortization base in level annual installments over the 5-plan-year period beginning with the succeeding plan year. Under section 430(e)(4), the waiver amortization base for a plan year is the amount of the waived funding deficiency (if any) for that plan year.

If a plan's funding shortfall for a plan year is zero (that is, the value of the plan's assets, reduced by the funding standard carryover balance and prefunding balance to the extent provided under section 430(f)(4)(B), is at least equal to the plan's funding target for the year), any shortfall amortization bases and waiver amortization bases for preceding plan years (and any associated shortfall amortization installments and waiver amortization installments) are eliminated.

Under section 430(j), as under pre-PPA '06 law, the due date for the payment of a minimum required contribution for a plan year is generally 8½ months after the end of the plan year. Any payment made on a date other than the valuation date for the plan year must be adjusted for interest accruing at the plan's effective interest rate under section 430(h)(2)(A) for the plan year for the period between the valuation date and the payment date. Pursuant to section 430(g)(2), the valuation date for a plan year must be the first day of the plan year except in the case of a small plan described in section 430(g)(2)(B).

Under section 430(j)(3)(A), quarterly contributions must be made during a plan year if the plan had a funding shortfall for the preceding plan year. Each quarterly installment is 25% of the required annual payment. The required annual payment is equal to the lesser of 90% of the minimum required contribution under section 430 for the plan year or 100% of the minimum required contribution under section 430 (determined without regard to any waiver under section 412) for the preceding plan year. If a quarterly installment is not made, the interest charge that applies for the period of underpayment is determined using the plan's effective interest rate plus 5 percentage points. The requirements regarding quarterly contributions are similar to the requirements that formerly applied under section 412(m) as in effect before amendments made by PPA '06.

Under section 430(j)(4), a plan sponsor of a plan that is subject to the quarterly contribution requirements for a plan year (other than a small plan described in section 430(g)(2)(B)) must make additional quarterly contributions in order to ensure that a minimum level of liquid assets is available to pay benefits as of the end of each quarter. Generally, this required minimum level of liquid assets is the amount of liquid assets needed to pay for three years of benefits, and an additional quarterly contribution (made in liquid assets) is due if the plan has insufficient liquid assets to meet this minimum level. A plan sponsor that fails to satisfy this liquidity requirement is treated as failing to make the required quarterly contribution and, pursuant to section 206(e) of ERISA, is required to cease making certain types of accelerated payments that are described in section 401(a)(32)(B) of the Code. Pursuant to section 430(j)(4)(C), the portion of an installment that is treated as not made because of the liquidity requirement continues to be treated as unpaid until the close of the quarter that contains the due date for the contribution. These liquidity requirements are substantially similar to the requirements that formerly applied under section 412(m)(5), as in effect before amendments made by PPA '06.

Section 402 of PPA '06 provides a series of special funding rules for a plan maintained by a commercial passenger airline (or by an employer whose principal business is providing catering services to a commercial passenger airline) if such an employer has made an election provided under that section. If an eligible employer has made the election described in section 402(a)(1) of PPA '06 (which is only available for a frozen plan), the calculation of the minimum required contribution for the plan is determined using a special 17-plan-year amortization period and an interest rate of 8.85%. If an eligible employer has made the election

described in section 402(a)(2) of PPA '06 (which can be made without regard to whether the plan is frozen), calculation of the minimum required contribution for the plan is determined using a special 10-plan-year amortization period for the initial shortfall amortization base (that is, the shortfall amortization base for the first plan year for which section 430 applies to the plan) and, pursuant to the amendment to section 402 of PPA '06 made by section 6615 of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28 (121 Stat. 112), an interest rate of 8.25% is used to determine the funding target for each of those 10 plan years.

Section 4971(a) provides an excise tax on a failure to meet applicable minimum funding requirements. In the case of a single employer plan, the tax is 10% of the aggregate unpaid minimum required contributions for all plan years remaining unpaid as of the end of any plan year ending with or within a taxable year. In the case of a multiemployer plan, the tax is 5% of the accumulated funding deficiency as of the end of any plan year ending with or within the taxable year. Section 4971(b) provides an additional excise tax that applies where the applicable minimum funding requirements remain unsatisfied for a specified period. Section 4971(c) provides definitions that apply for purposes of section 4971, including a definition of unpaid minimum required contribution (which is based on the new section 430 rules for determining the minimum required contribution for a year). Section 4971(f) imposes a tax of 10% of the amount of the liquidity shortfall for a quarter that is not paid by the due date for the installment for that quarter.

Regulations under section 4971 were issued on May 1, 1986 (TD 8084). In addition, proposed regulations regarding section 4971 were issued on the same date. Guidance regarding quarterly contribution requirements under former section 412(m) was issued in Notice 89–52 (1989–1 C.B. 692), and guidance regarding the liquidity requirements under former section 412(m)(5) was issued in Rev. Rul. 95–31 (1995–1 C.B. 76). See § 601.601(d)(2).

Explanation of Provisions

I. Overview

These proposed regulations are the fourth in a series of proposed regulations under new section 430.[2] These proposed regulations would provide guidance regarding the minimum contribution rules that apply to sponsors of single employer defined benefit plans under section 430. In addition, this document includes proposed regulations under section 4971, reflecting changes to the excise tax rules under PPA '06.

II. Section 1.430(a)–1 Determination of Minimum Required Contribution

Section 1.430(a)–1 would provide rules for determining the minimum required contribution for a single employer defined benefit plan (including a multiple employer plan under section 413(c)) for a plan year under section 430(a). The determination of the amount of the minimum required contribution for a plan year depends on whether the value of plan assets, as reduced to reflect certain funding balances pursuant to section 430(f)(4)(B) (but not below zero), equals or exceeds the plan's funding target for the plan year. If this value of plan assets is less than the funding target for the plan year, the minimum required contribution for that plan year is equal to the sum of the plan's target normal cost for the plan year plus any applicable shortfall amortization installments and waiver amortization installments. If this value of plan assets equals or exceeds the funding target for the plan year, the minimum required contribution for that plan year is equal to the target normal cost of the plan for the plan year reduced (but not below zero) by any such excess.

The proposed regulations provide that the shortfall amortization installments with respect to a shortfall amortization base established for a plan year are the annual amounts necessary to amortize that shortfall amortization base in level annual installments over the 7-year period beginning with that plan year. As provided in proposed § 1.430(h)(2)–1(f)(2), these installments are determined assuming that the installments are paid on the valuation date for each plan year and using the interest rates applicable under section 430(h)(2)(C) or (D). The shortfall amortization installments are determined using the interest rates that apply for the plan year for which the shortfall amortization base is established and are not redetermined in subsequent plan years to reflect changes in interest rates under section 430(h)(2) for those subsequent plan years.[3]

Under the proposed regulations, if the value of plan assets (reduced by the prefunding balance if the prefunding balance is used to offset the minimum required contribution for the plan year as provided under § 1.430(f)–1(c), but not below zero) is equal to or greater than the funding target for the plan year, then no shortfall amortization base is established for that plan year. If this value of plan assets is less than the funding target for the plan year, a shortfall amortization base is established for the plan year. In such a case, the shortfall amortization base (which can be either positive or negative) is equal to the funding shortfall of the plan for the plan year, minus the sum of the present values of any remaining shortfall amortization installments and waiver amortization installments (determined in accordance with § 1.430(h)(2)–1(f)(2) using the interest rates that apply for the current plan year). For this purpose, the funding shortfall of a plan for any plan year is the excess (if any) of the funding target of the plan for the plan year, over the value of plan assets for the plan year (as reduced to reflect the subtraction of the funding standard carryover balance and prefunding balance to the extent provided under § 1.430(f)–1(c)).

The proposed regulations reflect the transition rule under section 430(c)(5)(B) under which only a specified portion of the funding target is taken into account in determining whether a shortfall amortization base is established for plan years beginning before January 1, 2011. This transition rule does not apply with respect to any plan year beginning after 2008 if a shortfall amortization base was required to be established for any preceding year, nor does it apply to a plan that was not in effect for a plan year beginning in 2007 or to a plan that was subject to section 412(l) for the last plan year before section 430 applies to the plan (the pre-effective plan year), determined after the application of section 412(l)(6) and (9). The proposed regulations would not provide for any adjustment to the applicable percentages under this transition rule for a plan for which the effective date of section 430 is delayed under sections 104 through 106 of PPA '06.

[2] Proposed §§ 1.430(h)(3)–1 and 1.430(h)(3)–2, relating to the mortality tables used to determine liabilities under section 430(h)(3), were issued May 29, 2007 (REG–143601–06, 72 FR 29456), proposed § 1.430(f)–1, relating to prefunding and funding standard carryover balances under section 430(f), was issued August 31, 2007 (REG–113891–07, 72 FR 50544), and proposed §§ 1.430(d)–1, 1.430(g)–1, 1.430(h)(2)–1, and 1.430(i)–1, relating to measurement of plan assets and liabilities for pension funding purposes, were issued December 31, 2007 (REG–139236–07, 72 FR 74215).

[3] The proposed regulations reflect the alternative amortization periods and interest rates that apply to a commercial passenger airline (or other eligible employer) that has made an election under section 402 of PPA '06.

Under the proposed regulations, the waiver amortization installments with respect to a waiver amortization base established for a plan year are the annual amounts necessary to amortize that waiver amortization base in level annual installments over the 5-year period beginning with the following plan year. As provided in proposed § 1.430(h)(2)–1(f)(2), these installments are determined assuming that the installments are paid on the valuation date for each plan year and using the interest rates applicable under section 430(h)(2). Thus, if the plan is using segment rates, the installments are determined by applying the first segment rate to the first four installments and the second segment rate to the fifth (and final) installment. The waiver amortization installments established with respect to a waiver amortization base are determined using the interest rates that apply for the plan year for which the waiver is granted (even though the first installment with respect to the waiver amortization base is not due until the subsequent plan year) and are not redetermined in subsequent plan years to reflect changes in interest rates under section 430(h)(2) for those subsequent plan years. A waiver amortization base is established for each plan year for which a waiver of the minimum funding standard has been granted, and the amount of that waiver amortization base is equal to the amount of the minimum required contribution waived (or the waived funding deficiency) for the plan year.

In the case of a plan that received a funding waiver under section 412 for a plan year for which section 430 was not yet effective with respect to the plan, the proposed regulations provide that the waiver is treated as giving rise to a waiver amortization base, and the amortization charges with respect to that funding waiver are treated as waiver amortization installments. With respect to such a preexisting funding waiver, the amount of the annual waiver amortization installment is equal to the amortization charge with respect to that waiver determined using the interest rate or rates that applied for the pre-effective plan year. Thus, for a plan that received a waiver in the past, the plan sponsor would have to contribute the amounts needed to amortize that waiver over the original schedule as previously established.

In accordance with section 430(c)(6), the proposed regulations provide that, in any case in which the funding shortfall of a plan for a plan year is zero, the shortfall amortization bases for all preceding plan years (and all shortfall amortization installments determined with respect to those shortfall amortization bases) are reduced to zero, and the waiver amortization bases for all preceding plan years (and all waiver amortization installments determined with respect to such bases) are reduced to zero.

The proposed regulations would provide rules for determining the amount of a minimum required contribution for a short plan year. Under the proposed regulations, the amortization installments are prorated for a short plan year. The proposed regulations would not provide for any proration of the target normal cost. Instead, the determination of target normal cost would reflect actual accruals that accrue or are expected to accrue during the plan year.[4] The proposed regulations also provide rules for the treatment of installments in subsequent plan years to take into account the proration of these installments for short plan years and any change in valuation date.

III. Section 1.430(j)–1 Payment of Minimum Required Contributions

The proposed regulations under section 430(j) would provide rules related to the payment of minimum required contributions, including the payment of quarterly contributions and liquidity requirements. The proposed regulations provide that any payment of the minimum required contribution under section 430 for a plan year that is made on a date other than the valuation date for that plan year is adjusted for interest accruing for the period between the valuation date and the payment date, at the effective interest rate for the plan for that plan year determined pursuant to § 1.430(h)(2)–1(f)(1). The direction of the adjustment depends on whether the contribution is paid before or after the valuation date for the plan year. If the contribution is paid after the valuation date for the plan year, the contribution is discounted to the valuation date using the plan's effective interest rate. By contrast, if the contribution is paid before the valuation date for the plan year (which could only occur in the case of a small plan described in section 430(g)(2)(B)), the contribution is increased for interest at that same interest rate.

Under the proposed regulations, a payment of the minimum required contribution under section 430 for a plan year can be made no earlier than the first day of the plan year. The deadline for any payment of any minimum required contribution for a plan year is 8½ months after the close of the plan year. If a minimum required contribution is not paid by this deadline, an excise tax applies under section 4971.

The proposed regulations would provide rules for accelerated quarterly contributions for underfunded plans. These rules are similar to the rules provided under Notice 89–52; however, these rules have been updated to reflect statutory changes. These statutory changes include changes regarding which plans are subject to the quarterly contribution requirements as well as the interest rates applicable to missed quarterly contributions.

Under the proposed regulations, in any case in which the plan has a funding shortfall for the preceding plan year, the employer maintaining the plan must make the required quarterly installments.[5] The amount of each required quarterly installment is equal to 25% of the required annual payment. For this purpose, the required annual payment is equal to the lesser of 90% of the minimum required contribution under section 430(a) for the plan year, or 100% of the minimum required contribution under section 430(a) (determined without regard to any funding waiver under section 412) for the preceding plan year. These minimum required contributions are determined under section 430 as of the valuation date for each year and have no adjustment for interest.[6] The proposed regulations provide that, for purposes of determining the required annual payment, the minimum required contribution for a plan year is determined without regard to use of the prefunding balance or funding standard carryover balance in the current year or any prior year.

Pursuant to section 430(j)(3)(C), the proposed regulations would provide that the due dates for the four required quarterly installments with respect to a

[4] See 29 CFR 2530.204–2(e) for rules relating to changes in accrual computation periods.

[5] These proposed regulations do not provide rules for determining whether a plan has a funding shortfall for the 2007 plan year for purposes of determining whether the plan must make required quarterly installments for the 2008 plan year. Nonetheless, plans must make this determination on a reasonable basis. See the discussion in this preamble under the heading ''Proposed Legislation'' for a rule that the IRS and the Treasury Department are considering for this purpose.

[6] In determining required installations for the plan year that begins in 2008, the minimum required contribution for the 2007 plan year under section 412 is used as the minimum required contribution for the preceding plan year. This amount, which does not reflect either use of the credit balance or the granting of any funding waiver, is adjusted with interest to the end of the 2007 plan year at the plan's valuation interest rate for the 2007 plan year.

full plan year are as follows: The first installment is due on the 15th day of the 4th plan month, the second installment is due on the 15th day of the 7th plan month, the third installment is due on the 15th day of the 10th plan month, and the fourth installment is due on the 15th day following the close of the plan year. In the case of a short plan year, the proposed regulations would provide rules for determining the amount of the required annual payment, the number and due dates of installments, and the amount of those installments. The proposed regulations also provide rules for determining the plan month in the case of a plan year that does not begin on the first day of a calendar month.

The proposed regulations would provide that, if the employer fails to pay the full amount of a required installment, then the rate of interest used to adjust the amount of the contribution with respect to the underpayment of the required installment for the period of time that begins on the due date for the required installment and that ends on the date of payment is equal to the effective interest rate for the plan for that plan year determined pursuant to § 1.430(h)(2)–1(f)(1) plus 5 percentage points. This increased interest rate applies only to installments that are due after the valuation date for the plan year because section 430(j)(3) refers to interest being charged on late quarterly contributions. The amount of the underpayment is equal to the excess of the required installment over the amount (if any) of the installment contributed to or under the plan on or before the due date for the installment. For this purpose, the proposed regulations contain an ordering rule under which contributions are to be credited against unpaid required installments in the order in which those installments were required to be paid.

As was the case in Notice 89–52, the proposed regulations would provide that a plan sponsor generally can use a plan's funding balances to satisfy quarterly contribution requirements. However, this rule is subject to the new limitation on the use of funding balances by underfunded plans pursuant to section 430(f)(3)(C). An eligible plan sponsor's election to use the plan's prefunding balance and funding standard carryover balance under section 430(f) satisfies the obligation to make an installment on the date of the election, to the extent of the amount elected, as adjusted with interest at the plan's effective interest rate under section 430(h)(2)(A) for the plan year from the valuation date through the due date of the installment. Comments are requested regarding whether rules should be provided under which a plan sponsor is deemed to make an election to use a funding balance to the extent it is available to avoid a failure to make any required quarterly installment or under which a plan sponsor can make a single election that will apply to all future quarterly installments until revoked.

A plan sponsor that uses the plan's prefunding balance or funding standard carryover balance toward satisfaction of the plan's quarterly contribution requirement before the plan's effective interest rate for the plan year has been determined should assume, in order to ensure that the quarterly contribution requirements are satisfied, that the effective interest rate is equal to the lowest of the three segment rates (generally the first segment rate) to adjust the elected amount. Plan sponsors should also note that, pursuant to proposed § 1.430(f)–1(b)(1)(ii)(B), the amount of the funding balance that is used to satisfy the quarterly contribution requirements cannot later be added back to the prefunding balance (because only contributions in excess of the minimum funding requirement, determined without regard to the offset under section 430(f)(3), are eligible to be added to the prefunding balance).

The proposed regulations would provide rules for the liquidity requirements that generally apply to plans for which quarterly contributions are required. Under the proposed regulations, a plan subject to the requirement to make quarterly contributions (other than a small plan described in section 430(g)(2)(B)) is treated as failing to pay the full amount of the required installment for a quarter to the extent that the value of the liquid assets paid after the close of that quarter and on or before the due date for the installment is less than the liquidity shortfall for that quarter. Thus, in order to satisfy the quarterly contribution requirement for a quarter, liquid assets in the amount of the liquidity shortfall must be contributed after the close of that quarter and on or before the due date for the installment.[7] The use of funding balances or the contribution of illiquid assets cannot remedy a liquidity shortfall.

The rules under the proposed regulations relating to the liquidity requirements are similar to the rules provided under Rev. Rul. 95–31; however, these rules have been updated to reflect statutory changes. For example, the definition of liquid assets under the proposed regulations is the same as the definition of liquid assets under Rev. Rul. 95–31. Unlike Rev. Rul. 95–31, the proposed regulations measure satisfaction of a liquidity shortfall by reference to contributions made after the close of the quarter and by the due date for the installment while including contributions made during the plan quarter in plan assets. Although this appears to be a change from the rules of Rev. Rul. 95–31, the two formulations are mathematically identical.

The proposed regulations provide that, for purposes of applying the additional 5 percentage point interest adjustment in the case of a quarterly contribution that is not fully paid, the liquidity increment for the quarter (the portion of the quarterly installment that is due solely by reason of the liquidity requirements) continues to be treated as unpaid until the close of the quarter in which the due date for that installment occurs, regardless of when it is contributed. However, for purposes of adjusting the contribution to the valuation date at the effective interest rate, the adjustment is made from the actual contribution date (rather than from the close of the quarter). In addition, the proposed regulations provide an ordering rule under which, if a contribution for a quarter is less than the total amount needed to satisfy the quarterly contribution requirement taking into account the liquidity requirement, then the contribution is first attributed toward satisfying the quarterly contribution requirement determined without regard to the liquidity requirement.

Under the proposed regulations, if the amount of any required installment is increased because of the liquidity shortfall rules, that increase cannot exceed the amount that, when added to prior required installments determined under section 430(j) for the plan year, would increase the funding target attainment percentage of the plan for the plan year (taking into account the expected increase in funding target due to benefits accruing or earned during the plan year) to 100%.

The proposed regulations would provide that the rules under section 430(j) generally apply to a plan maintained by a commercial passenger airline (or other eligible employer) that has made an election under section 402(a)(1) or 402(a)(2) of PPA '06 in the same manner as they apply to any other

[7] In this context, see Department of Labor Interpretive Bulletin 94–3 (29 CFR 2509.94–3), which sets forth the Department's view that, in the absence of an applicable exemption, a contribution by an employer to a defined benefit plan in a form other than cash constitutes a prohibited transaction under section 406 of ERISA and section 4975 of the Code.

plan subject to section 430. However, in the case of a plan with respect to which the election under section 402(a)(1) of PPA '06 has been made, the determination of the funding shortfall for a plan year is made by reference to the unfunded liability under section 402(e)(3)(A) of PPA '06. In addition, the effective interest rate for a plan with respect to which the election under section 402(a)(1) of PPA '06 has been made is deemed to be 8.85%. Pursuant to proposed § 1.430(h)(2)–1(f)(1), the effective interest rate for a plan with respect to which the election under section 402(a)(2) of PPA '06 has been made will be 8.25% for the 10-year period during which the election applies to the plan.

IV. Section 54.4971(c)–1 Taxes on Failure To Meet Minimum Funding Standards

These proposed regulations set forth the definitions that apply for purposes of applying the rules of section 4971 that were modified by PPA '06.

The proposed regulations define the term *accumulated funding deficiency* (which is only relevant for a multiemployer plan) as having the meaning given to that term by section 431. A multiemployer plan's accumulated funding deficiency for a plan year takes into account all charges and credits to the funding standard account under section 412 for plan years before the first plan year for which section 431 applies to the plan.

The proposed regulations define the term *unpaid minimum required contribution*, with respect to any plan year, as any minimum required contribution under section 430 for the plan year that is not paid on or before the due date for the plan year under section 430(j)(1). The proposed regulations provide that a plan's accumulated funding deficiency under section 412 for the pre-effective plan year is treated as an unpaid minimum required contribution for that plan year until correction is made. Unlike the determination of accumulated funding deficiency which applied under section 412 prior to PPA '06, the total unpaid minimum required contributions is not adjusted with interest. However, as described in the following paragraph, correction of an unpaid minimum required contribution does require a contribution that includes an adjustment for interest.

The proposed regulations define the term *correct* as it applies to the accumulated funding deficiency and the unpaid minimum required contribution of a plan. With respect to an accumulated funding deficiency under a multiemployer plan, the proposed regulations set forth rules that are the same as the rules set forth in proposed § 54.4971–2(a). Under the proposed regulations, the correction of an unpaid minimum required contribution under a single employer plan for a plan year requires the contribution, to or under the plan, of the amount that, when discounted to the valuation date for the plan year for which the unpaid minimum required contribution is due at the appropriate rate of interest, equals or exceeds the unpaid minimum required contribution. For this purpose, the appropriate rate of interest is the plan's effective interest rate for the plan year for which the unpaid minimum required contribution is due except to the extent that the payments are subject to additional interest as provided under section 430(j)(3) or (4). With respect to an unpaid minimum required contribution, the proposed regulations provide an ordering rule under which a contribution is attributable first to the earliest plan year of any unpaid minimum required contribution for which correction has not yet been made. With respect to an accumulated funding deficiency under section 412 for the pre-effective plan year that is treated as an unpaid minimum required contribution, the proposed regulations provide that correction requires the contribution, to or under the plan, of the amount of that accumulated funding deficiency adjusted with interest from the end of the pre-effective plan year to the date of the contribution at the plan's valuation interest rate for the pre-effective plan year.

The IRS and the Treasury Department intend to issue further guidance in the future on the application of section 4971, including special rules applicable to multiemployer plans that are in critical or endangered status under section 432.

Proposed Legislation

As of the date of the issuance of these proposed regulations, bills have been passed in the House of Representatives and the Senate that would provide for technical corrections to PPA '06.[8] These bills would amend section 430(j)(3)(A) to authorize the Treasury Department to provide rules for determining the funding shortfall for purposes of the pre-effective plan year and would add section 430(j)(3)(E)(iii) to authorize the Treasury Department to provide special rules for the treatment of quarterly contributions in the case of a plan with a valuation date other than the first day of the plan year. These bills would also specify an effective date for the PPA '06 amendments to section 4971.

These proposed regulations have reserved § 1.430(j)–1(c)(6) and § 1.430(j)–1(g)(5)(ii) in order to accommodate any enacted changes to section 430(j). If legislation similar to that in the proposed technical corrections is enacted, the IRS and the Treasury Department are considering including the following provisions in final regulations. First, the funding shortfall for the pre-effective plan year would be determined as the excess (if any) of the plan's current liability determined pursuant to section 412(l)(7) on the valuation date for the plan's pre-effective plan year, over the net plan assets for the pre-effective plan year as determined under § 1.430(i)–1(f)(5)(ii). Second, if a quarterly installment is due before the valuation date for the plan year, the minimum required contribution for the plan year would be increased by an additional amount if that quarterly installment is not paid by the due date. This additional amount would be determined by applying interest at an annual rate of 5% to the underpayment of the required installment for the period of time between the due date for the required installment and the earlier of the date of payment or the valuation date.

Effective/Applicability Dates of Regulations

Section 430 generally applies to plan years beginning on or after January 1, 2008. The proposed regulations under section 430 are proposed to apply generally to plan years beginning on or after January 1, 2009. When the regulations are finalized, plans will be permitted to apply them for plan years beginning in 2008. In addition, for plan years beginning in 2008, plans are permitted to rely on the proposed regulations for purposes of satisfying the requirements of section 430. In the case of a plan for which the effective date of section 430 is delayed in accordance with sections 104 through 106 of PPA '06, the regulations are proposed to apply to plan years beginning on or after the date section 430 first applies with respect to the plan.

The amendments made to section 4971 by section 114 of PPA '06 do not have a specific effective date. The regulations provide that the amendments to section 4971 generally apply at the same time as the amendments to section 430 (or section 431, as applicable) apply to the plan. Thus, the regulations provide that the amendments to section 4971 generally

[8] See H.R. 3361 as passed by the House of Representatives on March 13, 2008 and S. 1974 as passed by the Senate on December 19, 2007.

apply to taxable years beginning on or after January 1, 2008, but only with respect to plan years for which section 430 (or section 431) applies to the plan that end with or within any such taxable year. In the case of a plan to which a delayed effective date applies pursuant to sections 104 through 106 of PPA '06, the regulations provide that the amendments made to section 4971 apply to the same taxable years, but only with respect to plan years for which section 430 applies to the plan. The regulations under section 4971 generally are proposed to apply at the same time the statutory changes to section 4971 under PPA '06 become effective but would not apply to taxable years ending before April 15, 2008. Thus, for example, the regulations under section 4971 would not apply to a short taxable year beginning January 1, 2008, and ending February 29, 2008.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations and, because the proposed regulations do not impose a collection of information on small entities, a regulatory flexibility analysis is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for August 4, 2008, beginning at 10 a.m. in the Auditorium, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written or electronic comments by July 15, 2008, and an outline of topics to be discussed and the amount of time to be devoted to each topic (a signed original and eight (8) copies) by July 15, 2008. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these regulations are Lauson C. Green and Linda S. F. Marshall, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and the Treasury Department participated in the development of these regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 54

Excise taxes, Insurance, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.430(a)–1 is added to read as follows:

§ 1.430(a)–1 Determination of minimum required contribution.

(a) *In general*—(1) *Overview.* This section sets forth rules for determining a plan's minimum required contribution for a plan year under section 430(a). Section 430 and this section apply to single employer defined benefit plans (including multiple employer plans as defined in section 413(c)) that are subject to section 412 but do not apply to multiemployer plans (as defined in section 414(f)). Paragraph (b) of this section defines a plan's minimum required contribution for a plan year. Paragraph (c) of this section provides rules for determining shortfall amortization installments. Paragraph (d) of this section provides rules for determining waiver amortization installments. Paragraph (e) of this section provides for early deemed amortization of shortfall and waiver amortization bases for fully funded plans. Paragraph (f) of this section provides definitions that apply for purposes of this section. Paragraph (g) of this section provides examples that illustrate the application of this section. Paragraph (h) of this section provides effective/applicability dates and transition rules.

(2) *Special rules for multiple employer plans.* In the case of a multiple employer plan to which section 413(c)(4)(A) applies, the rules of section 430 and this section are applied separately for each employer under the plan, as if each employer maintained a separate plan. Thus, the minimum required contribution is computed separately for each employer under such a multiple employer plan. In the case of a multiple employer plan to which section 413(c)(4)(A) does not apply (that is, a plan described in section 413(c)(4)(B) that has not made the election for section 413(c)(4)(A) to apply), the rules of section 430 and this section are applied as if all participants in the plan were employed by a single employer.

(b) *Definition of minimum required contribution*—(1) *In general.* In the case of a defined benefit plan that is not a multiemployer plan (within the meaning of section 414(f)), except as offset under section 430(f) and § 1.430(f)–1, the minimum required contribution for a plan year is determined as the applicable amount determined under paragraph (b)(2) of this section or paragraph (b)(3) of this section, reduced by the amount of any funding waiver under section 412(c) that is granted for the plan year. See paragraph (b)(4) of this section for special rules for a plan maintained by a commercial passenger airline (or other eligible employer) for which an election under section 402 of the Pension Protection Act of 2006, Public Law 109–280 (120 Stat. 780) (PPA '06), has been made, and see section 430(j) and § 1.430(j)–1 for rules regarding the required interest adjustment for a contribution that is paid on a date other than the valuation date for the plan year.

(2) *Plan assets less than funding target*—(i) *General rule.* For any plan year in which the value of plan assets of the plan (as reduced to reflect the subtraction of certain funding balances as provided under § 1.430(f)–1(c), but not below zero) is less than the funding target of the plan for the plan year, the minimum required contribution for that plan year is equal to the sum of—

(A) The target normal cost of the plan for the plan year;

(B) The total (not less than zero) of the shortfall amortization installments determined with respect to the shortfall amortization bases for the plan year and each of the 6 preceding plan years as described in paragraph (c) of this section; and

(C) The total of the waiver amortization installments determined with respect to the waiver amortization bases for each of the 5 preceding plan years as described in paragraph (d) of this section.

(ii) *Special rule for short plan years*—(A) *Proration of amortization installments.* In determining the minimum required contribution in the case of a plan year that is shorter than 12 months (and is not a 52-week plan year of a plan that uses a 52–53 week plan year), the shortfall amortization installments and waiver amortization installments that are taken into account under paragraphs (b)(2)(i)(B) and (C) of this section are determined by multiplying the amount of those installments that would be taken into account for a 12-month plan year by a fraction, the numerator of which is the duration of the short plan year and the denominator of which is 1 year.

(B) *Effect on subsequent years.* In plan years after the short plan year, installments with respect to a shortfall amortization base (or waiver amortization base) continue to be taken into account under paragraphs (b)(2)(i)(B) and (C) of this section until the total amount of those installments, as originally determined to be paid over 7 years (or 5 years in the case of waiver amortization installments), has been taken into account. Thus, for example, in the case of a plan that has a short plan year, an additional partial installment will be taken into account under paragraphs (b)(2)(i)(B) and (C) of this section during the plan year after the end of the original amortization period in an amount determined so that the total of the amortization installments (including the prorated installment payable for the short plan year and the additional partial installment) is equal to the total amount of the amortization installments as originally determined. Similarly, in the case of a plan that has a short plan year, the total number of plan years required to take into account the full amount of installments will exceed 7 plan years (or 5 plan years in the case of waiver amortization installments), and, accordingly, the number of preceding plan years taken into account in paragraphs (b)(2)(i)(B) and (C) of this section is correspondingly increased so that the total amount of the amortization installments as originally determined is taken into account. In addition, for plan years beginning after the close of the short plan year, the shortfall amortization installments and waiver amortization installments that are taken into account under paragraphs (b)(2)(i)(B) and (C) of this section are assumed to be paid on the valuation date for the new plan year (rather than on the valuation date for the short plan year and preceding plan years).

(3) *Plan assets equal or exceed funding target.* For any plan year in which the value of plan assets (as reduced to reflect the subtraction of certain funding balances as provided under § 1.430(f)–1(c), but not below zero) equals or exceeds the funding target of the plan for the plan year, the minimum required contribution for that plan year is equal to the target normal cost of the plan for the plan year reduced (but not below zero) by that excess.

(4) *Special rules for commercial passenger airlines*—(i) *In general.* This paragraph (b)(4) provides special rules for a plan maintained by a commercial passenger airline (or an employer whose principal business is providing catering services to a commercial passenger airline) for which an election under section 402 of PPA '06 has been made.

(ii) *Frozen plans*—(A) *Determinations during 17-year amortization period.* If an election described in section 402(a)(1) of PPA '06 applies for the plan year with respect to an eligible plan described in section 402(c)(1) of PPA '06, then the plan's minimum required contribution for purposes of section 430 of the Code for the plan year is equal to the amount necessary to amortize (at an interest rate of 8.85 percent) the unfunded liability of the plan in equal installments over the remaining amortization period. For this purpose, the unfunded liability means the excess of the accrued liability under the plan determined using the unit credit funding method and an interest rate of 8.85 percent over the fair market value of assets, and the remaining amortization period is the 17-plan-year period beginning with the first plan year for which the election was made, reduced by 1 year for each plan year after the first plan year for which the election was made. In addition, the section 430(f)(3) election to apply funding balances against the minimum required contribution does not apply to a plan to which the election described in section 402(a)(1) of PPA '06 applies for the plan year.

(B) *Determinations following 17-year amortization period.* If an election described in section 402(a)(1) of PPA '06 applied to the plan for any preceding plan year but does not apply for the current plan year, then the plan's minimum required contribution for purposes of section 430 of the Code for the plan year is determined without regard to that election. For the first plan year for which that election no longer applies to the plan, any prefunding balance or funding standard carryover balance is reduced to zero.

(iii) *Other plans of commercial passenger airlines.* If an election described in section 402(a)(2) of PPA '06 has been made for an eligible plan described in section 402(c)(1) of PPA '06, then the minimum required contribution for purposes of section 430 is determined under generally applicable rules, except that the shortfall amortization base for the first plan year for which section 430 applies to the plan is amortized over 10 years (rather than over 7 years as provided in paragraph (c)(1) of this section) in accordance with § 1.430(h)(2)–1(e) and (f) using the interest rates that apply for the first plan year for which section 430 applies to the plan. In such a case, the shortfall amortization installments with respect to the shortfall amortization base for that plan year will continue to be included in determining the minimum required contribution for 10 years rather than 7 years. See also § 1.430(h)(2)–1(b)(6) for a special rule for determining the funding target in the case of a plan for which an election under section 402(a)(2) of PPA '06 has been made.

(c) *Shortfall amortization installments*—(1) *In general.* For purposes of this section, the shortfall amortization installments with respect to a shortfall amortization base established for a plan year are the annual amounts necessary to amortize that shortfall amortization base in level annual installments over the 7-year period beginning with that plan year. See § 1.430(h)(2)–1(e) and (f) for rules regarding interest rates used for determining shortfall amortization installments and the date within each plan year on which the installments are assumed to be paid. The shortfall amortization installments are determined using the interest rates that apply for the plan year for which the

shortfall amortization base is established and are not redetermined in subsequent plan years to reflect changes in interest rates under section 430(h)(2) for those subsequent plan years.

(2) *Shortfall amortization base*—(i) *In general.* For purposes of this section, unless the value of plan assets (as reduced to reflect the subtraction of certain funding balances as provided under § 1.430(f)–1(c)(2), but not below zero) is equal to or greater than the funding target of the plan for the plan year, a shortfall amortization base is established for the plan year equal to—

(A) The funding shortfall of the plan for the plan year; minus

(B) The amount attributable to future installments determined under paragraph (c)(2)(ii) of this section.

(ii) *Amount attributable to future installments.* The amount attributable to future installments is equal to the sum of the present values (determined in accordance with § 1.430(h)(2)–1(e) and (f) using the interest rates that apply for the current plan year) of—

(A) The shortfall amortization installments that have been determined for the plan year and any succeeding plan year with respect to the shortfall amortization bases of the plan for any plan year preceding the plan year; and

(B) The waiver amortization installments that have been determined for the plan year and any succeeding plan year with respect to the waiver amortization bases of the plan for any plan year preceding the plan year.

(iii) *Transition rule.* See paragraph (h)(4) of this section for a transition rule under which only a portion of the funding target is taken into account in determining whether a shortfall amortization base is established under this paragraph (c)(2).

(d) *Waiver amortization installments*—(1) *In general.* For purposes of this section, the waiver amortization installments with respect to a waiver amortization base established for a plan year are the annual amounts necessary to amortize that waiver amortization base in level annual installments over the 5-year period beginning with the following plan year. See § 1.430(h)(2)–1(e) and (f) for rules regarding interest rates used for determining waiver amortization installments and the date within each plan year on which the installments are assumed to be paid. The waiver amortization installments established with respect to a waiver amortization base are determined using the interest rates that apply for the plan year for which the waiver is granted (even though the first installment with respect to the waiver amortization base is not due until the subsequent plan year) and are not redetermined in subsequent plan years to reflect changes in interest rates under section 430(h)(2) for those subsequent plan years.

(2) *Waiver amortization base*—(i) *In general.* For purposes of this section, a waiver amortization base is established for each plan year for which a waiver of the minimum funding standard has been granted in accordance with section 412(c). The amount of the waiver amortization base is equal to the amount of the minimum required contribution waived (or the waived funding deficiency) for the plan year.

(ii) *Transition rule.* See paragraph (h)(3) of this section for the treatment of funding waivers granted for plan years beginning before 2008.

(e) *Early deemed amortization upon attainment of funding target.* In any case in which the funding shortfall of a plan for a plan year is zero—

(1) The shortfall amortization bases for all preceding plan years (and all shortfall amortization installments determined with respect to those shortfall amortization bases) are reduced to zero; and

(2) The waiver amortization bases for all preceding plan years (and all waiver amortization installments determined with respect to such bases) are reduced to zero.

(f) *Definitions*—(1) *In general.* The definitions set forth in this paragraph (f) apply for purposes of this section.

(2) *Funding shortfall.* The term *funding shortfall* means the excess (if any) of—

(i) The funding target of the plan for a plan year; over

(ii) The value of plan assets for the plan year (as reduced to reflect the subtraction of the funding standard carryover balance and prefunding balance to the extent provided under § 1.430(f)–1(c), but not below zero).

(3) *Funding target.* The term *funding target* means the plan's funding target for a plan year determined under § 1.430(d)–1(b)(2), § 1.430(i)–1(c), or § 1.430(i)–1(e)(1), whichever applies to the plan for the plan year.

(4) *Target normal cost.* The term *target normal cost* means the plan's target normal cost for a plan year determined under § 1.430(d)–1(b)(1), § 1.430(i)–1(d), or § 1.430(i)–1(e)(2), whichever applies to the plan for the plan year.

(g) *Examples.* The following examples illustrate the rules of this section. Unless otherwise indicated, these examples are based on the following assumptions: the plan is subject to section 430 starting in 2008; the plan year is the calendar year; the valuation date is January 1; and the plan's funding standard carryover balance is $0.

Example 1. (i) Plan A has a funding target of $2,500,000 and assets totaling $1,800,000 as of January 1, 2008. The 2008 actuarial valuation is performed using the 24-month average segment rates applicable for September 2007 (determined without regard to the transitional rule of section 430(h)(2)(G)).

(ii) A $700,000 shortfall amortization base is established for 2008, which is equal to the $2,500,000 funding target less $1,800,000 of assets.

(iii) With respect to this shortfall amortization base of $700,000, there is a shortfall amortization installment of $116,852 (which is equal to the $700,000 shortfall amortization base amortized over 7 years) for each year from 2008 through 2014. The amount of this shortfall amortization installment is determined by discounting the first five installments using the first segment interest rate of 5.26%, and by discounting the sixth and seventh installments using the second segment rate of 5.82%.

Example 2. (i) The facts are the same as in Example 1, except that the plan was granted a funding waiver of $300,000 in 2006, as of December 31, 2006. The valuation interest rate for the January 1, 2007, actuarial valuation is 8.50% (which exceeds 150% of the applicable federal mid-term rate).

(ii) The waiver amortization installment for the plan year beginning January 1, 2007, is $70,166, which is equal to the $300,000 funding waiver base amortized over 5 years at the valuation interest rate of 8.50%.

(iii) As of January 1, 2008, the present value of the remaining waiver amortization installments is $260,318, which is determined by discounting the remaining four waiver amortization installments of $70,166 to January 1, 2008, using the first segment rate of 5.26%. See paragraph (h)(3) of this section.

(iv) A $439,682 shortfall amortization base is established for 2008, which is equal to the $2,500,000 funding target, less $1,800,000 of assets, less $260,318 (which is the present value of the remaining waiver amortization installments).

(v) With respect to this shortfall amortization base of $439,682, there is a shortfall amortization installment of $73,397 (which is equal to the $439,682 shortfall amortization base amortized over 7 years) for each year from 2008 through 2014.

Example 3. (i) The facts are the same as in Example 2. Plan A has a $100,000 target normal cost for the 2008 plan year and was granted a funding waiver for 2008 to the largest extent permitted under section 412(c).

(ii) The minimum required contribution is $243,563 as of January 1, 2008. This is equal to the $100,000 target normal cost, plus the $70,166 waiver amortization installment from the 2006 waiver, plus the $73,397 January 1, 2008, shortfall amortization installment.

(iii) In accordance with section 412(c)(1)(C), the portion of the minimum required contribution attributable to the amortization of the 2006 funding waiver cannot be waived. Therefore, the maximum amount of the January 1, 2008, minimum

required contribution that can be waived is $173,397.

(iv) In accordance with paragraph (d) of this section, a waiver amortization base of $173,397 is established as of January 1, 2008, to be amortized over 5 years beginning with the 2009 plan year. Although the waiver amortization installments for the 2008 funding waiver are not included in the minimum required contribution until 2009, the amount of those installments is determined based on the interest rates used for the 2008 plan year.

(v) The waiver amortization installments are calculated using the first segment interest rate of 5.26% for the first four installments (calculated as of January 1, 2009, through January 1, 2012) and the second segment interest rate of 5.82% for the final installment payable as of January 1, 2013. Accordingly, the waiver amortization installments that are payable beginning January 1, 2009, are $40,530 each.

Example 4. (i) The facts are the same as in Example 3. As of January 1, 2009, Plan A has a funding target of $2,750,000 and assets totaling $1,900,000. The 2009 actuarial valuation is performed using the 24-month average segment rates applicable for September 2008 (determined without regard to the transitional rule of section 430(h)(2)(G)). For the 2009 plan year, the first segment rate is equal to 5.50%, the second segment rate is equal to 6.00%, and the third segment rate is equal to 6.50%.

(ii) As of January 1, 2009, the present value of the remaining three waiver amortization installments with respect to the 2006 waiver is $199,715, which is determined using the first segment rate of 5.50%.

(iii) As of January 1, 2009, the present value of the remaining five waiver amortization installments with respect to the 2008 waiver is $182,594, which is determined using the first segment rate of 5.50%.

(iv) As of January 1, 2009, the present value of the remaining six shortfall amortization installments with respect to the 2008 shortfall amortization base is $385,511, which is determined using the first segment rate of 5.50% for the first five installments and the second segment rate of 6.00% for the sixth installment.

(v) A shortfall amortization base of $82,180 is established for 2009, which is equal to the $2,750,000 funding target, less $1,900,000 of assets, less $199,715 (the present value of the remaining waiver amortization installments with respect to the 2006 waiver), less $182,594 (the present value of the remaining waiver amortization installments with respect to the 2008 waiver), less $385,511 (the present value of the remaining installments with respect to the 2008 shortfall amortization base).

(vi) With respect to this shortfall amortization base of $82,180, there is a shortfall amortization installment of $13,795 (which is equal to the $82,180 shortfall amortization base amortized over 7 years) for each year from 2009 through 2015.

Example 5. (i) The facts are the same as in Example 4, except that Plan A has assets totaling $2,000,000 as of January 1, 2009. Plan A has a target normal cost of $110,000 as of January 1, 2009.

(ii) A shortfall amortization base of −$17,820 is established for 2009, which is equal to the $2,750,000 funding target, less $2,000,000 of assets, less $199,715 (the present value of the remaining installments with respect to the 2006 waiver), less $182,594 (the present value of the remaining installments with respect to the 2008 waiver), less $385,511 (the present value of the remaining installments with respect to the 2008 shortfall amortization base).

(iii) The shortfall amortization installment for the 2009 shortfall amortization base is −$2,991, which is equal to the −$17,820 shortfall amortization base amortized over 7 years. The first five shortfall amortization installments are discounted using the first segment rate of 5.50% and the sixth and seventh shortfall amortization installments are discounted using the second segment rate of 6.00%.

(iv) The minimum required contribution for the 2009 plan year is $291,102. This is equal to the target normal cost of $110,000 plus the shortfall amortization charge of $70,406 (that is, $73,397 minus $2,991) plus the waiver amortization charge of $110,696 (that is, $70,166 plus $40,530).

Example 6. (i) The facts are the same as in Example 5, except that Plan A has assets totaling $2,800,000 as of January 1, 2009.

(ii) Because the assets of $2,800,000 exceed the funding target of $2,750,000 as of January 1, 2009, no new shortfall amortization base is established under paragraph (c)(2) of this section.

(iii) Furthermore, under paragraph (e) of this section, all shortfall amortization bases and waiver amortization bases (and all shortfall amortization installments and waiver amortization installments associated with those bases) are reduced to zero as of January 1, 2009.

(iv) The minimum required contribution for the 2009 plan year is $60,000, which is equal to the $110,000 target normal cost less the excess of the assets over the funding target ($2,800,000 minus $2,750,000).

Example 7. (i) The actuarial valuation for Plan B as of January 1, 2008, based on a 12-month plan year, determines a target normal cost of $110,000 and a shortfall amortization installment for 2008 of $185,000. The plan year for Plan B is changed to April 1 through March 31, effective April 1, 2008, resulting in a short plan year beginning January 1, 2008, and ending March 31, 2008.

(ii) The target normal cost for the short plan year is redetermined in order to reflect the fact that there is a short plan year. An actuarial valuation shows that the target normal cost is $25,000 for the short plan year based on the accruals for that short plan year (determined in accordance with 29 CFR § 2530.204–2(e)).

(iii) In accordance with paragraph (b)(2)(ii)(A) of this section, the shortfall amortization base is prorated to reflect the three months covered by the short plan year. Accordingly, the shortfall amortization installment for the short plan year is $46,250 (that is, $185,000 multiplied by 3/12).

(iv) The total minimum required contribution for the short plan year (without offset for any carryover balance as of January 1, 2008) is $71,250 (that is, the sum of the target normal cost of $25,000 plus the shortfall amortization installment of $46,250).

Example 8. (i) The facts are the same as in Example 7. The first segment rate for the plan year beginning April 1, 2008, is 5.30%, and the second segment rate is 5.80%.

(ii) The present value of the remaining shortfall amortization installments with respect to the January 1, 2008, shortfall amortization base is equal to $1,074,937.

This is determined by discounting the remaining installments (6 full-year installments due April 1, 2008 through April 1, 2013, and a final 9-month installment due April 1, 2014) using the first segment rate of 5.30% for the first five installments and the second segment rate of 5.80% for the remaining installments.

(h) *Effective/applicability dates and transition rules*—(1) *In general.* Section 430 generally applies to plan years beginning on or after January 1, 2008. In general, this section applies to plan years beginning on or after January 1, 2009. However, plans are permitted to apply this section in determining the minimum required contribution for plan years beginning in 2008.

(2) *Plans with delayed effective date.* In the case of a plan for which the effective date of section 430 is delayed in accordance with sections 104 through 106 of PPA '06, this section applies to plan years beginning on or after the date section 430 first applies with respect to the plan.

(3) *Treatment of pre-2008 funding waivers.* In the case of a plan that has received a funding waiver under section 412 for a plan year for which section 430 was not yet effective with respect to the plan, the waiver is treated as giving rise to a waiver amortization base and the amortization charges with respect to that funding waiver are treated as waiver amortization installments as described in paragraph (d) of this section. With respect to such a preexisting funding waiver, the amount of the waiver amortization installment is equal to the amortization charge with respect to that waiver determined using the interest rate or rates that applied for the pre-effective plan year.

(4) *Transition rule for determining whether shortfall amortization base is established*—(i) *In general.* Except as provided in paragraphs (h)(4)(iii) and (iv) of this section, in the case of plan years beginning after 2007 and before 2011, only the applicable percentage of the funding target is taken into account in determining whether a shortfall amortization base is established for the plan year under paragraph (c)(2) of this section.

(ii) *Applicable percentage.* For purposes of paragraph (h)(4)(i) of this section, the applicable percentage is

determined in accordance with the following table:

Calendar year in which the plan year begins	Applicable percentage
2008	92
2009	94
2010	96

(iii) *Transition rule not available if funding falls below applicable percentage.* The transition rule of paragraph (h)(4)(i) of this section does not apply with respect to any plan year beginning after 2008 if a shortfall amortization base was required to be established under paragraph (c)(2) of this section for any preceding year.

(iv) *Transition rule not available for new plans or deficit reduction plans.* The transition rule of paragraph (h)(4)(i) of this section does not apply to a plan—

(A) That was not in effect for a plan year beginning in 2007; or

(B) That was subject to section 412(l) for the pre-effective plan year, determined after the application of sections 412(l)(6) and (9) (regardless of whether the deficit reduction contribution for the pre-effective plan year was equal to zero).

(v) *Pre-effective plan year.* For purposes of this section, the pre-effective plan year for a plan is the last plan year beginning before section 430 applies to the plan. Thus, except for plans with a delayed effective date under paragraph (h)(2) of this section, the pre-effective plan year for a plan is the last plan year beginning before January 1, 2008.

Par. 3. Section 1.430(j)–1 is added to read as follows:

§ 1.430(j)–1 Payment of minimum required contributions.

(a) *In general*—(1) *Overview.* This section provides rules related to the payment of minimum required contributions, including the payment of quarterly contributions. Section 430(j) and this section apply to single employer defined benefit plans (including multiple employer plans as defined in section 413(c)) but do not apply to multiemployer plans (as defined in section 414(f)). Paragraph (b) of this section describes the general timing requirement for minimum required contributions. Paragraph (c) of this section describes the accelerated quarterly contribution schedule for plans with a funding shortfall in the preceding plan year. Paragraph (d) of this section provides rules regarding liquidity requirements. Paragraph (e) of this section provides definitions. Paragraph (f) of this section provides examples that illustrate the rules of this section. Paragraph (g) of this section sets forth effective/applicability dates and transition rules.

(2) *Special rules for multiple employer plans.* In the case of a multiple employer plan to which section 413(c)(4)(A) applies, the rules of section 430 and this section are applied separately for each employer under the plan, as if each employer maintained a separate plan. Thus, for example, required quarterly contributions are determined separately for each employer under such a multiple employer plan. In the case of a multiple employer plan to which section 413(c)(4)(A) does not apply (that is, a plan described in section 413(c)(4)(B) that has not made the election for section 413(c)(4)(A) to apply), the rules of section 430 and this section are applied as if all participants in the plan were employed by a single employer.

(3) *Applicability of section 430(j) to plans of commercial passenger airlines*—(i) *In general.* Except as otherwise provided in this section, the rules of section 430(j) and this section apply to a plan for which an election described in section 402 of the Pension Protection Act of 2006, Public Law 109–280 (120 Stat. 780) (PPA '06), has been made in the same manner as those rules apply to any other plan subject to section 430.

(ii) *Special rules for plans for which election was made pursuant to section 402(a)(1) of PPA '06.* For purposes of applying the rules of section 430(j) and this section to a plan with respect to which the election under section 402(a)(1) of PPA 06 has been made, the effective interest rate for the plan is deemed to be 8.85% during the period for which the election applies. In addition, see paragraph (e)(4)(ii) of this section for a special determination of the funding shortfall for a plan for which the election in section 402(a)(1) of PPA '06 has been made.

(b) *General timing requirement for minimum required contributions*—(1) *Earliest date for contributions.* A payment of the minimum required contribution under section 430 for a plan year can be made no earlier than the first day of the plan year.

(2) *Deadline for contributions.* The deadline for any payment of any minimum required contribution for a plan year is 8½ months after the close of the plan year. See section 4971 and the regulations thereunder regarding an excise tax that applies with respect to minimum required contributions not paid by this deadline. See also section 430(k) of the Code and section 101(d) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1021(d), for additional rules that apply in the case of a failure to pay minimum required contributions by this deadline.

(3) *Adjustment for interest.* Any payment of the minimum required contribution under section 430 for a plan year that is made on a date other than the valuation date for that plan year is adjusted for interest accruing for the period between the valuation date and the payment date, at the effective interest rate for the plan for that plan year determined pursuant to § 1.430(h)(2)–1(f)(1). The direction of the adjustment depends on whether the contribution is paid before or after the valuation date for the plan year. If the contribution is paid after the valuation date for the plan year, the contribution is discounted to the valuation date using the plan's effective interest rate. By contrast, if the contribution is paid before the valuation date for the plan year (which could only occur in the case of a small plan described in section 430(g)(2)(B)), the contribution is increased for interest using the plan's effective interest rate.

(c) *Accelerated quarterly contribution schedule for underfunded plans*—(1) *In general*—(i) *Plan subject to quarterly contribution requirement.* In any case in which the plan has a funding shortfall for the preceding plan year, the employer maintaining the plan shall make the required installments described in paragraph (c)(3) of this section by the due dates described in paragraph (c)(4) of this section.

(ii) *Satisfaction of installments through use of funding balances.* In the case of a plan that is subject to the quarterly contribution requirement under this paragraph (c), if the plan sponsor makes an election to use the plan's prefunding balance or funding standard carryover balance under section 430(f), then the plan sponsor is treated as satisfying the obligation to make a required installment under paragraph (c)(1)(i) of this section on the date of the election to the extent of the amount elected, as adjusted with interest. This interest adjustment is made at the plan's effective interest rate under section 430(h)(2)(A) for the plan year from the valuation date through the due date of the installment.

(iii) *Consequences of failure to make quarterly contribution*—(A) *Interest adjustment.* If the full amount of a required installment is not paid by the due date for that installment, then an increased rate of interest applies in adjusting the payment to the valuation date. This increased rate of interest is equal to the rate otherwise used under paragraph (b) of this section plus 5

percentage points, and applies with respect to the underpayment of the required installment (determined pursuant to paragraph (c)(2) of this section) for the period of time that begins on the due date for the required installment and that ends on the date on which payment is made.

(B) *Application to required installments due before the valuation date.* The modified interest rate described in paragraph (c)(1)(iii)(A) of this section only applies to a required installment that is due on or after the valuation date for the plan year. See paragraph (c)(6) of this section for rules that apply to required installments that are due before the valuation date for the plan year.

(C) *Additional consequences.* See section 430(k) of the Code and section 101(d) of ERISA for examples of additional consequences of failure to make quarterly contributions.

(2) *Determination of underpayment*—(i) *Underpayment for a quarter.* For purposes of this section, the amount of the underpayment with respect to a required installment for a quarter is equal to the excess of—

(A) The required installment; over

(B) The amount (if any) of the installment contributed to or under the plan on or before the due date for the installment.

(ii) *Order of crediting contributions.* For purposes of this section, contributions are first credited against the earliest unpaid required installments.

(3) *Amount of required installment*—(i) *In general.* For purposes of this section, the amount of any required installment is equal to 25% of the required annual payment described in paragraph (c)(3)(ii) of this section.

(ii) *Required annual payment.* The required annual payment is equal to the lesser of—

(A) 90% of the minimum required contribution under section 430 for the plan year; or

(B) 100% of the minimum required contribution under section 430 (determined without regard to any funding waiver under section 412) for the preceding plan year.

(iii) *Treatment of funding balances.* For purposes of paragraph (c)(3)(ii) of this section, the minimum required contribution for a plan year is determined without regard to the use of the prefunding balance or funding standard carryover balance in the current year or any prior year. However, see paragraph (c)(1)(ii) of this section regarding a plan sponsor's election to use the plan's prefunding balance or funding standard carryover balance in the current year for the payment of quarterly installments.

(4) *Due dates for installments.* For purposes of this section, there is a required installment for each quarter of the plan year. The due dates for the four required quarterly installments with respect to a full plan year are set forth in the following table:

Installment	Due date
First quarter's installment.	15th day of 4th plan month.
Second quarter's installment.	15th day of 7th plan month.
Third quarter's installment.	15th day of 10th plan month.
Fourth quarter's installment.	15th day after the close of the plan year.

(5) *Special rules for short plan years*—(i) *In general.* In the case of a short plan year, the rules of this paragraph (c) are modified as provided in this paragraph (c)(5).

(ii) *Current plan year is short plan year*—(A) *Amount of required annual payment.* In determining the required annual payment pursuant to paragraph (c)(3)(ii) of this section for a short plan year, the amount otherwise determined under paragraph (c)(3)(ii)(B) (based on the prior year's minimum required contribution) is multiplied by a fraction, the numerator of which is the duration of the short plan year and the denominator of which is 1 year.

(B) *Number and due dates of installments.* If the plan has a short plan year, then an installment is due 15 days after the close of that short plan year. In addition, an installment is required for each due date determined under paragraph (c)(4) of this section that falls within the short plan year. Thus, for example, if the short plan year ends before the 15th day of the 4th plan month of the plan year, there will be only one installment for that short plan year, and that installment will be due on the 15th day after the close of the short plan year.

(C) *Amount of installments.* The amount of each installment required to be paid for the short plan year is equal to the required annual payment determined pursuant to paragraph (c)(3)(ii) of this section (as modified by paragraph (c)(5)(ii)(A) of this section) divided by the number of installments determined pursuant to paragraph (c)(5)(ii)(B) of this section.

(iii) *Prior plan year is short plan year.* If the prior plan year is a short plan year, then the rule of paragraph (c)(3)(ii)(B) regarding the use of 100% of the prior year's minimum required contribution in determining the required annual payment does not apply. Accordingly, in such a case, the required annual payment is equal to 90% of the minimum required contribution under section 430 for the current plan year.

(6) *Special rule for plans with valuation dates after the first day of the plan year. [Reserved]*

(d) *Liquidity requirement in connection with quarterly contributions*—(1) *In general*—(i) *Requirement to make additional quarterly contributions.* Except as provided in paragraphs (d)(1)(ii) and (iii) of this section, if a plan is subject to the requirement to make quarterly contributions under paragraph (c) of this section, then the plan is treated as failing to pay the full amount of a required installment for a quarter to the extent that the value of the liquid assets contributed after the close of that quarter and on or before the due date for the installment is less than the liquidity shortfall for that quarter.

(ii) *Limitation on increase.* The amount by which any required installment is increased by reason of paragraph (d)(1)(i) of this section cannot exceed the amount that, when added to prior required installments for the plan year, would increase the funding target attainment percentage of the plan for the plan year (taking into account the expected increase in the funding target due to benefits accruing or earned during the plan year) to 100%.

(iii) *Small plan exception.* The liquidity requirement of this paragraph (d) does not apply to a small plan that is described in § 1.430(g)–1(b)(2).

(2) *Period of underpayment*—(i) *General rule.* For purposes of applying the additional 5 percentage point interest adjustment pursuant to paragraph (c)(1)(iii) of this section, the liquidity increment with respect to a quarter as described in paragraph (d)(2)(ii) of this section continues to be treated as unpaid until the close of the quarter in which the due date for that installment occurs without regard to when that portion is paid. However, for purposes of adjusting the contribution to the valuation date at the effective interest rate under paragraph (b)(3) of this section, the adjustment is made from the contribution date (rather than the close of the quarter).

(ii) *Liquidity increment.* For purposes of this paragraph (d), the liquidity increment with respect to a quarter is the portion of the required installment for that quarter that is treated as not paid solely by reason of paragraph (d)(1)(i) of this section.

(iii) *Ordering rule.* If the employer makes a contribution for a quarter that,

after application of paragraph (c)(2)(ii) of this section, is less than the total amount needed to satisfy the requirements of paragraph (c) of this section as increased by this paragraph (d) for a quarter, then the contribution is first attributed toward satisfying the requirements of paragraph (c) of this section (without regard to this paragraph (d)) and then to the liquidity increment.

(3) *Consequences of failure to pay liquidity shortfall.* See section 4971(f) for an excise tax on the failure to pay a liquidity shortfall. See also section 206(e) of ERISA.

(e) *Definitions*—(1) *In general.* The definitions set forth in this paragraph (e) apply for purposes of this section.

(2) *Adjusted disbursements.* The term *adjusted disbursements* means disbursements from the plan reduced by the product of—

(i) The plan's funding target attainment percentage determined under section 430(d)(2) for the plan year; and

(ii) The sum of the purchases of annuities and payments of single sums.

(3) *Disbursements from the plan.* The term *disbursements from the plan* means all disbursements from the trust, including purchases of annuities, payments of single sums and other benefits, and administrative expenses.

(4) *Funding shortfall*—(i) *In general.* The term *funding shortfall* means the excess (if any) of—

(A) The funding target of the plan for a plan year; over

(B) The value of plan assets for the plan year (as reduced to reflect the subtraction of certain funding balances as provided under § 1.430(f)–1(c), but not below zero).

(ii) *Special rule for plans of commercial passenger airlines.* In the case of a plan year for which an election described in section 402(a)(1) of PPA '06 is in effect, the term *funding shortfall* means the unfunded liability for that plan year determined under § 1.430(a)–1(b)(4)(ii).

(iii) *Special rule for first effective plan year.* See paragraph (g)(5)(ii) of this section for a calculation of the funding shortfall for the plan's pre-effective plan year.

(iv) *Special rule for plan spinoffs and mergers.* [Reserved]

(5) *Liquid assets*—(i) *In general.* The term *liquid assets* means cash, marketable securities, and other assets described in this paragraph (e)(5)(i). For this purpose, marketable securities include financial instruments such as stocks and other equity interests, evidences of indebtedness (including certificates of deposit), options, futures contracts, and other derivatives, for which there is a liquid financial market, and other interests in entities (such as partnerships, trusts, or regulated investment companies) for which there is a liquid financial market. For purposes of the preceding sentence, a liquid financial market is an established financial market described in § 1.1092(d)–1(b) (other than an interbank market or an interdealer market described in § 1.1092(d)–1(b)(1)(v) and (vi), respectively). Any security that is issued or guaranteed by the government of the United States or an agency or instrumentality thereof for which there is an established financial market described in § 1.1092(d)–1(b) is a marketable security. Finally, any financial instrument or other interest in an entity that, under its terms, contains a right by which the instrument or other interest may immediately be redeemed, exchanged, or converted into cash or a marketable security, is a marketable security, provided there are no restrictions on the exercise of that right.

(ii) *Insurance and annuity contracts.* Other assets that are treated as liquid assets of a plan are insurance, annuity, or other contracts issued by an insurance company that is licensed to do business under the laws of any State, but only if the insurance, annuity, or other contract—

(A) Would be treated as a marketable security under paragraph (e)(5)(i) of this section if it were a financial instrument;

(B) Provides for substantially equal monthly disbursements to the extent provided in paragraph (e)(5)(iii) of this section; or

(C) Is benefit responsive within the meaning of paragraph (e)(5)(iv) of this section.

(iii) *Insurance and annuity contracts providing for substantially equal periodic payments.* If the contract provides for substantially equal monthly disbursements (for example, an annuity contract in pay status), the only portion of the contract that may be treated as liquid assets for a quarter is the amount equal to 36 times the monthly disbursement (in the month containing the last day of the quarter) which is available under the terms of the contract, provided there are no restrictions (within the meaning of paragraph (e)(5)(v) of this section) on the disbursements.

(iv) *Benefit responsive insurance and annuity contracts.* A contract is considered benefit responsive if, under applicable law and contractual provisions, the plan has the right to receive disbursements from the contract in order to pay plan benefits for any participant in the plan, without restrictions (within the meaning of paragraph (e)(5)(v) of this section).

(v) *Restrictions.* For purposes of paragraphs (e)(5)(iii) and (iv) of this section, a restriction on a redemption, exchange or conversion right, or a restriction on a disbursement, may result not only from applicable law or contractual provisions, but also from rehabilitation, conservatorship, receivership, insolvency, bankruptcy or similar proceedings.

(6) *Liquidity shortfall*—(i) *In general.* The term *liquidity shortfall* means, with respect to any required installment, an amount equal to the excess (as of the last day of the quarter for which that installment is made) of—

(A) The base amount with respect to the quarter, over

(B) The value (as of the last day of the quarter) of the plan's liquid assets.

(ii) *Base amount*—(A) *In general.* For purposes of this paragraph (e)(6)(ii), the term *base amount* means, with respect to any quarter, an amount equal to 3 times the sum of the adjusted disbursements from the plan for the 12 months ending on the last day of such quarter.

(B) *Special rule.* If the generally applicable base amount for a quarter determined under paragraph (e)(6)(ii)(A) of this section exceeds an amount equal to 2 times the sum of the adjusted disbursements from the plan for the 36 months ending on the last day of the quarter and the enrolled actuary for the plan certifies to the satisfaction of the Commissioner that such excess is the result of nonrecurring circumstances, the base amount with respect to that quarter is determined without regard to amounts related to those nonrecurring circumstances.

(7) *Plan month*—(i) *Plan year begins on the first day of a calendar month.* For a plan year that begins with the first day of a calendar month, the term *plan month* means any calendar month that begins during the plan year.

(ii) *Plan year begins on a date other than the first day of a calendar month.* For a plan year that begins on a date other than the first day of a calendar month, the first day of each *plan month* is the day of the calendar month that corresponds to the day of the calendar month that is the first day of the plan year. Thus, for example, if the first day of a plan year is January 15, then a plan month starts on the 15th of each calendar month. However, if a calendar month does not contain a day that corresponds to the day of the calendar month which is the first day of the plan year (for example, if a calendar month has only 30 days and the first day of the plan year is the 31st day of a calendar

month), then the first day of the plan month that begins during that calendar month is the last day of that calendar month.

(8) *Quarter.* The term *quarter* means, with respect to any required installment, the 3-plan-month period preceding the plan month in which the due date for that installment occurs.

(9) *Short plan year.* The term *short plan year* means a plan year that is shorter than 12 months (and is not a 52-week plan year of a plan that uses a 52–53 week plan year).

(f) *Examples.* The following examples illustrate the rules of this section.

Example 1. (i) Plan A has a calendar year plan year and a January 1 valuation date. Plan A has a funding standard carryover balance of $15,000 as of January 1, 2008, and the plan's funding ratio for 2007 (determined using the transition rule in § 1.430(f)–1(h)(5)) was over 80%. The minimum required contribution for Plan A (prior to any offset for the carryover balance) is $100,000 for 2008 and is $125,000 for 2009.

The effective interest rate for the 2009 plan year is 5.90%. Plan A is subject to the quarterly contribution requirements for 2008.

(ii) The required annual payment for 2009 is equal to the lesser of (a) 100% of the 2008 minimum required contribution ($100,000) or (b) 90% of the 2009 minimum required contribution (90% of $125,000, or $112,500). Therefore, each required quarterly installment for 2009 is 25% of $100,000, or $25,000.

(iii) Installments of $25,000 each are due by April 15, 2009, July 15, 2009, October 15, 2009, and January 15, 2010. The final contribution for the 2009 plan year is due by September 15, 2010. The amount of this contribution is equal to $125,000, less the contributions made prior to that date, with all contributions adjusted to the valuation date using the effective interest rate for the 2009 plan year. If the plan sponsor makes each required quarterly installment on the date due, the remaining amount due is determined as follows:

(A) The contribution paid April 15, 2009, is adjusted by discounting the contribution amount for 3 ½ months at the effective interest rate ($25,000 ÷ $1.0590^{(3.5/12)}$ = $24,585).

(B) The contribution paid July 15, 2009, is discounted for 6½ months at the effective interest rate ($25,000 ÷ $1.0590^{(6.5/12)}$ = $24,236).

(C) The contribution paid October 15, 2009, is discounted for 9½ months at the effective interest rate ($25,000 ÷ $1.0590^{(9.5/12)}$ = $23,891).

(D) The contribution paid January 15, 2010, is discounted for 12½ months at the effective interest rate ($25,000 ÷ $1.0590^{(12.5/12)}$ = $23,551).

(E) The sum of the above contributions for the 2009 plan year paid through January 15, 2010, adjusted for interest to the valuation date, is $96,263. The remaining amount due for the 2009 plan year is $125,000 minus $96,263, or $28,737, as of January 1, 2009.

(iv) If the final contribution is made on September 15, 2010, the remaining amount due must be increased for interest at the plan's effective interest rate for the 20½ months between January 1, 2009, and September 15, 2010 (so that when it is discounted with interest for those 20½ months the resulting amount will equal $28,737). Therefore, the remaining contribution made on September 15, 2010, is $28,737 × $1.0590^{(20.5/12)}$ = $31,694.

Example 2. (i) The facts are the same as in Example 1, except that the plan sponsor elects to use the $15,000 carryover balance as of January 1, 2008, to offset the minimum required contribution for the 2008 plan year. The plan sponsor makes a contribution on January 1, 2008, of $85,000, which satisfies the minimum contribution requirement for 2008.

(ii) The required quarterly installment for 2009 is unaffected by the plan sponsor's election to offset the minimum required contribution by the carryover balance for 2008. Therefore, the required annual payment is $100,000 (determined as the lesser of (a) 100% of $100,000 or (b) 90% of $125,000) and the amount of each required quarterly installment for 2009 is 25% of the required annual payment, or $25,000.

Example 3. (i) The facts are the same as in Example 1. Plan A's funding standard carryover balance has increased to $17,000 as of January 1, 2009, based on the actual rate of return of plan assets for the 2008 plan year. Plan A's funding ratio for 2008 (determined under § 1.430(f)–1(d)(3)) is over 80%. On April 13, 2009, the plan sponsor elects to use the entire amount of the carryover balance to offset the minimum required contribution for 2009.

(ii) The plan sponsor's election to use the carryover balance to offset the minimum required contribution is treated as satisfying the requirement to make a required installment to the extent of the amount elected, adjusted with interest. This adjustment is made at the plan's effective interest rate for the 2009 plan year, and applies for the period between January 1, 2009, and April 15, 2009. Therefore, the $17,000 carryover balance as of January 1, 2009, offsets $17,000 × $1.0590^{(3.5/12)}$ or $17,287 of the $25,000 quarterly contribution installment due April 15, 2009, and the remaining contribution due on April 15, 2009, is $25,000 minus $17,287, or $7,713.

(iii) The interest adjustments in paragraph (ii) of this Example 3 are based on the effective interest rate even if that rate is not determined by the time that the quarterly contribution is due. If the plan's effective interest rate for the plan year has not been determined at the time that the quarterly contribution is due, the actual amount of the required installment satisfied by the use of the carryover balance is determined after the effective interest rate is determined. If the extent to which the carryover balance satisfies the installment requirement is overestimated and the result is the full amount of the required quarterly installment is not paid by the due date, the plan is subject to the consequences for late or unpaid quarterly contributions as described in paragraph (c)(1)(iii) of this section.

Example 4. (i) The facts are the same as in Example 3. The plan sponsor makes a contribution of $7,713 (which is equal to the remaining portion of the first required quarterly installment) on April 15, 2009. For the 2009 plan year, the plan sponsor makes another contribution of $200,000 on June 30, 2009. No further contributions are made for the 2009 plan year.

(ii) The contributions made for the 2009 plan year are adjusted to the valuation date using the plan's effective interest rate for the 2009 plan year. The contribution paid April 15, 2009, is discounted for the 3½ months between January 1, 2009, and the date of payment, using the effective interest rate of 5.90% ($7,713/$1.0590^{(3.5/12)}$ = $7,585). The contribution paid June 30, 2009, is discounted for 6 months using the effective interest rate ($200,000/$1.0590^{(6/12)}$ = $194,349), for a total interest-adjusted contribution of $201,934.

(iii) The minimum required contribution for 2009 (prior to any offset for the carryover balance) is $125,000 and, under § 1.430(f)–1(b)(1)(ii)(B), this amount is used to determine the interest-adjusted excess contribution. Accordingly, the interest-adjusted excess contribution for 2009 is $201,934 minus $125,000, or $76,934, increased for interest to January 1, 2010, using the effective interest rate for 2009 of 5.90%. Thus, the interest-adjusted excess contribution as of January 1, 2010, is $76,934 multiplied by 1.059, or $81,473. All or a portion of this amount may be credited to the prefunding balance at the election of the plan sponsor.

Example 5. (i) The facts are the same as in Example 3. The plan sponsor pays the required quarterly installment of $7,713 on April 15, 2009, and installments of $25,000 each on July 15, 2009, and October 15, 2009. However, only $10,000 of the installment due on January 15, 2010, is paid. No additional contributions are made until the final contribution for the plan year of $55,000 is paid on September 15, 2010.

(ii) The 2009 Schedule SB shows that the contributions for the plan year exceed the minimum required contribution. This is determined by comparing the minimum required contribution of $108,000 ($125,000 offset by $17,000 for the amount of carryover balance used) and the interest-adjusted contributions made for the 2009 plan year, developed as shown below:

(A) The contribution paid April 15, 2009, is adjusted by discounting the contribution amount for 3½ months at the effective interest rate ($7,713 ÷ $1.0590^{(3.5/12)}$ = $7,585).

(B) The contribution paid July 15, 2009, is discounted for 6½ months at the effective interest rate ($25,000 ÷ $1.0590^{(6.5/12)}$ = $24,236).

(C) The contribution paid October 15, 2009, is discounted for 9½ months at the effective interest rate ($25,000 ÷ $1.0590^{(9.5/12)}$ = $23,891).

(D) The contribution paid January 15, 2010, is discounted for 12½ months at the effective interest rate ($10,000 ÷ $1.0590^{(12.5/12)}$ = $9,420).

(E) Pursuant to paragraph (c)(1)(iii)(A) of this section, the adjustment for interest on the $15,000 underpayment of the quarterly installment due January 15, 2010, is increased by 5 percentage points for the 8-

month period of underpayment (January 15, 2010, through September 15, 2010). Accordingly, $15,000 of the contribution paid on September 15, 2010, is discounted using a rate of 10.90% for 8 months and at the 5.90% effective interest rate for the remaining 12½ months between the quarterly contribution due date of January 15, 2010, and the valuation date of January 1, 2009. This portion of the September 15, 2010, contribution results in an adjusted amount of $13,189 as of January 1, 2009 ($15,000 ÷ $1.1090^{(8/12)}$ ÷ $1.0590^{(12.5/12)}$).

(F) The remaining $40,000 of the contribution paid on September 15, 2010, is discounted using the effective interest rate of 5.90% for the 20½-month period between the date of payment and the valuation date. This portion of the payment is therefore adjusted to $36,268 as of the valuation date (that is, $40,000 ÷ $1.0590^{(20.5/12)}$).

(G) The sum of the above contributions for the 2009 plan year paid through January 15, 2010, adjusted for interest to the valuation date, is $114,589. This is greater than the minimum required contribution for the 2009 plan year of $108,000.

Example 6. (i) The facts are the same as in Example 5, except that the plan sponsor does not make a contribution on September 15, 2010. Another contribution is not made until December 15, 2010.

(ii) The 2009 Schedule SB shows an unpaid minimum required contribution of $42,868 as of January 1, 2009. This is equal to the difference between the minimum required contribution of $108,000 ($125,000 offset by $17,000 for the amount of carryover balance used) and $65,132 (the interest-adjusted contributions made for the 2009 plan year before the 8½ month deadline, as illustrated in paragraphs (ii)(A) through (ii)(D) of Example 5).

Example 7. (i) The facts are the same as in Example 1, except that the plan year is changed to an August 1–July 31 plan year effective August 1, 2009. This results in a short plan year beginning January 1, 2009, and ending July 31, 2009. The minimum required contribution for the 7-month period covered by the plan year is calculated as $72,917 in accordance with § 1.430(a)–1(b)(2)(ii).

(ii) As provided in paragraph (c)(5) of this section, a required installment is due 15 days after the close of the short plan year (August 15, 2009), and required installments are also due on the regularly scheduled due dates for quarterly installments that occur within the short plan year (April 15, 2009, and July 15, 2009).

(iii) The required installments are determined based on the lesser of (a) 90% of the minimum required contribution for the short plan year ending July 31, 2009 (90% of $72,917, or $65,625) or (b) 7/12 of 100% of the 2008 minimum required contribution ($100,000 × 7/12, or $58,333). The required installments are thus based on $58,333 since that is the smaller amount.

(iv) The amount of each required installment is determined by dividing the amount determined in paragraph (iii) of this Example 7 by the number of required installments for the short plan year. This calculation results in required installments of $19,444 each (that is, $58,333 divided by 3 installments).

(v) The deadline for the remaining payment is 8½ months after the end of the short plan year, or April 15, 2010. If the plan sponsor pays the minimum required amount at each installment date, does not elect to offset any amounts by any carryover or prefunding balance, and makes a final payment on April 15, 2010, then the remaining payment is $17,429, determined as follows:

(A) The contribution paid April 15, 2009, is adjusted by discounting the contribution amount for 3½ months at the effective interest rate ($19,444 ÷ $1.0590^{(3.5/12)}$ = $19,122).

(B) The contribution paid July 15, 2009, is discounted for 6½ months at the effective interest rate ($19,444 ÷ $1.0590^{(6.5/12)}$ = $18,850).

(C) The contribution paid August 15, 2009, is discounted for 7½ months at the effective interest rate ($19,444 ÷ $1.0590^{(7.5/12)}$ = $18,760).

(D) The sum of the above contributions for the 2009 plan year paid through August 15, 2009, adjusted for interest to the valuation date, is $56,732. The remaining amount paid April 15, 2010, for the 2009 plan year is ($72,917 − $56,732) × $1.059^{(15.5/12)}$ = $17,429.

Example 8. (i) Plan B has an August 10 to August 9 plan year. Quarterly installments are required for the plan year that begins August 10, 2009.

(ii) For the plan year that begins on August 10, 2009, a plan month begins on the 10th day of each calendar month. Accordingly, the due dates for the required installments for that plan year are November 24, 2009, February 24, 2010, May 24, 2010, and August 24, 2010. The deadline for the final contribution for the plan year is April 24, 2011.

Example 9. (i) Plan C has a calendar-year plan year and is not a small plan described in section 430(g)(2)(B). Plan C is subject to the requirement to pay quarterly contributions under paragraph (c) of this section for the 2009 plan year. The valuation date for Plan C is January 1, and Plan C's funding target attainment percentage (''FTAP'') is 85% as of January 1, 2009. Before taking the liquidity requirement of paragraph (d) of this section into account, quarterly contributions are required for the 2009 plan year in the amount of $50,000 each. During the 12-month period ending March 31, 2009, periodic annuity payments of $350,000 and lump sum payments of $200,000 were made by Plan C. None of these payments were due to nonrecurring circumstances. In addition, administrative expenses of $100,000 were paid from the plan trust. The market value of Plan C's assets is $1,500,000 as of March 31, 2008, of which $1,300,000 is in liquid assets. The amount needed to increase the plan's FTAP (including the expected increase in the funding target due to benefits accruing or earned during the plan year) to 100% is $500,000.

(ii) The amount of the adjusted disbursements from Plan C for the 12-month period ending March 31, 2009, is calculated as the sum of the annuity benefits, lump sum payments, and administrative expenses paid during the 12-month period, reduced by the product of the lump sum payments and the plan's FTAP. This results in adjusted disbursements for the period of $480,000 (that is, $350,000 plus $200,000 plus $100,000, reduced by 85% of $200,000 in lump sum payments).

(iii) The base amount is calculated in accordance with paragraph (e)(6)(ii) of this section as three times the adjusted disbursements determined in paragraph (ii) of this Example 9, or $1,440,000.

(iv) The liquidity shortfall is the difference between the base amount of $1,440,000 determined in paragraph (iii) of this Example 9 and the $1,300,000 in liquid assets as of March 31, 2008, or $140,000. The quarterly contribution due on April 15, 2009, is therefore $140,000, since this amount is larger than the $50,000 quarterly contribution requirement otherwise applicable but less than the $500,000 needed to increase the plan's FTAP (including the expected increase in the funding target due to benefits accruing or earned during the plan year) to 100%. The liquidity increment is $90,000.

(v) Note that any contributions made through March 31, 2009, are included in Plan C's assets as of March 31, 2009, and would therefore not be applied toward satisfying the liquidity shortfall contribution requirement due April 15, 2009. Similarly, any funding standard carryover balance or prefunding balance as of January 1, 2009, cannot be applied to offset the liquidity shortfall contribution requirement. Only contributions made in cash or other liquid assets made after March 31, 2009, and by April 15, 2009, can be used to timely satisfy this requirement.

Example 10. (i) The facts are the same as in Example 9. The plan sponsor makes a contribution of $30,000 on April 15, 2009, and makes an additional contribution of $110,000 on April 30, 2009. The effective interest rate for Plan C for the 2009 plan year is 5.90%.

(ii) The contribution paid on April 15, 2009, is applied first to the portion of the quarterly contribution that is required under paragraph (c) of this section (that is, the portion not attributable to the liquidity shortfall contribution). This results in an underpayment of this portion of the quarterly contribution due April 15, 2009, of $20,000 (that is, $50,000 minus $30,000). In accordance with paragraph (c)(1)(iii)(A) of this section, the interest rate used to adjust this portion of the late quarterly contribution is increased by 5 percentage points for the ½ month period of underpayment. Accordingly, $20,000 of the April 15, 2009, contribution is adjusted to the January 1, 2009, valuation date using an interest rate of 10.90% for the ½ month between the April 15, 2009, due date and the April 30, 2009, payment date, and by 5.90% for the 3½ month period between January 1, 2009, and the April 15, 2009, due date. This portion results in an interest-adjusted contribution of $19,584 as of January 1, 2009 ($20,000 ÷ $1.1090^{(0.5/12)}$ ÷ $1.059^{(3.5/12)}$).

(iii) Under paragraph (d)(2) of this section, the interest rate used to adjust the portion of

the underpayment attributable to the liquidity shortfall contribution is increased by 5 percentage points, and the contribution is treated as unpaid until the close of the quarter in which the due date occurs. Therefore, even though the full amount of the liquidity shortfall was paid by April 30, 2009, the increase in the interest rate is applied as if the late liquidity shortfall contribution was not made until June 30, 2009, 2½ months after the contribution was due.

(iv) However, in accordance with paragraph (d)(2) of this section, each payment is discounted for interest based on the date of the actual payment, despite the fact that the 5-percentage-point increase in the interest rate is calculated as if the payment was not made until the end of the quarter. Therefore, the portion of the underpayment due to the liquidity increment ($140,000 minus the $50,000 quarterly contribution requirement otherwise required, or $90,000) is adjusted for interest for the 4-month period between the January 1, 2009, valuation date and the April 30, 2009, date of payment. An interest rate of 10.90% is used for 2½ months (corresponding to the period between the April 15, 2009, due date and June 30, 2009, the end of the quarter in which the payment was due), and Plan C's effective interest rate for the 2009 plan year (5.90%) is used for the remaining 1½ months. Therefore, the portion of the April 30, 2009, contribution attributable to the liquidity increment is adjusted to $87,452 as of January 1, 2009 ($90,000 ÷ $1.1090^{(2.5/12)}$ ÷ $1.0590^{(1.5/12)}$).

Example 11. (i) The facts are the same as in Example 10, except that the plan sponsor does not make the second contribution of $110,000 until July 15, 2009.

(ii) The July 15, 2009, contribution is adjusted for interest for a total of 6½ months for the period between January 1, 2009, and the payment date of July 15, 2009. In accordance with paragraph (d)(2) of this section, the 5-percentage-point increase in the interest rate used to adjust the portion of the contribution attributable to the unpaid liquidity shortfall contribution is applied as if the contribution was made at the end of the quarter in which the payment was due. Therefore, the interest adjustment for the $90,000 attributable to the late liquidity shortfall contribution uses an interest rate of 10.90% for the 2½-month period corresponding to the period between the April 15, 2009, due date and June 30, 2009, the end of the quarter in which the payment was due, and the effective interest rate of 5.90% for the remaining 4 months.

(iii) The liquidity shortfall is recalculated as of June 30, 2009, and the larger of the resulting amount or the $50,000 quarterly contribution otherwise applicable is due on July 15, 2009. This amount is required to be paid in addition to the unpaid liquidity shortfall contribution due April 15, 2009. Note that the amount of liquid assets as of June 30, 2009 is smaller than it would have been had the April 15, 2009, liquidity shortfall payment been made. Therefore, the fact that the April 15, 2009, liquidity shortfall payment was not made before June 30, 2009, means that the plan sponsor is required to contribute more than the amount needed to increase the liquid assets to the base amount as of June 30, 2009. However, in accordance with paragraph (d)(1)(ii) of this section, the total amount of the required installments (including those due but not paid) is limited so that it is no larger than the amount that would increase the plan's FTAP (taking into account the expected increase in the funding target due to benefits accruing or earned during the plan year) to 100%.

Example 12. (i) Plan D, which is a small plan described in section 430(g)(2)(B), has a calendar year plan year and a valuation date of December 31. The quarterly required installments for the 2009 plan year are $30,000 each and each of the required installments is paid on the due date. The effective interest rate for Plan D for the 2009 plan year is 5.90%.

(ii) The total contributions made for the plan year and before the valuation date, adjusted with interest to the valuation date, equal $92,402. This is developed as shown below:

(A) The contribution paid April 15, 2009, is adjusted by increasing the contribution amount for 8½ months at the effective interest rate ($30,000 × $1.0590^{(8.5/12)}$ = $31,243).

(B) The contribution paid July 15, 2009, is increased for 5½ months at the effective interest rate ($30,000 × $1.0590^{(5.5/12)}$ = $30,799).

(C) The contribution paid October 15, 2009, is increased for 2½ months at the effective interest rate ($30,000 × $1.0590^{(2.5/12)}$ = $30,360).

(iii) Pursuant to § 1.430(g)–1(d)(2), the interest-adjusted value of the contributions for the 2009 plan year that are made before the valuation date is subtracted from the December 31, 2009, plan assets in determining the value of plan assets for the December 31, 2009 actuarial valuation.

(g) *Effective/applicability dates and transition rules*—(1) *In general.* Section 430 generally applies to plan years beginning on or after January 1, 2008. In general, this section applies to plan years beginning on or after January 1, 2009. However, plans are permitted to apply this section in applying the rules of section 430(j) for plan years beginning in 2008.

(2) *Plans with delayed effective date.* In the case of a plan for which the effective date of section 430 is delayed in accordance with sections 104 through 106 of PPA '06, this section applies to plan years beginning on or after the first day of the first effective plan year.

(3) *First effective plan year.* For purposes of this section, the first effective plan year for a plan is the first plan year for which section 430 applies to the plan.

(4) *Pre-effective plan year.* For purposes of this section, the pre-effective plan year for a plan is the last plan year before the first effective plan year. Thus, except for plans with a delayed effective date under paragraph (g)(2) of this section, the pre-effective plan year for a plan is the last plan year beginning before January 1, 2008.

(5) *Special rules relating to first effective plan year*—(i) *Determination of minimum required contribution for pre-effective plan year.* In the case of the plan's first effective plan year, the minimum required contribution for the preceding plan year for purposes of paragraph (c)(3)(ii)(B) of this section is equal to the minimum required contribution under section 412 for the pre-effective plan year (determined without regard to any funding waiver under section 412), which is determined as of the last day of the pre-effective plan year and is determined without regard to the use of the plan's credit balance.

(ii) *Determination of funding shortfall for pre-effective plan year.* [Reserved]

PART 54—PENSION EXCISE TAXES

Par. 4. The authority citation for part 54 continues to read in part as follows:

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

Par. 5. Section 54.4971(c)–1 is added to read as follows:

§ 54.4971(c)–1 Taxes on failure to meet minimum funding standards; definitions

(a) *In general.* This section sets forth definitions that apply for purposes of applying the rules of section 4971.

(b) *Accumulated funding deficiency.* With respect to a multiemployer plan, the term *accumulated funding deficiency* has the meaning given to that term by section 431. A plan's accumulated funding deficiency for a plan year takes into account all charges and credits to the funding standard account under section 412 for plan years before the first plan year for which section 431 applies to the plan.

(c) *Unpaid minimum required contribution*—(1) *In general.* The term *unpaid minimum required contribution* means, with respect to any plan year, any minimum required contribution under section 430 for the plan year that is not paid on or before the due date for the plan year under section 430(j)(1).

(2) *Accumulated funding deficiency for pre-effective plan year.* For purposes of this section, a plan's accumulated funding deficiency under section 412 for the pre-effective plan year is treated as an unpaid minimum required contribution for that plan year until correction is made under the rules of paragraph (d)(2) of this section.

(d) *Correct*—(1) *Accumulated funding deficiency.* The term *correct* means, with respect to an accumulated funding deficiency for a plan year, the contribution, to or under the plan, of the

amount necessary to reduce the accumulated funding deficiency as of the end of that plan year to zero. To reduce the deficiency to zero, the contribution must include interest at the plan's valuation interest rate for the period between the end of that plan year and the date of the contribution.

(2) *Unpaid minimum required contribution*—(i) *Interest adjustments*—(A) *General rule*. The term *correct* means, with respect to an unpaid minimum required contribution for a plan year, the contribution, to or under the plan, of an amount that, when discounted to the valuation date for the plan year for which the unpaid minimum required contribution is due at the appropriate rate of interest, equals or exceeds the unpaid minimum required contribution. For this purpose, the appropriate rate of interest is the plan's effective interest rate for the plan year for which the unpaid minimum required contribution is due except to the extent that the payments are subject to additional interest as provided under section 430(j) (3) or (4).

(B) *Pre-PPA accumulated funding deficiency*. The term *correct* means, with respect to the accumulated funding deficiency under section 412 for the pre-effective plan year that is described in paragraph (c)(2) of this section, the contribution, to or under the plan, of the amount of that accumulated funding deficiency increased with interest from the end of the pre-effective plan year to the date of the contribution at the plan's valuation interest rate for the pre-effective plan year.

(ii) *Ordering rule*. For purposes of section 4971 and this section, a contribution is attributable first to the earliest plan year of any unpaid minimum required contribution for which correction has not yet been made.

(3) *Corrective action of certain retroactive plan amendments*. Certain retroactive plan amendments that meet the requirements of section 412(d)(2) may reduce the minimum required contribution for a plan year, which would reduce the accumulated funding deficiency or the amount of the unpaid minimum required contribution for a plan year.

(e) *Taxable period*. The term *taxable period* has the same meaning given that term under § 54.4971–1(e).

(f) *Examples*. The following examples illustrate the rules of this section.

Example 2. (i) Example 1. Plan A, a single employer defined benefit plan, has a calendar year plan year and a January 1 valuation date. The sponsor of Plan A has a calendar taxable year. Plan A has no funding shortfall as of the end of 2008, and Plan A has no unpaid minimum required contributions for 2008 or any earlier plan year. The minimum required contribution for the 2009 plan year is $250,000. The plan sponsor makes one contribution for 2009 on July 1, 2009, in the amount of $200,000, and the sponsor does not make an election to use the prefunding balance or funding standard carryover balance to offset the minimum required contribution for 2009. The effective interest rate for Plan A for the 2009 plan year is 5.90%.

(ii) The interest-adjusted contribution for 2009 is $200,000 divided by $1.0590^{(6/12)}$, or $194,349, as of January 1, 2009. The unpaid minimum required contribution for the 2009 plan year is $250,000 minus $194,349, or $55,651. The excise tax due under section 4971(a) is 10% of the unpaid minimum required contribution, or $5,565.

(i) The facts are the same as in *Example 1*. The plan sponsor makes a contribution of $175,000 on December 31, 2010.

(ii) Under the ordering rule in paragraph (d)(2)(ii) of this section, the contribution made on December 31, 2010, is applied first to correct the unpaid minimum required contribution for 2009. The portion of the contribution paid December 31, 2010, that is required to eliminate the unpaid minimum required contribution for 2009 (taking into account the 2009 effective interest rate for the 24 months between January 1, 2009, and the payment date of December 31, 2010), is $55,651 multiplied by $1.059^{(24/12)}$ or $62,412. The remaining payment of $112,588 ($175,000 minus $62,412) is applied to the contribution required for the 2010 plan year.

Example 3. (i) Plan B, a single employer defined benefit plan, has a calendar plan year. The sponsor of Plan B has a calendar taxable year. Plan B has an accumulated funding deficiency of $100,000 as of December 31, 2007, including additional interest due to late quarterly contributions during 2007. The valuation interest rate for the 2007 plan year is 7.5%.

(ii) In accordance with paragraph (c)(2) of this section, the accumulated funding deficiency under section 412 as of December 31, 2007, is considered an unpaid minimum required contribution until it is corrected. Pursuant to paragraph (d)(2)(i)(B) of this section, the amount needed to correct that accumulated funding deficiency is $100,000 plus interest at the valuation interest rate of 7.5% for the period between December 31, 2007, and the date of payment of the contribution.

(iii) The funding shortfall as of January 1, 2008, is calculated as the difference between the funding target and the value of assets as of that date. The assets are not adjusted by the amount of the accumulated funding deficiency; the fact that the contribution was not made for the 2007 plan year means that the January 1, 2008, funding shortfall is larger than it would have been otherwise.

Example 4. (i) The facts are the same as in Example 3. The minimum required contribution for the 2008 plan year is $125,000, but the plan sponsor does not make any required contributions for 2008.

(ii) The total unpaid minimum required contribution as of December 31, 2008, is the sum of the $100,000 accumulated funding deficiency under section 412 from 2007 and the $125,000 unpaid minimum required contribution for 2008, or $225,000. The section 4971(a) excise tax applies to the aggregate unpaid minimum required contributions for all plan years that remain unpaid as of the end of 2008. In this case, there is an unpaid minimum required contribution of $100,000 for the 2007 plan year and an unpaid minimum required contribution of $125,000 for the 2008 plan year. The section 4971(a) excise tax is 10% of the aggregate of those unpaid amounts, or $22,500.

Example 5. (i) The facts are the same as in Example 4, except that the plan sponsor makes a contribution of $150,000 on December 31, 2008. No additional contributions are paid through September 15, 2009. Quarterly contributions of $25,000 each are due April 15, 2008, July 15, 2008, October 15, 2008, and January 15, 2009. Plan B's effective interest rate for the 2008 plan year is 5.75%.

(ii) In accordance with paragraph (c)(2) of this section, the accumulated funding deficiency under section 412 as of December 31, 2007, is treated as an unpaid minimum required contribution until it is corrected.

(iii) The December 31, 2008, contribution is first applied to the 2007 accumulated funding deficiency under section 412 that is treated as an unpaid minimum required contribution. Accordingly, the amount needed to correct the 2007 unpaid required minimum contribution ($100,000 multiplied by 1.075, or $107,500) is applied to eliminate this unpaid minimum required contribution for the 2007 plan year.

(iv) The remaining December 31, 2008, contribution ($150,000 minus $107,500, or $42,500) is then applied to the 2008 minimum required contribution. This amount is first allocated to the quarterly contribution due April 15, 2008. In accordance with § 1.430(j)–1(c)(1)(iii)(A), the adjustment for interest on late quarterly contributions is increased by 5 percentage points for the period of underpayment. Therefore, $25,000 of the remaining December 31, 2008, contribution is discounted using an interest rate of 10.75% for the 8½-month period between the payment date of December 31, 2008 and the quarterly contribution due date of April 15, 2008, and at the 5.75% effective interest rate for the 3½ months between April 15, 2008, and January 1, 2008. This portion of the December 31, 2008, contribution results in an adjusted amount of $22,880 (that is, $25,000 $\div 1.1075^{(8.5/12)} \div 1.0575^{(3.5/12)}$) as of January 1, 2008.

(v) The remaining December 31, 2008, contribution is then applied to the quarterly contribution due July 15, 2008. The balance

of the December 31, 2008, contribution ($150,000 minus $107,500 minus $25,000, or $17,500) is paid after the due date for the second required quarterly installment. Accordingly, the remaining $17,500 contribution is adjusted using an interest rate of 10.75% for the 5½-month period between the payment date of December 31, 2008 and the quarterly contribution due date of July 15, 2008, and at the 5.75% effective interest rate for the 6½ months between July 15, 2008, and January 1, 2008. This portion of the December 31, 2008, contribution results in an adjusted amount of $16,202 (that is, $17,500 ÷ $1.1075^{(5.5/12)}$ ÷ $1.0575^{(6.5/12)}$) as of January 1, 2008.

(vi) The remaining unpaid minimum required contribution for 2008 is $125,000 minus the interest-adjusted amounts of $22,880 and $16,202 applied towards the 2008 minimum required contribution as determined in paragraphs (iv) and (v) of this *Example 5*. This results in an unpaid minimum required contribution of $85,918 for 2008. The section 4971(a) excise tax is 10% of the unpaid minimum required contribution, or $8,592.

Example 6. (i) Plan C, a single employer defined benefit plan, has a calendar year plan year and a January 1 valuation date, and has no funding standard carryover balance or prefunding balance as of January 1, 2008. Plan C's sponsor has a calendar year taxable year. The minimum required contributions for Plan C are $100,000 for the 2008 plan year, $110,000 for the 2009 plan year, $125,000 for the 2010 plan year, and $135,000 for the 2011 plan year. No contributions for these plan years are made until September 15, 2012, at which time the plan sponsor contributes $273,000 (which is exactly enough to correct the unpaid minimum required contributions for the 2008 and 2009 plan years).

(ii) The excise tax under section 4971(a) is 10% of the aggregate unpaid minimum required contributions for all plan years remaining unpaid as of the end of any plan year ending within the 2008 taxable year. Accordingly, the excise tax for the 2008 taxable year is $10,000 (that is, 10% of $100,000). The excise tax for the 2009 taxable year is $21,000 (that is, 10% of the sum of $100,000 and $110,000) and the excise tax for the 2010 taxable year is $33,500 (that is, 10% of the sum of $100,000, $110,000, and $125,000).

(iii) The contribution made on September 15, 2012, is applied to correct the unpaid minimum required contributions for the 2008 and 2009 plan years by the deadline for making contributions for the 2011 plan year. Therefore, the excise tax under section 4971(a) for the 2011 taxable year is based only on the remaining unpaid minimum required contributions for the 2010 and 2011 plan years, or $26,000 (that is, 10% of the sum of $125,000 and $135,000).

(iv) The plan sponsor may also be required to pay an excise tax of 100% under section 4971(b), if the unpaid minimum required contributions are not corrected by the end of the taxable period.

(g) *Effective/applicability dates and transition rules*—(1) *Statutory effective date*—(i) *In general*. In general, the amendments made to section 4971 by section 114 of the Pension Protection Act of 2006, Public Law 109–280, 120 Stat. 780 (PPA '06), apply to taxable years beginning on or after January 1, 2008, but only with respect to plan years that end with or within any such taxable year.

(ii) *Plans with delayed PPA '06 effective dates*. In the case of a plan for which the effective date of section 430 is delayed in accordance with sections 104 through 106 of PPA '06, the amendments made to section 4971 by section 114 of PPA '06 apply to taxable years beginning on or after January 1, 2008, but only with respect to plan years beginning on or after the date section 430 first applies with respect to the plan.

(2) *Effective date of regulations*. This section is effective for taxable years beginning on and after the statutory effective date described in paragraph (g)(1) of this section, but in no event does this section apply to taxable years ending before April 15, 2008.

(3) *Pre-effective plan year*. For purposes of this section, the pre-effective plan year for a plan is the last plan year beginning before section 430 applies to the plan. Thus, except for plans with a delayed effective date under paragraph (g)(1)(ii) of this section, the pre-effective plan year for a plan is the last plan year beginning before January 1, 2008.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 08–1133 Filed 4–11–08; 10:10 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0180]

RIN 1625–AA00

Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone upon certain waters of the Patapsco River, Northwest Harbor and Inner Harbor during the movements of the historic sloop-of-war USS CONSTELLATION. This action is necessary to provide for the safety of life on navigable waters during two tows of the vessel in Baltimore, Maryland; one from its berth at Baltimore's Inner Harbor to a berth at the South Locust Point Marine Terminal, and the other from the South Locust Point Marine Terminal to its berth at Baltimore's Inner Harbor. This action will restrict vessel traffic in portions of the Patapsco River, Northwest Harbor, and Inner Harbor during these events.

DATES: Comments and related material must reach the Coast Guard on or before May 30, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0180 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Online: *http://www.regulations.gov.*

(2) Mail: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) Hand delivery: Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) Fax: 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Mr. Ronald Houck, at Coast Guard Sector Baltimore, Waterways Management Division, at telephone number (410) 576–2674 or (410) 576–2693. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0180), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing comments and documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time. Enter the docket number for this rulemaking (USCG–2008–0180) in the Search box, and click ''Go >>.'' You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or the Commander, U.S. Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Building 70, Waterways Management Division, Baltimore, Maryland, 21226–1791 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov*.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The USS CONSTELLATION Museum is planning to conduct a ceremony in the Port of Baltimore, Maryland, involving the sloop-of-war USS CONSTELLATION on Friday, August 8, 2008. Scheduled events include a four-hour tow of the USS CONSTELLATION beginning at 6 p.m., from its berth at Pier 1 Inner Harbor to the Locust Point Cruise Ship Terminal berth at the South Locust Point Marine Terminal, with an onboard salute with navy pattern cannon while the historic vessel is positioned off Fort McHenry National Monument and Historic Site. A one-hour return tow of the CONSTELLATION is scheduled for Sunday, August 10, 2008. Departure from the Locust Point Cruise Ship Terminal will occur at 7 a.m. and arrival at Pier 1 Inner Harbor at 8 a.m. For both tows, the historic Sloop-of-War USS CONSTELLATION will be towed ''dead ship,'' which means that the vessel will be underway without the benefit of mechanical or sail propulsion. While berthed at the Locust Point Cruise Ship Terminal, the vessel will participate in the commissioning ceremonies for the U.S. Navy's new Arleigh Burke class Aegis guided missile destroyer USS STERETT, DDG 104. The Coast Guard anticipates a large recreational boating fleet during these events, scheduled on a weekend during the summer in Baltimore, Maryland. Operators should expect significant vessel congestion along the planned route.

The purpose of this proposed rule is to promote maritime safety and protect participants and the boating public in the Port of Baltimore immediately prior to, during, and after the scheduled event. The proposed rule will provide for a clear transit route for the participating vessels, and provide a safety buffer around the participating vessels while they are in transit. The proposed rule will impact the movement of all vessels operating upon certain waters of the Patapsco River, Northwest Harbor and Inner Harbor.

Discussion of Proposed Rule

The historic sloop-of-war USS CONSTELLATION is scheduled to be towed ''dead ship'' on August 8, 2008 and on August 10, 2008. The CONSTELLATION is scheduled to be towed within the Port of Baltimore, Maryland, from its berth at Pier 1 in Baltimore's Inner Harbor to the Locust Point Cruise Ship Terminal, at South Locust Point Marine Terminal, along a one-way, planned route of approximately four nautical miles, which includes specified waters of the Patapsco River, Northwest Harbor and Inner Harbor.

The safety of dead ship tow participants requires that persons and vessels be kept at a safe distance from the intended route during this evolution. The Coast Guard proposes to establish a temporary moving safety zone around the USS CONSTELLATION dead ship tow participants for all waters within 200 yards ahead of, 100 yards outboard and 100 yards aft of the historic Sloop-of-War USS CONSTELLATION while operating in the Inner Harbor, the Northwest Harbor and the Patapsco River on August 8, 2008 and on August 10, 2008, to ensure the safety of participants and spectators immediately prior to, during, and following the dead ship tows. Interference with normal port operations will be kept to the minimum considered necessary to ensure the safety of life on the navigable waters immediately before, during, and after the scheduled event.

Regulatory Evaluation

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analysis based on 13 of these statutes or executive orders.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate, remain or anchor within certain waters of the Patapsco River, Northwest

Harbor and Inner Harbor, in Baltimore, Maryland, from 5 p.m. through 11 p.m. on August 8, 2008 and from 6 a.m. through 11 a.m. on August 10, 2008. Because the zone is of limited size and duration, it is expected that there will be minimal disruption to the maritime community. Before the effective period, the Coast Guard will issue maritime advisories widely available to users of the river and harbors to allow mariners to make alternative plans for transiting the affected areas. In addition, smaller vessels not constrained by their draft, which are more likely to be small entities, may transit around the safety zone.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Mr. Ronald Houck, at Coast Guard Sector Baltimore, Waterways Management Division, at telephone number (410) 576–2674 or (410) 576–2693. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment. A preliminary ''Environmental Analysis Check List'' supporting this preliminary determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Words of Issuance and Proposed Regulatory Text

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR

1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T08–019 to read as follows:

§ 165.T08–019 Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD.

(a) *Definitions.* For the purposes of this section:

(1) *Captain of the Port, Baltimore, Maryland* means the Commander, Coast Guard Sector Baltimore or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port, Baltimore, Maryland to act on his or her behalf.

(2) *USS CONSTELLATION ''turn-around'' participants* means the USS CONSTELLATION, its support craft and the accompanying towing vessels.

(b) *Location.* The following area is a moving safety zone: all waters within 200 yards ahead of, 100 yards outboard and 100 yards aft of the historic Sloop-of-War USS CONSTELLATION, surface to bottom, while operating in the Inner Harbor, the Northwest Harbor and the Patapsco River.

(c) *Regulations:*

(1) The general regulations governing safety zones, found in § 165.23, apply to the safety zone described in paragraph (b) of this section.

(2) With the exception of USS CONSTELLATION ''turn-around'' participants, entry into or remaining in this zone is prohibited, unless authorized by the Captain of the Port, Baltimore, Maryland.

(3) Persons or vessels requiring entry into or passage through the moving safety zone must first request authorization from the Captain of the Port, Baltimore, Maryland to seek permission to transit the area. The Captain of the Port, Baltimore, Maryland can be contacted at telephone number (410) 576–2693. The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF Channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the person or vessel shall proceed as directed. If permission is granted, all persons or vessels must comply with the instructions of the Captain of the Port, Baltimore, Maryland, and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(d) Enforcement. The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State and local agencies. This section will be enforced from 5 p.m. through 11 p.m. on August 8, 2008 and from 6 a.m. through 11 a.m. on August 10, 2008.

Dated: March 21, 2008.

Brian D. Kelley,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. E8–7938 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0189]

RIN 1625–AA00

Safety Zones; Fireworks Displays Within the Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise the list of permanent safety zones established for fireworks displays at various locations within the geographic boundary of the Fifth Coast Guard District. This action is necessary to protect the life and property of the maritime public from the hazards posed by fireworks displays. Entry into or movement within these proposed zones during the enforcement periods is prohibited without approval of the appropriate Captain of the Port.

DATES: Comments and related material must reach the Coast Guard on or before May 15, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0189 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Dennis Sens, Project Manager, Fifth Coast Guard District, Prevention Division, Inspections and Investigations Branch, at (757) 398–6204. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0189), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on ''Search for Dockets,'' and enter the docket number for this rulemaking (USCG–2008–0189) in the Search box, and click ''Go>>.'' You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC

20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or the Commander (dpi), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004 between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov.*

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard proposes to revise the list of permanent safety zones at 33 CFR 165.506, established for fireworks displays at various locations within the geographic boundary of the Fifth Coast Guard District. For a description of the geographical area of the Fifth District and subordinate Coast Guard Sectors—Captain of the Port Zones, please see 33 CFR 3.25. Currently there are 49 permanent safety zones established that are enforced for fireworks displays occurring throughout the year that are held on an annual basis and normally in one of these 49 locations.

The Coast Guard proposes to revise the list of permanent safety zones at 33 CFR 165.506, established for fireworks displays, by adding 22 new locations and modifying 4 previously established locations within the geographic boundary of the Fifth Coast Guard District. This rule will increase the total number of permanent safety zones to 71 locations for fireworks displays within the boundary of the Fifth Coast Guard District.

This rule proposes to add 22 new safety zone locations to the permanent safety zones listed in 33 CFR 165.506. The new safety zones are listed in the following table.

TABLE OF PROPOSED FIREWORKS SAFETY ZONES

1. Delaware River, Chester, PA.
2. Delaware River, Marcus Hook, PA.
3. North Atlantic Ocean, Avalon, NJ.
4. Barnegat Bay, Barnegat Township, NJ.
5. North Atlantic Ocean, Cape May, NJ.
6. Great Egg Harbor Inlet, Margate City, NJ.
7. North Atlantic Ocean, Ocean City, NJ.
8. North Atlantic Ocean, Bethany Beach, DE.
9. Baltimore Inner Harbor, Patapsco River, MD.
10. Potomac River, Charles County, MD.
11. Potomac River, National Harbor, MD.
12. Patuxent River, Calvert County, MD.
13. Patuxent River, Solomons Island, Calvert County, MD.
14. Appomattox River, Hopewell, VA.
15. John H. Kerr Reservoir, Clarksville, VA
16. Chesapeake Bay, Hampton, VA.
17. Atlantic Ocean, Virginia Beach, VA, Safety Zone. B.
18. Atlantic Ocean, Virginia Beach, VA, Safety Zone. C.
19. Nansemond River, Suffolk, VA.
20. James River, Williamsburg, VA.
21. Motts Channel, Banks Channel, Wrightsville Beach, NC.
22. New River, Jacksonville, NC.

The previously established safety zone locations proposed for modification by this rule are: Potomac River, Charles County, MD; Northwest Harbor (West Channel) Patapsco River, MD; Delaware River, Essington, PA; and Atlantic Ocean, Virginia Beach, VA, safety zone A.

The Coast Guard typically receives numerous applications in these areas for fireworks displays. Previously a temporary safety zone was usually established on an emergency basis for each display. This limited the opportunity for public comment. Establishing permanent safety zones through notice and comment rulemaking provides the public the opportunity to comment on the zone locations, size and length of time the zones will be enforced.

Each year organizations in the Fifth Coast Guard District sponsor fireworks displays in the same general location and time period. Each event uses a barge or an on-shore site near the shoreline as the fireworks launch platform. A safety zone is used to control vessel movement within a specified distance surrounding the launch platforms to ensure the safety of persons and property. Coast Guard personnel on scene could allow persons within the safety zone if conditions permit.

The Coast Guard would publish notices in the **Federal Register** if an event sponsor reported a change to the listed event venue or date. In the case of inclement weather the event usually will be conducted on the day following the date listed in the Table to § 165.506. Coast Guard Captains of the Port would give notice of the enforcement of each safety zone by all appropriate means to provide the widest publicity among the affected segments of the public. This would include publication in the Local Notice to Mariners and Marine Information Broadcasts. Marine information and facsimile broadcasts may also be made for these events, beginning 24 to 48 hours before the event is scheduled to begin, to notify the public. Fireworks barges or launch sites on land used in the locations stated in this rulemaking would also display a sign. The sign would be affixed to the port and starboard side of the barge or mounted on a post 3 foot above ground level when on land and in close proximity to the shoreline facing the water labeled ''FIREWORKS—DANGER—STAY AWAY''. This would provide on scene notice that the safety zone is or will be enforced on that day. This notice will consist of a diamond shaped sign 4 foot by 4 foot with a 3-inch orange retro-reflective border. The word ''DANGER'' shall be 10 inch black block letters centered on the sign with the words ''FIREWORKS'' and ''STAY AWAY'' in 6 inch black block letters placed above and below the word ''DANGER'' respectively on a white background. There would also be a Coast Guard patrol vessel on scene 30 minutes before the display is scheduled to start until 30 minutes after its completion to enforce the safety zone.

The enforcement period for these proposed safety zones is from 5:30 p.m. to 1 a.m. local time. However, vessels may enter, remain in, or transit through these safety zones during this timeframe if authorized by the Captain of the Port or designated Coast Guard patrol personnel on scene, as provided for in 33 CFR 165.23.

This rule is being proposed to provide for the safety of life on navigable waters during the events and to give the marine community the opportunity to comment on the proposed zone locations, size, and length of time the zones will be active.

Discussion of Proposed Rule

(a) The Coast Guard proposes to revise the regulations at 33 CFR 165.506 by adding the following 22 permanent safety zone locations. All coordinates listed for the following safety zones reference Datum NAD 1983.

Delaware River, Chester, PA, Safety Zone

All waters of the Delaware River near Chester, PA just south of the

Commodore Barry Bridge within a 250 yards radius of the fireworks barge located in approximate position latitude 39°43′2″ N, longitude 075°22′42″ W.

Delaware River, Marcus Hook, PA, Safety Zone

All waters of the Delaware River near Marcus Hook, PA adjacent to the Marcus Hook Municipal Park, in approximate position latitude 39°48′40.2″ N, longitude 075°24′36.6″ W.

North Atlantic Ocean, Avalon, NJ, Safety Zone

The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate location latitude 39°05′31″ N, longitude 074°43′00″ W, in the vicinity of the shoreline at Avalon, NJ.

Barnegat Bay, Barnegat Township, NJ, Safety Zone

The waters of Barnegat Bay within a 500 yard radius of the fireworks barge in approximate position latitude 39°44′50″ N, longitude 074°11′21″ W, approximately 500 yards north of Conklin Island, NJ.

North Atlantic Ocean, Cape May, NJ, Safety Zone

The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate location latitude 38°55′36″ N, longitude 074°55′26″ W, immediately adjacent to the shoreline at Cape May, NJ.

Great Egg Harbor Inlet, Margate City, NJ, Safety Zone

All waters within a 500 yard radius of the fireworks barge in approximate location latitude 39°19′32.50″ N, longitude 074°31′27.54″ W, on the Intracoastal Waterway near Margate City, NJ.

North Atlantic Ocean, Ocean City, NJ, Safety Zone

The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate location latitude 39°16′22″ N, longitude 074°33′54″ W, approximately 500 yards east of the shoreline at Ocean City, NJ.

North Atlantic Ocean, Bethany Beach, DE, Safety Zone

The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate position latitude 38°32′17.8″ N, longitude 075°02′59.1″ W, adjacent to shoreline of Bethany Beach, DE.

Baltimore Inner Harbor, Patapsco River, MD, Safety Zone

The waters of the Patapsco River within a 100 yard radius of approximate position latitude 39°17′03″ N, longitude 076°36′36″ W, located in Baltimore Inner Harbor, approximately 150 yards southeast of pier 1.

Potomac River, Charles County, MD,—Mount Vernon Safety Zone

All waters of the Potomac River within a 300 yard radius of the fireworks launch site near the Mount Vernon Estate, in Fairfax County, Virginia, located at latitude 38°42′24″ N, longitude 077°04′56″ W.

Potomac River, National Harbor, MD, Safety Zone

All waters of the Potomac River within an area bound by a line drawn from the following points: latitude 38°47′18″ N, longitude 077°01′01″ W; thence to latitude 38°47′11″ N, longitude 077°01′26″ W; thence to latitude 38°47′25″ N, longitude 077°01′33″ W; thence to latitude 38°47′32″ N, longitude 077°01′08″ W; thence to the point of origin, located at National Harbor, Maryland.

Patuxent River, Calvert County, MD, Safety Zone

All waters of the Patuxent River within a 280 yard radius of the fireworks barge in approximate position latitude 38°19′06.6′ N, longitude 076°26′10.1″; W, approximately 1450 yards west of Drum Point, MD.

Patuxent River, Solomons Island, Calvert County, MD Safety Zone

All waters of the Patuxent River within a 400 yard radius of the fireworks barge located at latitude 38°19′03″ N, longitude 076°26′07.6″ W.

Appomattox River, Hopewell, VA, Safety Zone

All waters of the Appomattox River within a 400 yard radius of the fireworks barge in approximate position latitude 37°19′11″ N, longitude 077°16′55 ′ W.

John H. Kerr Reservoir, Clarksville, VA, Safety Zone

All waters of John H. Kerr Reservoir within a 400 yard radius of approximate position latitude 36°37′51″ N, longitude 078°32′50″ W, located near the south end of the State Route 15 Highway Bridge.

Chesapeake Bay, Hampton, VA, Safety Zone

All waters of the Chesapeake Bay within a 350 yard radius of approximate position latitude 37°02′23″ N, longitude 076°17′22″ W, located near Buckroe Beach.

Atlantic Ocean, VA Beach, VA, Safety Zone. B

All waters of the Atlantic Ocean within a 350 yard radius of approximate position latitude 36°50′35″ N, longitude 075°58′09″ W, located on the 14th Street Fishing Pier.

Atlantic Ocean, VA Beach, VA, Safety Zone. C

All waters of the Atlantic Ocean within a 350 yard radius of approximate position latitude 36°49′55″ N, longitude 075°58′00″ W, located off the beach between 2nd and 6th streets.

Nansemond River, Suffolk, VA, Safety Zone

All waters of the Nansemond River within a 350 yard radius of approximate position latitude 36°44′27″ N, longitude 076°34′42″ W, located near Constant's Wharf in Suffolk, VA.

James River, Williamsburg, VA, Safety Zone

All waters of the James River within a 350 yard radius of approximate position latitude 37°13′23.3″ N, longitude 076°40′11.8″; W, located near Kingsmill Resort.

Motts Channel, Banks Channel, Wrightsville Beach, NC, Safety Zone

All waters of Motts Channel within a 500-yard radius of the fireworks launch site in approximate position latitude 34°12′42″ N, longitude 077°48′26″ W, located southwest of Harbor Island.

New River, Jacksonville, NC, Safety Zone

All waters of the New River within a 300-yard radius of the fireworks launch site in approximate position latitude 34°44′45″ N, longitude 077°26′18″ W, approximately one half mile south of the Hwy 17 Bridge, Jacksonville, North Carolina.

(b) The Coast Guard proposes to revise regulations at 33 CFR 165.506 by modifying 4 existing permanent safety zone locations as follows. All coordinates listed for the following safety zones reference Datum NAD 1983.

Potomac River, Charles County, MD, Safety Zone

All waters of the Potomac River within a 300-yard radius of the fireworks barge in approximate position latitude 38°20′18″ N, longitude 077°15′00″ W, approximately 700-yards north of the shoreline at Fairview Beach, Virginia.

Northwest Harbor (West Channel) Patapsco River, MD, Safety Zone

All waters of the Patapsco River within a 300-yard radius of the fireworks barge in approximate position latitude 39°16′21″ N, longitude 076°34′38″ W, located adjacent to the West Channel of Northwest Harbor.

Delaware River, Essington, PA, Safety Zone

All the waters of the Delaware River near Essington, PA, west of Little Tinicum Island within a 250-yard radius of the fireworks barge located in the approximate position latitude 39°51′18″ N, longitude 075°18′57″ W.

Atlantic Ocean, Virginia Beach, VA, Safety Zone. A

All waters of the Atlantic Ocean within a 360-yard radius of the center located near the shoreline at approximate position latitude 36°51′12″ N, longitude 075°58′23″ W, located off the beach between 24th and 25th streets.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. This finding is based on the short amount of time that vessels would be restricted from the zones, and the small zone sizes positioned in low vessel traffic areas. Vessels would not be precluded from getting underway, or mooring at any piers or marinas currently located in the vicinity of the proposed safety zones. Advance notifications would also be made to the local maritime community by issuing Local Notice to Mariners, Marine information and facsimile broadcasts so mariners can adjust their plans accordingly. Notifications to the public for most events will usually be made by local newspapers, radio and TV stations. The Coast Guard anticipates that these safety zones will only be enforced 2 to 3 times per year.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities some of which may be small entities: The owners and operators of vessels intending to transit or anchor in the proposed safety zones during the times these zones are enforced.

These proposed safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: The enforcement period will be short in duration and in many of the zones vessels can transit safely around the safety zones. Generally, blanket permission to enter, remain in, or transit through these safety zones will be given except during the period that the Coast Guard patrol vessel is present. Before the enforcement period, we will issue maritime advisories widely.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have

determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment. A preliminary ''Environmental Analysis Check List supporting this determination is available in the docket where indicated under the ''public Participation and Request for Comments'' section of this preamble. We seek any comments or information that may lead to discovery of a significant environmental impact from the proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

Words of Issuance and Proposed Regulatory Text

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165— REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Revise § 165.506 to read as follows:

§ 165.506 Safety Zones; Fifth Coast Guard District Fireworks Displays.

(a) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) The following regulations apply to the fireworks safety zones listed in the Table to § 165.506. These regulations will be effective annually, for the duration of each fireworks event listed in the Table to § 165.506. In the case of inclement weather the event may be conducted on the day following the date listed in the Table to § 165.506. Annual notice of the exact dates and times of the effective period of the regulation with respect to each safety zone, the geographical area, and other details concerning the nature of the fireworks event will be published in Local Notices to Mariners and via Broadcast Notice to Mariners over VHF–FM marine band radio.

(3) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. Those personnel are comprised of commissioned, warrant, and petty officers of the U.S. Coast Guard. Other Federal, State and local agencies may assist these personnel in the enforcement of the safety zone. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(b) Notification. (1) Fireworks barges and launch sites on land that operate within the regulated areas contained in the Table to § 165.506 will have a sign affixed to the port and starboard side of the barge or mounted on a post 3 foot above ground level when on land immediately adjacent to the shoreline and facing the water labeled ''FIREWORKS—DANGER—STAY AWAY''. This will provide on scene notice that the safety zone will be enforced on that day. This notice will consist of a diamond shaped sign 4 foot by 4 foot with a 3-inch orange retro reflective border. The word ''DANGER'' shall be 10 inch black block letters centered on the sign with the words ''FIREWORKS'' and ''STAY AWAY'' in 6 inch black block letters placed above and below the word ''DANGER'' respectively on a white background.

(2) Coast Guard Captains of the Port in the Fifth Coast Guard District will notify the public of the enforcement of these safety zones by all appropriate means to effect the widest publicity among the affected segments of the public. Publication in the Local Notice to Mariners, marine information broadcasts, and facsimile broadcasts may be made for these events, beginning 24 to 48 hours before the event is scheduled to begin, to notify the public.

(c) *Contact Information.* Questions about safety zones and related events should be addressed to the local Coast Guard Captain of the Port for the area in which the event is occurring. Contact information is listed below. For a description of the geographical area of each Coast Guard Sector—Captain of the Port zone, please see 33 CFR 3.25.

(1) Coast Guard Sector Delaware Bay—Captain of the Port Zone, Philadelphia, Pennsylvania: (215) 271–4944.

(2) Coast Guard Sector Baltimore—Captain of the Port Zone, Baltimore, Maryland: (410) 576–2525.

(3) Coast Guard Sector Hampton Roads—Captain of the Port Zone, Norfolk, Virginia: (757) 483–8567.

(4) Coast Guard Sector North Carolina—Captain of the Port Zone, Atlantic Beach, North Carolina: (252) 247–4545.

(5) Coast Guard Marine Safety Unit Wilmington—Cape Fear River Captain of the Port Zone, Wilmington, North Carolina: (910) 772–2200.

(d) *Enforcement Period.* The safety zones in the Table to § 165.506 will be enforced from 5:30 p.m. to 1 a.m. each day a barge with a ''FIREWORKS—DANGER—STAY AWAY'' sign on the port and starboard side is on-scene or a ''FIREWORKS—DANGER—STAY AWAY'' sign is posted on land adjacent to the shoreline, in a location listed in the Table to § 165.506. Vessels may not enter, remain in, or transit through the safety zones during these enforcement periods unless authorized by the Captain of the Port or designated Coast Guard patrol personnel on scene.

TABLE TO § 165.506.—ALL COORDINATES LISTED IN THE TABLE TO § 165.506 REFERENCE DATUM NAD 1983

No. and date	Location	Regulated area
Coast Guard Sector Delaware Bay—COTP Zone		
1. July 4th	North Atlantic Ocean, Bethany Beach, DE, Safety Zone.	The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate position latitude 38°32′17.8″ N, longitude 075°02′59.1″ W, adjacent to shoreline of Bethany Beach, DE.
2. Labor Day	Indian River Bay, DE, Safety Zone	All waters of the Indian River Bay within a 360 yard radius of the fireworks launch location on the pier in approximate position latitude 38°36′42″ N, longitude 075°08′18″ W, about 700 yards east of Pots Net Point, DE.
3. July 4th	Atlantic Ocean, Rehoboth Beach, DE, Safety Zone.	All waters of the Atlantic Ocean within a 360 yard radius of the fireworks barge in approximate position latitude 38°43′01.2″ N, longitude 075°04′21″ W, approximately 400 yards east of Rehoboth Beach, DE.
4. July 4th	North Atlantic Ocean, Avalon, NJ, Safety Zone.	The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate location latitude 39°05′31″ N, longitude 074°43′00″ W, in the vicinity of the shoreline at Avalon, NJ.
5. July 4th, September—2nd Saturday.	Barnegat Bay, Barnegat Township, NJ, Safety Zone.	The waters of Barnegat Bay within a 500 yard radius of the fireworks barge in approximate position latitude 39°44′50″ N, longitude 074°11′21″ W, approximately 500 yards north of Conklin Island, NJ.
6. July 4th.	North Atlantic Ocean, Cape May, NJ, Safety Zone.	The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate location latitude 38°55′36″ N, longitude 074°55′26″ W, immediately adjacent to the shoreline at Cape May, NJ.
7. July 3rd	Delaware Bay, North Cape May, NJ, Safety Zone.	All waters of the Delaware Bay within a 500 yard radius of the fireworks barge in approximate position latitude 38°58′00″ N, longitude 074°58′30″ W.
8. August—3rd Sunday	Great Egg Harbor Inlet, Margate City, NJ, Safety Zone.	All waters within a 500 yard radius of the fireworks barge in approximate location latitude 39°19′32.50″ N, longitude 074°31′27.54″ W, on the Intracoastal Waterway near Margate City, NJ.
9. July 4th	North Atlantic Ocean, Ocean City, NJ, Safety Zone.	The waters of the North Atlantic Ocean within a 500 yard radius of the fireworks barge in approximate location latitude 39°16′22″ N, longitude 074°33′54″ W, approximately 500 yards east of the shoreline at Ocean City, NJ.
10. May—4th Saturday	Barnegat Bay, Ocean Township, NJ, Safety Zone.	All waters of Barnegat Bay within a 500 yard radius of the fireworks barge in approximate position latitude 39°47′33″ N, longitude 074°10′46″ W.
11. July 4th	Little Egg Harbor, Parker Island, NJ, Safety Zone.	All waters of Little Egg Harbor within a 500 yard radius of the fireworks barge in approximate position latitude 39°34′18″ N, longitude 074°14′43″ W, approximately 100 yards north of Parkers Island.
12. September—3rd Saturday	Delaware River, Chester, PA, Safety Zone.	All waters of the Delaware River near Chester, PA, just south of the Commodore Barry Bridge within a 250 yard radius of the fireworks barge located in approximate position latitude 39°49′43.2″ N, longitude 075°22′42″ W.
13. September—3rd Saturday	Delaware River, Essington, PA, Safety Zone.	All the waters of the Delaware River near Essington, PA, west of Little Tinicum Island within a 250 yard radius of the fireworks barge located in the approximate position latitude 39°51′18″ N, longitude 075°18′57″ W.
14. September—3rd Saturday	Delaware River, Marcus Hook, PA, Safety Zone.	All waters of the Delaware River near Marcus Hook, PA, adjacent to the Marcus Hook Municipal Park, in approximate position latitude 39°48′40.2″ N, longitude 075°24′36.6″ W.
15. July 4th, Columbus Day, December 31st, January 1st.	Delaware River, Philadelphia, PA, Safety Zone.	All waters of Delaware River, adjacent to Penns Landing, Philadelphia, PA, bounded from shoreline to shoreline, bounded on the south by a line running east to west from points along the shoreline at latitude 39°56′31.2″ N, longitude 075°08′28.1″ W; thence to latitude 39°56′29.1″ N, longitude 075°07′56.5″ W, and bounded on the north by the Benjamin Franklin Bridge.
Coast Guard Sector Baltimore—COTP Zone		
16. April—1st Saturday	Washington Channel, Upper Potomac River, Washington, DC, Safety Zone.	All waters of the Upper Potomac River within a 150 yard radius of the fireworks barge in approximate position latitude 38°52′09″ N, longitude 077°01′13″ W, located within the Washington Channel in Washington Harbor, DC.
17. July 4th, December—1st and 2nd Saturday, December 31st.	Severn River and Spa Creek, Annapolis, MD, Safety Zone.	All waters of the Severn River and Spa Creek within an area bounded by a line drawn from latitude 38°58′39.6″ N, longitude 076°28′49″ W; thence to latitude 38°58′41″ N, longitude 076°28′14″ W; thence to latitude 38°59′01″ N, longitude 076°28′37″ W; thence to latitude 38°58′57″ N, longitude 076°28′40″ W, located near the entrance to Spa Creek in Annapolis, Maryland.

TABLE TO § 165.506.—ALL COORDINATES LISTED IN THE TABLE TO § 165.506 REFERENCE DATUM NAD 1983—Continued

No. and date	Location	Regulated area
18. Saturday before Independence Day holiday.	Middle River, Baltimore County, MD, Safety Zone.	All waters of the Middle River within a 300 yard radius of the fireworks barge in approximate position latitude 39°17′45″ N, longitude 076°23′49″ W, approximately 300 yards east of Rockaway Beach, near Turkey Point.
19. July 4th, December 31st	Patapsco River (Middle Branch), Baltimore, MD, Safety Zone.	All waters of the Patapsco River, Middle Branch, within an area bound by a line drawn from the following points: latitude 39°15′22″ N, longitude 076°36′36″ W; thence to latitude 39°15′10″ N, longitude 076°36′00″ W; thence to latitude 39°15′40″ N, longitude 076°35′23″ W; thence to latitude 39°15′49″ N, longitude 076°35′47″ W; thence to the point of origin, located approximately 600 yards east of Hanover Street (SR–2) Bridge.
20. June 14th, July 4th, September—2nd Saturday, December 31st.	Northwest Harbor (East Channel), Patapsco River, MD, Safety Zone.	All waters of the Patapsco River within a 300 yard radius of the fireworks barge in approximate position 39°15′55″ N, 076°34′35″ W, located adjacent to the East Channel of Northwest Harbor.
21. May—3rd Friday, July 4th, December 31st.	Baltimore Inner Harbor, Patapsco River, MD, Safety Zone.	All waters of the Patapsco River within a 150 yard radius of the fireworks barge in approximate position latitude 39°16′55″ N, longitude 076°36′17″ W, located at the entrance to Baltimore Inner Harbor, approximately 150 yards southwest of pier 6.
22. May—3rd Friday, July 4th, December 31st.	Baltimore Inner Harbor, Patapsco River, MD, Safety Zone.	The waters of the Patapsco River within a 100 yard radius of approximate position latitude 39°17′03″ N, longitude 076°36′36″ W, located in Baltimore Inner Harbor, approximately 150 yards southeast of pier 1.
23. July 4th, December 31st	Northwest Harbor (West Channel) Patapsco River, MD, Safety Zone.	All waters of the Patapsco River within a 300 yard radius of the fireworks barge in approximate position latitude 39°16′21″ N, longitude 076°34′38″ W, located adjacent to the West Channel of Northwest Harbor.
24. July 4th	Patuxent River, Calvert County, MD, Safety Zone.	All waters of the Patuxent River within a 280 yard radius of the fireworks barge in approximate position latitude 38°19′06.6″ N, longitude 076°26′10.1″ W, approximately 1450 yards west of Drum Point, MD.
25. July 4th	Patuxent River, Solomons Island, Calvert County, MD, Safety Zone.	All waters of the Patuxent River within a 400 yard radius of the fireworks barge located at latitude 38°19′03″ N, longitude 076°26′07.6″ W.
26. July 4th	Patuxent River, Solomons Island, MD, Safety Zone.	All waters of Patuxent River within a 300 yard radius of the fireworks barge in an area bound by the following points: latitude 38°19′42″ N, longitude 076°28′02″ W; thence to latitude 38°19′26″ N, longitude 076°28′18″ W; thence to latitude 38°18′48″ N, longitude 076°27′42″ W; thence to latitude 38°19′06″ N, longitude 076°27′25″ W; thence to the point of origin, located near Solomons Island, MD.
27. July 4th	Chester River, Kent Island Narrows, MD, Safety Zone.	All waters of the Chester River, within an area bound by a line drawn from the following points: latitude 38°58′50″ N, longitude 076°15′00″ W; thence north to latitude 38°59′00″ N, longitude 076°15′00″ W; thence east to latitude 38°59′00″ N, longitude 076°14′46″ W; thence southeast to latitude 38°58′50″ N, longitude 076°14′28″ W; thence southwest to latitude 38°58′37″ N, longitude 076°14′36″ W, thence northwest to latitude 38°58′42″ N, longitude 076°14′55″ W, thence to the point of origin, located approximately 900 yards north of Kent Island Narrows (US–50/301) Bridge.
28. July 3rd	Chesapeake Bay, Chesapeake Beach, MD, Safety Zone.	All waters of the Chesapeake Bay within a 150 yard radius of the fireworks barge in approximate position latitude 38°41′33″ N, longitude 076°31′48″ W, located near Chesapeake Beach, Maryland.
29. July 4th	Choptank River, Cambridge, MD, Safety Zone.	All waters of the Choptank River within a 300 yard radius of the fireworks launch site at Great Marsh Point, located at latitude 38°35′06″ N, longitude 076°04′46″ W.
30. July—2nd and last Saturday	Potomac River, Charles County, MD, Safety Zone.	All waters of the Potomac River within a 300 yard radius of the fireworks barge in approximate position latitude 38°20′18″ N, longitude 077°15′00″ W, approximately 700 yards north of the shoreline at Fairview Beach, Virginia.
31. May—last Saturday, July 4th	Potomac River, Charles County, MD—Mount Vernon, Safety Zone.	All waters of the Potomac River within a 300 yard radius of the fireworks launch site near the Mount Vernon Estate, in Fairfax County, Virginia, located at latitude 38°42′24″ N, longitude 077°04′56″ W.
32. October—1st Saturday	Dukeharts Channel, Potomac River, MD, Safety Zone.	All waters of the Potomac River within a 300 yard radius of the fireworks barge in approximate position latitude 38°13′48″ N, longitude 076°44′37″ W, located adjacent to Dukeharts Channel near Coltons Point, Maryland.

TABLE TO § 165.506.—ALL COORDINATES LISTED IN THE TABLE TO § 165.506 REFERENCE DATUM NAD 1983—Continued

No. and date	Location	Regulated area
33. June and July—Day before Independence Day holiday.	Potomac River, National Harbor, MD, Safety Zone.	All waters of the Potomac River within an area bound by a line drawn from the following points: latitude 38°47′18″ N, longitude 077°01′01″ W; thence to latitude 38°47′11″ N, longitude 077°01′26″ W; thence to latitude 38°47′25″ N, longitude 077°01′33″ W; thence to latitude 38°47′32″ N, longitude 077°01′08″ W; thence to the point of origin, located at National Harbor, Maryland.
34. July 4th, September—last Saturday.	Susquehanna River, Havre de Grace, MD, Safety Zone.	All waters of the Susquehanna River within a 150 yard radius of the fireworks barge in approximate position latitude 39°32′42″ N, longitude 076°04′30″ W, approximately 800 yards east of the waterfront at Havre de Grace, MD.
35. June and July—Saturday before Independence Day holiday.	Miles River, St. Michaels, MD, Safety Zone.	All waters of the Miles River within a 200 yard radius of the fireworks barge in approximate position latitude 38°47′42″ N, longitude 076°12′23″ W, located near the waterfront of St. Michaels, Maryland.
36. June and July—Saturday or Sunday before Independence Day holiday.	Tred Avon River, Oxford, MD, Safety Zone.	All waters of the Tred Avon River within a 150 yard radius of the fireworks barge in approximate position latitude 38°41′48″ N, longitude 076°10′38″ W, approximately 500 yards northwest of the waterfront at Oxford, MD.
37. July 3rd	Northeast River, North East, MD, Safety Zone.	All waters of the Northeast River within a 300 yard radius of the fireworks barge in approximate position latitude 39°35′26″ N, longitude 075°57′00″ W, approximately 400 yards south of North East Community Park.
38. June—2nd or 3rd Saturday, July—1st or 2nd Saturday, September—1st or 2nd Saturday..	Upper Potomac River, Alexandria, VA, Safety Zone.	All waters of the Upper Potomac River within a 300 yard radius of the fireworks barge in approximate position 38°48′37″ N, 077°02′02″ W, located near the waterfront of Alexandria, Virginia.
39. June—last Saturday	Potomac River, Prince William County, VA, Safety Zone.	All waters of the Potomac River within a 200 yard radius of the fireworks barge in approximate position latitude 38°34′08″ N, longitude 077°15′34″ W, located near Cherry Hill, Virginia.
Coast Guard Sector Hampton Roads—COTP Zone		
40. July 4th	Atlantic Ocean, Ocean City, MD, Safety Zone.	All waters of the Atlantic Ocean in an area bound by the following points: latitude 38°19′39.9″ N, longitude 075°05′03.2″ W; thence to latitude 38°19′36.7″ N, longitude 075°04′53.5″ W; thence to latitude 38°19′45.6″ N, longitude 075°04′49.3″ W; thence to latitude 38°19′49.1″ N, longitude 075°05′00.5″ W; thence to point of origin. The size of the proposed zone extends approximately 300 yards offshore from the fireworks launch area located at the High Water mark on the beach.
41. May—4th Sunday, June—3rd Monday, July 4th, August—1st and 4th Sunday, September—1st and 4th Sunday.	Isle of Wight Bay, Ocean City, MD, Safety Zone.	All waters of Isle of Wight Bay within a 350 yard radius of the fireworks barge in approximate position latitude 38°22′32″ N, longitude 075°04′30″ W.
42. July 4th	Assawoman Bay, Fenwick Island—Ocean City, MD, Safety Zone.	All waters of Assawoman Bay within a 360 yard radius of the fireworks launch location on the pier at the West end of Northside Park, in approximate position latitude 38°25′57.6″ N, longitude 075°03′55.8″ W.
43. July 4th	Broad Bay, Virginia Beach, VA, Safety Zone.	All waters of the Broad Bay within a 400 yard radius of the fireworks display in approximate position latitude 36°52′08″ N, longitude 076°00′46″ W, located on the shoreline near the Cavalier Golf and Yacht Club, Virginia Beach, Virginia.
44. October—1st Friday	York River, West Point, VA, Safety Zone.	All waters of the York River near West Point, VA, within a 400 yard radius of the fireworks display located in approximate position latitude 37°31′25″ N, longitude 076°47′19″ W.
45. July 4th	York River, Yorktown, VA, Safety Zone.	All waters of the York River within a 400 yard radius of the fireworks display in approximate position latitude 37°14′14″ N, longitude 076°30′02″ W, located near Yorktown, Virginia.
46. July 4th	Chincoteague Channel, Chincoteague, VA, Safety Zone.	All waters of the Chincoteague Channel within a 360 yard radius of the fireworks launch location at the Chincoteague carnival waterfront in approximate position latitude 37°55′40.3″ N, longitude 075°23′10.7″ W, approximately 900 yards southwest of Chincoteague Swing Bridge.
47. May—1st Friday, July 4th	James River, Newport News, VA, Safety Zone.	All waters of the James River within a 325 yard radius of the fireworks barge in approximate position latitude 36°58′30″ N, longitude 076°26′19″ W, located in the vicinity of the Newport News Shipyard, Newport News, Virginia.
48. July 9th	Chesapeake Bay, Hampton, VA, Safety Zone.	All waters of the Chesapeake Bay within a 350 yard radius of approximate position latitude 37°02′23″ N, longitude 076°17′22″ W, located near Buckroe Beach.

TABLE TO § 165.506.—ALL COORDINATES LISTED IN THE TABLE TO § 165.506 REFERENCE DATUM NAD 1983—Continued

No. and date	Location	Regulated area
49. June—4th Friday	Chesapeake Bay, Norfolk, VA, Safety Zone.	All waters of the Chesapeake Bay within a 400 yard radius of the fireworks display located in position latitude 36°57′21″ N, longitude 076°15′00″ W, located near Ocean View Fishing Pier.
50. July 4th	Chesapeake Bay, Virginia Beach, VA, Safety Zone.	All waters of the Chesapeake Bay 400 yard radius of the fireworks display in approximate position latitude 36°55′02″ N, longitude 076°03′27″ W, located at the First Landing State Park at Virginia Beach, Virginia.
51. Memorial Day, June—1st and 2nd Friday, Saturday and Sunday, July 4th, November—4th Saturday, December—1st Saturday and December 31st, January 1st.	Elizabeth River, Southern Branch, Norfolk, VA, Safety Zone.	All waters of the Elizabeth River Southern Branch in an area bound by the following points: latitude 36°50′54.8″ N, longitude 076°18′10.7″ W; thence to latitude 36°51′7.9″ N, longitude 076°18′01″ W; thence to latitude 36°50′45.6″ N, longitude 076°17′44.2″ W; thence to latitude 36°50′29.6″ N, longitude 076°17′23.2″ W; thence to latitude 36°50′7.7″ N, longitude 076°17′32.3″ W; thence to latitude 36°49′58″ N, longitude 076°17′28.6″ W; thence to latitude 36°49′52.6″ N, longitude 076°17′43.8″ W; thence to latitude 36°50′27.2″ N, longitude 076°17′45.3″ W thence to the point of origin.
52. May—2nd Saturday, September—1st Saturday and Sunday, December—1st Saturday.	Appomattox River, Hopewell, VA, Safety Zone.	All waters of the Appomattox River within a 400 yard radius of the fireworks barge in approximate position latitude 37°19′11″ N, longitude 077°16′55 ″ W.
53. July—3rd Saturday	John H. Kerr Reservoir, Clarksville, VA, Safety Zone.	All waters of John H. Kerr Reservoir within a 400 yard radius of approximate position latitude 36°37′51″ N, longitude 078°32′50″ W, located near the south end of the State Route 15 Highway Bridge.
54. May, June, July, August, September, October—every Wednesday, Friday, Saturday and Sunday, July 4th.	Atlantic Ocean, Virginia Beach, VA, Safety Zone A.	All waters of the Atlantic Ocean within a 360 yard radius of the center located near the shoreline at approximate position latitude 36°51′12″ N, longitude 075°58′23″ W, located off the beach between 24th and 25th streets.
55. September—4th Saturday	Atlantic Ocean, VA Beach, VA, Safety Zone B.	All waters of the Atlantic Ocean within a 350 yard radius of approximate position latitude 36°50′35″ N, longitude 075°58′09″ W, located on the 14th Street Fishing Pier.
56. August—4th Friday and Saturday.	Atlantic Ocean, VA Beach, VA, Safety Zone C.	All waters of the Atlantic Ocean within a 350 yard radius of approximate position latitude 36°49′55″ N, longitude 075°58′00″ W, located off the beach between 2nd and 6th streets.
57. July 4th	Nansemond River, Suffolk, VA, Safety Zone.	All waters of the Nansemond River within a 350 yard radius of approximate position latitude 36°44′27″ N, longitude 076°34′42″ W, located near Constant's Wharf in Suffolk, VA.
58. February—4th Saturday, July 4th.	Chickahominy River, Williamsburg, VA, Safety Zone.	All waters of the Chickahominy River within a 400 yard radius of the fireworks display in approximate position latitude 37°14′50″ N, longitude 076°52′17″ W, near Barrets Point, Virginia.
59. July 4th	James River, Williamsburg, VA, Safety Zone.	All waters of the James River within a 350 yard radius of approximate position latitude 37°13′23.3″ N, longitude 076°40′11.8″ W, located near Kingsmill Resort.
Coast Guard Sector North Carolina—COTP Zone		
60. July 4th, October—1st Friday	Morehead City Harbor Channel, NC, Safety Zone.	All waters of the Morehead City Harbor Channel that fall within a 360 yard radius of latitude 34°43′01″ N, longitude 076°42′59.6″ W, a position located at the west end of Sugar Loaf Island, NC.
61. April—2nd Saturday, July 4th, August—3rd Monday, October—1st Friday.	Cape Fear River, Wilmington, NC, Safety Zone.	All waters of the Cape Fear River within an area bound by a line drawn from the following points: latitude 34°14′12″ N, longitude 077°57′07.2″ W; thence to latitude 34°14′12″ N, longitude 077°57′06″ W; thence to latitude 34°13′54″ N, longitude 077°57′00″ W; thence to latitude 34°13′54″ N, longitude 077°57′06″ W; thence to the point of origin, located 500 yards north of Cape Fear Memorial Bridge.
62. July 4th	Green Creek and Smith Creek, Oriental, NC, Safety Zone.	All waters of Green Creek and Smith Creek that fall within a 300 yard radius of the fireworks launch site at latitude 35°01′29.6″ N, longitude 076°42′10.4″ W, located near the entrance to the Neuse River in the vicinity of Oriental, NC.
63. July 4th	Pasquotank River, Elizabeth City, NC, Safety Zone.	All waters of the Pasquotank River within a 300 yard radius of the fireworks launch site in approximate position latitude 36°18′00″ N, longitude 076°13′00″ W, approximately 200 yards south of the east end of the Elizabeth City Bascule Bridges.
64 July 4th	Currituck Sound, Corolla, NC, Safety Zone.	All waters of the Croatan Sound within a 300 yard radius of the fireworks barge in approximate position latitude 36°22′48″ N, longitude 075°51′15″ W.

TABLE TO § 165.506.—ALL COORDINATES LISTED IN THE TABLE TO § 165.506 REFERENCE DATUM NAD 1983—Continued

No. and date	Location	Regulated area
65. July 4th, November—3rd Saturday.	Middle Sound, Figure Eight Island, NC, Safety Zone.	All waters of the Figure Eight Island Causeway Channel from latitude 34°16′32″ N, longitude 077°45′32″ W, thence east along the marsh to a position located at latitude 34°16′19″ N, longitude 077°44′55″ W, thence south to the causeway at position latitude 34°16′16″ N, longitude 077°44′58″ W, thence west along the shoreline to position latitude 34°16′29″ N, longitude 077°45′34″ W, thence back to the point of origin.
66. June—2nd Saturday, July—1st Saturday after July 4th.	Pamlico River, Washington, NC, Safety Zone.	All waters of the Pamlico River that fall within a 300 yard radius of the fireworks launch site at latitude 35°32′19″ N, longitude 077°03′20.5″ W, located 500 yards north of Washington railroad trestle bridge.
67. July 4th	Neuse River, New Bern, NC, Safety Zone.	All waters of the Neuse River within a 360 yard radius of the fireworks barge in approximate position latitude 35°06′07.1″ N, longitude 077°01′35.8″ W, located 420 yards north of the New Bern, Twin Span, high rise bridge.
68. July 4th, November—4th Monday.	Motts Channel, Banks Channel, Wrightsville Beach, NC, Safety Zone.	All waters of Motts Channel within a 500 yard radius of the fireworks launch site in approximate position latitude 34°12′42″ N, longitude 077°48′26″ W, located southwest of Harbor Island.
69. July 4th	Cape Fear River, Southport, NC, Safety Zone.	All waters of the Cape Fear River within a 600 yard radius of the fireworks barge in approximate position latitude 33°54′40″ N, longitude 078°01′18″ W, approximately 700 yards south of the waterfront at Southport, NC.
70. July 4th	Big Foot Slough, Ocracoke, NC, Safety Zone.	All waters of Big Foot Slough within a 300 yard radius of the fireworks launch site in approximate position latitude 35°06′54″ N, longitude 075°59′24″ W, approximately 100 yards west of the Silver Lake Entrance Channel at Orcacoke, NC.
71. August—1st Tuesday	New River, Jacksonville, NC, Safety Zone.	All waters of the New River within a 300 yard radius of the fireworks launch site in approximate position latitude 34°44′45″ N, longitude 077°26′18″ W, approximately one half mile south of the Hwy 17 Bridge, Jacksonville, North Carolina.

Dated: April 7, 2008.

Fred M. Rosa, Jr.,

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

[FR Doc. E8–7936 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 168

[Docket No. USCG–2006–23556, formerly CGD91–202a]

RIN 1625–AA10, formerly RIN 2115–AE56

Escort Vessels in Certain U.S. Waters

AGENCY: Coast Guard, DHS.

ACTION: Notice of withdrawal and request for comments.

SUMMARY: The Coast Guard announces its intent to withdraw a 1993 advance notice of proposed rulemaking (ANPRM). Because of the length of time since the ANPRM was published, the Coast Guard requests additional public comment before proceeding with withdrawal. The rulemaking deals with supplementing a statutory requirement that single-hulled oil tankers in Prince William Sound, Alaska, and Puget Sound, Washington, be accompanied through those waters by escort vessels. It would extend those requirements to other U.S. waters, and possibly to vessels other than single-hulled oil tankers. Subject to reconsideration in light of public comment, the Coast Guard believes that this rulemaking is inappropriate and inefficient and therefore not the best way to consider such extensions.

DATES: Comments and related material must reach the Docket Management Facility on or before July 14, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2006–23556 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact Lieutenant Commander Vivianne Louie, U.S. Coast Guard, telephone 202–372–1358 or e-mail *Vivianne.W.Louie@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Request for Comments

We request public comment on our intent to withdraw this rulemaking. In particular, we are interested in comments that tell us:

- Why we should not withdraw this rulemaking;
- How to go about this rulemaking, if it continues; and
- What criteria should govern the extension of escort vessel requirements to waters other than Prince William Sound and Puget Sound, or to vessels other than single-hulled oil tankers.

All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have

provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please identify the docket number for this notice (USCG–2006–23556) and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments received during the comment period.

Viewing comments and documents: To view comments, go to *http://www.regulations.gov* at any time. Enter the docket number for this rulemaking (USCG–2006–23556) in the Search box, and click ''Go >>.'' You may also visit the Docket Management Facility in room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov*.

Changes in Docket Numbering

This notice is the first document published since 1994 for a rulemaking that began in 1993, under Coast Guard docket number CGD 91–202a. Until now, public comment letters and other material pertinent to CGD 91–202a were only available for public inspection at Coast Guard Headquarters in Washington, DC. Beginning in 1998, the Coast Guard adopted a new docket numbering system in order to make its Headquarters rulemaking documents available to the public on the Internet. The format of the new docketing system is incompatible with the ''CGD'' system that we used in 1993. Therefore, in order to complete the CGD 91–202a rulemaking in a way that makes our actions visible to the public on the *http://www.regulations.gov* Web site, we opened an Internet-compatible docket number, USCG–2006–23556. The public comments we received on CGD 91–202a will be placed in the *http://www.regulations.gov* docket for USCG–2006–23556.

Background and Purpose

The Coast Guard has broad authority under the Ports and Waterways Safety Act (PWSA, 33 U.S.C. 1221 *et seq.*) to control vessel traffic in navigable waters of the United States. In addition, section 4116(c) of the Oil Pollution Act of 1990 (OPA 90, Pub. L. 101–380) required the Coast Guard to initiate a rulemaking to identify any navigable waters of the United States on which single-hulled oil tankers over 5,000 gross tons should require escort vessels. OPA 90 specified that escort vessels must be provided in Prince William Sound, Alaska, and in Puget Sound, Washington. Requirements for escort vessels in Prince William Sound and Puget Sound were set in a rulemaking that was originally docketed as CGD 91–202, and completed in 2005 under docket number USCG–2003–14734; the final rule appears at 70 FR 55728 (Sep. 23, 2005), and the regulations appear in 33 CFR part 168. The CGD 91–202 rulemaking originally sought to deal with escort vessel requirements in waters other than Prince William Sound and Puget Sound, but in 1993 the Coast Guard opened a new docket, CGD 91–202a, to address those other waters. Public meetings held in 1993, in Anchorage and Valdez, Alaska, and in Seattle, Washington, addressed both rulemakings.

In an advance notice of proposed rulemaking (ANPRM; 58 FR 25766, April 27, 1993) issued under docket number CGD 91–202a, the Coast Guard asked for public comment on three general questions: (1) Whether escort vessel requirements should apply to any navigable waters of the United States other than Prince William Sound and Puget Sound; (2) whether escort vessel requirements should apply to vessels other than single-hulled oil tankers; and (3) what an escort vessel should be expected to do. In its discussion, the ANPRM listed numerous subsidiary questions to put the general questions in perspective.

In 1994, the Coast Guard published a notice of meeting and request for comments (59 FR 65741, Dec. 21, 1994) to follow up on the ANPRM. The 1994 notice said that numerous comments had been received in response to the ANPRM, but that they lacked consensus and tended to be based on subjective arguments without supporting data. The notice acknowledged that the 1993 ANPRM had been issued before publication of the Prince William Sound and Puget Sound regulations in 33 CFR part 168, and included no special guidance on how waterways should be evaluated or nominated for escort vessel requirements. Accordingly, the 1994 notice sought to engage the public's assistance in developing criteria for evaluating the navigational risks of a waterway, and how to determine if escorting is an effective strategy to offset those risks. Noting that OPA 90 called for oil tankers to have two escort vessels and that, in some circumstances, this could be undesirable, the notice stated that any escort vessel requirements for waters other than Prince William Sound or Puget Sound would rely on PWSA in addition to OPA 90.

The 1994 notice proposed 13 criteria, derived from the PWSA, for use in determining when escort vessels are necessary, and illustrated the scope of each criterion through a set of follow-on questions. It announced a public meeting in Washington, DC on January 23, 1995, and asked for comment on these and other criteria that could be used in evaluating waterways with respect to escorting.

Discussion of Comments

In response to the 1993 ANPRM and 1994 notice, the Coast Guard received nearly 700 written comments as well as the oral testimony of hundreds of attendees at four public meetings. We thank all these commenters for their interest. For convenience, we discuss the comments under four subheadings:

Escort vessel criteria. We received many thoughtful comments analyzing the 13 criteria we proposed and offering background information or constructive criticism. Most of these commenters stressed the importance of understanding local waters and the specific vessels and cargoes transiting those waters. A number of commenters suggested development of a nationwide risk assessment program, in order to allocate escort vessel or other safety resources in an objective way that prioritizes where those resources can do the most good. A nationwide risk assessment program may be a good concept but it would be very expensive and time-consuming to implement. The reliability of such an assessment would be hard to validate, making its usefulness questionable.

We agree with many commenters that local conditions are very important in determining what safety measures should be taken. If the need for specific resources in specific waters can be shown, it is better to focus directly on addressing that need, than on the more conceptual exercise of ranking that need relative to the needs of other areas. For many years the Coast Guard has sponsored Ports and Waterway Safety Assessments (PAWSAs) that bring public and private stakeholders together to identify major safety hazards in specific local waterways, evaluate potential mitigation measures including escorting, and set the stage for implementing selected measures. You can get more information about PAWSAs at *http://www.navcen.uscg.gov/mwv/projects/pawsa/PAWSA_home.htm*, or read reports on any of the 38 PAWSAs conducted to date, at *http://www.navcen.uscg.gov/mwv/projects/pawsa/PAWSA_FinalReports.htm*. We believe that the PAWSA program provides a more comprehensive alternative for evaluating local risks and conditions. Therefore, we think it is neither appropriate nor beneficial to continue developing nationwide Coast Guard escort vessel criteria within the context of this 1993 rulemaking.

Escort vessel effectiveness. Most commenters who discussed the effectiveness of escort vessels agreed that different ''escorts'' have different capabilities, and that under certain conditions it is unrealistic to think that escorts will provide added safety. While some commenters recommended that we specify the capabilities desired in an escort vessel, many others pointed out that escort vessels should be considered as just one of many tools available for enhancing the safety of specific waters, along with aids to navigation, local regulated navigation areas, vessel traffic services, response vessels, or other means. We agree with these commenters that any consideration of escort vessels should begin by assessing specific local conditions and analyzing other possible safety measures. As previously described, the Coast Guard's PAWSA program can provide this assessment and analysis. Therefore, we think it is neither appropriate nor beneficial to continue a nationwide Coast Guard assessment of escort vessel effectiveness within the context of this 1993 rulemaking.

Specific waters other than Cook Inlet; vessels other than single-hulled oil tankers. Numerous commenters made recommendations for or against requiring escort vessels in specific waters other than Prince William Sound or Puget Sound. A few commenters also recommended extending escort vessel requirements to vessels other than single-hulled oil tankers. As noted above, we have concluded that any such requirements should be considered by the Coast Guard at a local level, in light of local conditions and the possibility of increased effectiveness of alternative safety measures. The Coast Guard's PAWSA program can provide that consideration. Therefore, we think it is neither appropriate nor beneficial to continue the consideration of escort vessels for use in specific waters or with specific types of vessel within the nationwide context of this 1993 rulemaking.

Cook Inlet. Between 1993 and 1995, hundreds of commenters focused on whether or not escort vessels should be required in Cook Inlet, Alaska. Those opposed to requiring escort vessels in Cook Inlet tended to cite favorable local conditions, the availability of alternative safety measures, and adverse economic impact as their reasons. Those in favor of requiring escort vessels in Cook Inlet tended to cite unfavorable local conditions, the superiority of escort vessels to other possible safety measures, and the economic and environmental risks posed by tanker traffic as their reasons. The Coast Guard has carefully considered the 1993–1995 comments, but finds that they are inconclusive on the merits of extending escort vessel requirements to Cook Inlet. Further study, in light of current conditions, would be needed before the Coast Guard would propose such an extension.

In 2000, a Ports and Waterways Safety Assessment was conducted for Cook Inlet. The PAWSA report is available at *http://www.navcen.uscg.gov/mwv/projects/pawsa/PAWSA_FinalReports.htm*. It noted a ''significant drop off in oil spills'' over the preceding 5 years, and listed 9 ''existing mitigations'' in place to control the risk from petroleum cargoes. Although escort vessels for oil tankers were considered, they were not among the new mitigation measures adopted by the PAWSA final report.

The Coast Guard understands that concerns over navigational safety in Cook Inlet persist. We take these concerns seriously, because they relate directly to two of the Coast Guard's strategic goals: Maritime safety and maritime stewardship.

The Alaska-based Coast Guard Seventeenth District is planning to conduct additional studies of the local waterways in an effort to more fully define the need for risk reduction measures or other mitigating factors in areas such as Cook Inlet, Prince William Sound and the Aleutian Islands. Any findings from these risk assessments would be addressed in local Coast Guard policies or rulemakings. Therefore, we think it is neither appropriate nor beneficial to continue considering Cook Inlet's navigational safety within the nationwide context of this 1993 rulemaking.

Conclusion

The Coast Guard has tentatively decided that nationwide Coast Guard action to extend statutory escort vessel requirements is not advisable, and that escort vessels may be required in other waters or for vessels other than single-hulled oil tankers only after specific Coast Guard consideration of local conditions and possible alternative safety measures. We request public comment on this tentative decision. If, after receiving public comment, we affirm this tentative decision, we will withdraw the rulemaking, using another **Federal Register** notice to do so.

Please note that, regardless of our final decision to withdraw or continue this rulemaking, you may request Coast Guard regulatory action for specific U.S. waters, by using the Coast Guard rulemaking petition process detailed in 33 CFR 1.05–20. Send your request to the Marine Safety and Security Council (CG–0943), United States Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001.

Dated: April 4, 2008.

Brian M. Salerno,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine, Safety, Security and Stewardship.

[FR Doc. E8–7935 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2007–1120; FRL–8554–7]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Reasonably Available Control Technology Requirements for Marine Vessel and Barge Loading

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Maryland Department of Environment. The revision pertains to the control of

volatile organic compound (VOC) emissions by establishing reasonable available control technology (RACT) requirements for marine vessel and barge loading. EPA is proposing to approve the revision to the Maryland SIP in accordance with the Clean Air Act (CAA).

DATES: Written comments must be received on or before May 15, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2007–1120 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. E-mail: *fernandez.cristina@epa.gov*.

C. Mail: EPA–R03–OAR–2007–1120, 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–2007–1120. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *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 *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Gobeail McKinley, (215) 814–2033, or by e-mail at *mckinley.gobeail@epa.gov*.

SUPPLEMENTARY INFORMATION: On October 24, 2007, the Maryland Department of Environment (MDE) submitted a revision to its SIP to establish RACT requirements for marine vessel and barge loading. The SIP revision (Maryland SIP #07–12) consists of amendments to Regulation .01 and adoption of new Regulation .08 under COMAR 26.11.13—Control of Gasoline and Volatile Organic Compound Storage and Handling.

I. Background

This SIP revision was submitted pursuant to the reasonable available control technology requirements of sections 182 and 184 of the Clean Air Act. RACT is the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility. Maryland is located in the Ozone Transport Region (OTR) that was statutorily created by section 184 of the CAA.

Section 184(b)(1)(B) of the CAA requires States to implement RACT regulations on all VOC sources that have the potential to emit 50 tons per year (TPY) or more. In addition, section 182(b)(2) requires States to implement RACT regulations on all ''major'' sources of VOC in moderate or above ozone nonattainment areas. Major VOC sources are those with the potential to emit at least 100 TPY in moderate areas, 50 TPY in serious areas, and 25 TPY in severe areas.

Maryland is in the OTR and the State is required to implement RACT regulations for all sources with the potential to emit 50 TPY or more, throughout the State. In Maryland's severe ozone nonattainment areas, RACT is required for all VOC sources with the potential to emit 25 TPY or more.

The amendment to Regulation .01 and adoption of new Regulation .08 under COMAR 26.11.13 control emissions of volatile organic compounds throughout the state. MDE submitted this SIP revision request pursuant to the reasonable available control technology requirements of sections 182 and 184 of the Clean Air Act. Although the EPA has developed a maximum achievable control technology standard for barge loading (40 CFR Part 63 Subpart Y), the liquid throughput threshold requiring controls is very high. For this reason, MDE has adopted RACT requirements for marine vessel and barge loading.

A marine vessel is defined as any tank ship or barge that transports VOCs in bulk as cargo. Marine tank vessel loading operations are facilities that load and unload liquid commodities in bulk. Due to the increased demand for ethanol which is blended with gasoline, there is a renewed interest in transferring liquid products from stationary storage tanks into marine vessels or barges for further distribution. During marine tank vessel and barge loading operations, emissions result as the liquid that is being loaded into the vessel displaces vapors from the vessel's tank. VOC vapors are released from the vent of the barge in quantities that may be significant and contribute to ground level ozone. Maryland has decided to revise their RACT requirements to include marine vessel and barge loading.

II. Summary of SIP Revision

The Maryland Department of the Environment is requesting a revision to the state's SIP to establish reasonable available control technology requirements for marine vessel and barging loading. The amendment to COMAR 26.11.13.01 consist of a new definition that defines a marine vessel as any tank ship or barge that transports VOCs in bulk as cargo. The new regulation COMAR 26.11.13.08 requires owners or operators of barge loading facilities in Baltimore City or Anne Arundel, Baltimore, Calvert, Carroll, Cecil, Charles, Frederick, Harford, Howard, Montgomery, and Prince George's Counties to reduce capture of VOC vapors by 90 percent if emissions from the barge loading equal or exceed 25 TPY. In the rest of the state

(Allegheny, Caroline, Dorchester, Garrett, Kent, Queen Anne's, St. Mary's, Somerset, Talbot, Washington, Wicomico, and Worchester Counties), controls are required if emissions are equal to or exceed 50 TPY.

III. Proposed Action

EPA is proposing to approve the Maryland SIP revision for the establishment of RACT requirements to control VOC emissions from marine vessel and barging loading, which the state submitted on October 24, 2007. 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 Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely 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 Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule to approve Maryland's amendments to the control of volatile organic compound emissions by establishing reasonable available control technology requirements for marine vessel and barge loading 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, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: April 9, 2008.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. E8–8005 Filed 4–14–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2008–0241; FRL–8552–9]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Iowa State Implementation Plan submitted on January 16, 2008. The revision includes changes to the definition of ''permitting authority'' in each of Iowa's rules used for compliance with EPA's Clean Air Interstate Rule. Iowa's SIP revision is in response to EPA's request of Iowa to revise the definitions to ensure that all allowances issued in the EPA Budget Trading Programs can be traded and used for compliance with the allowance-holding requirement in any State in the program.

DATES: Comments on this proposed action must be received in writing by May 15, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2008–0241, by mail to Michael Jay, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Michael Jay at (913) 551–7460, or by e-mail at *jay.michael@epa.gov*.

SUPPLEMENTARY INFORMATION: In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: April 3, 2008.

William Rice,

Acting Regional Administrator, Region 7.

[FR Doc. E8–7782 Filed 4–14–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R8–ES–2008–0034; 92210–1117–0000–B4]

RIN 1018–AV24

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Bay Checkerspot Butterfly (Euphydryas editha bayensis)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period, notice of availability of draft economic analysis, and amended required determinations.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the comment period on the proposed revised designation of critical habitat for the Bay checkerspot butterfly (*Euphydryas editha bayensis*) under the Endangered Species Act of 1973, as amended (Act). We also announce the availability of the draft economic analysis (DEA) of the proposed revised critical habitat designation and an amended required determinations section of the proposal. We are reopening the comment period to allow all interested parties an opportunity to comment simultaneously on the proposed rule, the associated DEA, and the amended required determinations section. You do not have to resend comments sent earlier. We will incorporate them into the public record as part of this comment period, and we will fully consider them when preparing our final determination.

DATES: We will accept public comments received or postmarked on or before May 15, 2008.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R8–ES–2008–0034; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Susan Moore, Field Supervisor or Arnold Roessler, Listing Program Coordinator, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Room W–2605, Sacramento, CA 95825; telephone 916–414–6600; or facsimile 916–414–6712. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information during this reopened comment period on our proposed revised critical habitat designation for the Bay checkerspot butterfly published in the **Federal Register** on August 22, 2007 (72 FR 48178), the DEA of the proposed revised designation, and the amended required determinations provided in this document. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) The reasons why we should or should not designate habitat as critical habitat under section 4 of the Act (16 U.S.C. 1531 *et seq.*).

(2) *Specific information on:*

- The amount and distribution of Bay checkerspot butterfly habitat,
- What areas occupied at the time of listing that contain features essential to the conservation of the species we should include in the designation and why, and
- What areas not occupied at the time of listing are essential for the conservation of the species and why.

(3) Land-use designations and current or planned activities in the subject areas and their possible effects on proposed critical habitat.

(4) Information on the extent to which any State and local environmental protection measures we reference in the DEA may have been adopted largely as a result of the listing of the Bay checkerspot butterfly, and which were either already in place at the time of listing or enacted for other reasons.

(5) Information on whether the DEA identifies all State and local costs and benefits attributable to the proposed critical habitat designation, and information on any costs or benefits that we have overlooked.

(6) Information on whether the DEA makes appropriate assumptions regarding current practices and any regulatory changes likely if we designate revised critical habitat.

(7) Information on whether the DEA correctly assesses the effect on regional costs associated with any land use controls that may result from the revised critical habitat designation.

(8) Information on areas that the revised critical habitat designation could potentially impact to a disproportionate degree.

(9) Any foreseeable economic, national-security, or other potential impacts resulting from the proposed revised designation and, in particular, any impacts on small entities, and the benefits of including or excluding areas that exhibit these impacts.

(10) Information on whether the DEA identifies all costs that could result from the revised designation.

(11) Information on any quantifiable economic benefits of the revised designation of critical habitat.

(12) Whether the benefits of excluding any particular area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(13) Economic data on the incremental costs of designating any particular area as revised critical habitat.

(14) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

If you submitted comments or information during the initial comment period from August 22 to October 22, 2007, on the proposed rule (72 FR 48178), please do not resubmit them. We will incorporate them into the public record as part of this comment period, and we will fully consider them in preparation of our final determination. Our final determination concerning revised critical habitat will take into consideration all written comments and any additional information we receive during both comment periods. On the basis of public comments, we may, during the development of our final designation, find that areas proposed are not essential, are appropriate for exclusion under section 4(b)(2) of the Act, or are not appropriate for exclusion.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by e-mail or fax or to an address not listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you

may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this notice will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

You may obtain copies of the proposed rule and DEA by mail from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**) or by visiting our Web site at *http://www.fws.gov/sacramento.*

Background

On April 30, 2001, we published in the **Federal Register** the final designation of critical habitat for the Bay checkerspot butterfly (66 FR 21450, April 30, 2001) which encompassed approximately 23,903 acres (ac) (9,673 hectares (ha)). On March 30, 2005, the Home Builders Association of Northern California (Home Builders) filed a complaint contending, among other things, that the Service failed to adequately analyze the economic costs of the designation of critical habitat for this subspecies (*Home Builders of Northern California* v. *U.S. Fish and Wildlife Service, et al.* Case No. cv–01363–LKK–JFM). On February 24, 2006, the Service entered into a settlement agreement with Home Builders to submit for publication a proposed revised critical habitat designation for this subspecies to the **Federal Register** by August 14, 2007, and to submit a final determination of critical habitat for publication by August 14, 2008. The April 30, 2001, designation remains in place during this revision process. On August 22, 2007, we published a proposed rule to revise critical habitat for the Bay checkerspot butterfly (72 FR 48178), identifying a total of approximately 19,746 ac (7,990 ha) of land in San Mateo and Santa Clara Counties, California.

Section 3 of the Act defines critical habitat as the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection, and specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting areas designated as critical habitat must consult with us on the effects of their proposed actions, pursuant to section 7(a)(2) of the Act.

Under section 4(b)(2) of the Act, we may exclude an area from critical habitat if we determine that the benefits of such exclusion outweigh the benefits of including that particular area as critical habitat, unless failure to designate that specific area as critical habitat will result in the extinction of the species. We may exclude an area from designation as critical habitat based on economic impacts, national security, or any other relevant impact.

If we make final the proposed rule of August 22, 2007, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting areas designated as critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

Draft Economic Analysis

Section 4(b)(2) of the Act requires that we designate or revise critical habitat based upon the best scientific and commercial data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat. We have prepared a DEA of the proposed revised critical habitat designation based on our August 22, 2007, proposed rule to revise the critical habitat designation for the Bay checkerspot butterfly (72 FR 48178).

The intent of the DEA is to quantify the economic impacts of all potential conservation efforts for the Bay checkerspot butterfly; some of these costs will likely be incurred regardless of whether we revise the designated critical habitat. The DEA provides estimated costs of the foreseeable potential economic impacts of the proposed revised critical habitat designation (incremental impacts) and other conservation-related actions (baseline impacts) for this species over the next 22 years. A 22-year period was chosen because information was available to reliably forecast economic activity to 2030. It also considers past costs associated with conservation of the species from the time it was listed in 1987 (52 FR 35366, September 18, 1987), until the year the proposed revised critical habitat rule was published (72 FR 48178, August 22, 2007). Because the current DEA is analyzing the future costs of the proposed revised designation (72 FR 48178), the costs associated with the current designation of critical habitat (66 FR 21450) have been included only in the past baseline economic impacts.

The economic analysis quantifies impacts associated with the conservation of the Bay checkerspot butterfly including future urban development, management of invasive plants, pesticide use, and over or under grazing. These activities were identified as factors that may require special management (72 FR 48183–48184). Pre-designation (1987 to 2007) impacts associated with species conservation activities in areas proposed for designation are estimated at approximately $9 million in 2007 dollars. The DEA forecasts baseline economic impacts in the areas proposed for designation to be approximately $390 million ($18 million annualized) (2008 dollars) applying a 3 percent discount rate over the next 22 years, $270 million ($13 million annualized) (2008 dollars) applying a 7 percent discount rate over the next 22 years, and $550 million (25 million annualized) (2008 dollars) at an undiscounted rate over the next 22 years. The DEA forecasts incremental economic impacts to be approximately $0 to $750,000 ($0 to $44,000 annualized) (2008 dollars) applying a 3 percent discount rate over the next 22 years. The cost estimates are based on the proposed revised designation of critical habitat published in the **Federal Register** on August 22, 2007 (72 FR 48178).

The DEA considers the potential economic effects of actions relating to the conservation of the Bay checkerspot butterfly, including costs associated with sections 4, 7, and 10 of the Act, as well as costs attributable to the designation of revised critical habitat. It further considers the economic effects of protective measures taken as a result of other Federal, State, and local laws that aid habitat conservation for the Bay checkerspot butterfly in areas containing features essential to the conservation of the species. The DEA considers both economic efficiency and distributional effects. In the case of habitat conservation, efficiency effects generally reflect the ''opportunity costs'' associated with the commitment of resources to comply with habitat protection measures (such as lost

economic opportunities associated with restrictions on land use).

The DEA also addresses how potential economic impacts are likely to be distributed, including an assessment of any local or regional impacts of habitat conservation and the potential effects of conservation activities on government agencies, private businesses, and individuals. The DEA measures lost economic efficiency associated with residential and commercial development and public projects and activities, such as economic impacts on water management and transportation projects, Federal lands, small entities, and the energy industry. Decision-makers can use this information to assess whether the effects of the revised designation might unduly burden a particular group or economic sector. Finally, the DEA looks retrospectively at costs that have been incurred since the date we listed the Bay checkerspot butterfly as endangered (52 FR 35366, September 18, 1987) and considers those costs that may occur in the 22 years following the designation of critical habitat. Because the DEA considers the potential economic effects of all actions relating to the conservation of the Bay checkerspot butterfly, including costs associated with sections 4, 7, and 10 of the Act and those attributable to a revised designation of critical habitat, the DEA may have overestimated the potential economic impacts of the revised critical habitat designation.

As stated earlier, we are soliciting data and comments from the public on this DEA, as well as on all aspects of the proposed rule and our amended required determinations. We may revise the proposed rule or its supporting documents to incorporate or address information we receive during this comment period. In particular, we may exclude an area from the revised critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area as revised critical habitat, provided the exclusion will not result in the extinction of the species.

Required Determinations—Amended

In our August 22, 2007, proposed rule (72 FR 48178), we indicated that we would defer our determination of compliance with several statutes and Executive Orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have not made use of the DEA data to make these determinations. In this document we affirm the information contained in our proposed rule concerning Executive Order (E.O.) 13132; E.O. 12988; the Paperwork Reduction Act; and the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments (59 FR 22951). However, based on the DEA data, we revise our required determinations concerning E.O. 12866 and the Regulatory Flexibility Act, E.O. 13211 (Energy, Supply, Distribution, and Use), the Unfunded Mandates Reform Act, and E.O. 12630 (Takings).

Regulatory Planning and Review

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this rule under Executive Order 12866 (E.O. 12866). OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 802(2)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed revised designation, we provide our analysis for determining whether the proposed rule would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revised this determination as part of our final rulemaking.

According to the Small Business Administration (SBA), small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this revised designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the proposed revised designation of critical habitat for the Bay checkerspot butterfly would affect a substantial number of small entities, we considered the number of affected small entities within particular types of economic activities, such as residential and commercial development. In order to determine whether it is appropriate for our agency to certify that this rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement. Critical habitat designation will not affect activities that do not have any Federal involvement; designation of critical habitat affects activities conducted, funded, permitted, or authorized by Federal agencies.

If we finalize this proposed revised critical habitat designation, Federal agencies must consult with us under section 7 of the Act if their activities may affect designated critical habitat. Consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our DEA of the proposed revised critical habitat designation, we evaluated the potential economic effects on small business entities from conservation actions related to the listing of the Bay checkerspot butterfly

and the proposed revised designation of the species' critical habitat.

The DEA did not identify any small entities according to the Small Business Administration's (SBA) definition of small entities. As a result there are no economic impacts to small businesses with the designation of this critical habitat. We have considered whether this rule would result in a significant economic effect on a substantial number of small entities. We have determined and therefore certify that, for the above reasons and based on currently available information, the proposed designation will not have a significant economic impact on a substantial number of small business entities.

In summary, we have considered whether the proposed rule would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if promulgated, this proposed rule would not have a significant economic impact on a substantial number of small entities. Therefore, an initial regulatory flexibility analysis is not required.

Executive Order 13211—Energy Supply, Distribution, and Use

On May 18, 2001, the President issued E.O. 13211 on regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. OMB's guidance for implementing this Executive Order outlines nine outcomes that may constitute ''a significant adverse effect'' when compared to no regulatory action. The DEA has identified one electric energy firm (Calpine Corporation) which owns land within the proposed revised designation of critical habitat (Unit 5). In 2000, the Calpine Corporation proposed to construct and operate a 600-megawatt, natural gas-fired, combined cycle electric generation facility. The land located within the proposed revised designation of critical habitat was purchased by the Calpine Corporation as compensation to off-set project-related effects to the Bay checkerspot butterfly and its habitat as a result of the U.S. Environmental Protection Agency (EPA) permitting of the Calpine Corporation's Metcalf Energy Center in Santa Clara County, California (Service File 1–1–00–F–235) in 2001. The Calpine Corporation does not plan to expand its facilities or construct new facilities associated with the Metcalf Energy Center on any of its land within or near the area. The biological opinion under section 7 of the Act for this project identifies the measures already taken by the Calpine Corporation to compensate for effects to the butterfly and its habitat, and the designation of revised critical habitat is not expected to lead to any reduction in electricity production or an increase in cost of energy production or distribution.

Thus, based on information in the DEA, we do not expect Bay checkerspot butterfly conservation activities within proposed revised critical habitat to lead to energy-related impacts. As such, we do not expect the proposed revised designation of critical habitat to significantly affect energy supplies, distribution, or use, and a Statement of Energy Effects is not required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*), the Service makes the following findings:

(a) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments,'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program.''

Critical habitat designation does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. Designation of critical habitat may indirectly impact non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action that may be indirectly impacted by the designation of critical habitat. However, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(b) We do not believe that this rule will significantly or uniquely affect small governments. As discussed in the DEA, the majority of lands proposed as revised critical habitat are comprised of privately owned lands, which do not qualify as a small government. Consequently, we do not believe that revised critical habitat designation would significantly or uniquely affect small government entities. As such, a Small Government Agency Plan is not required.

Executive Order 12630—Takings

In accordance with E.O. 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of proposing revised critical habitat for the Bay checkerspot butterfly in a takings implications assessment. Our takings implications assessment concludes that this proposed revised designation of critical habitat for the Bay checkerspot butterfly does not pose significant takings implications.

References Cited

A complete list of all references we cited in the proposed rule is available on *http://www.regulations.gov.*

Author

The primary author of this notice is staff of the Sacramento Fish and Wildlife Office.

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*)

Dated: April 2, 2008.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–7689 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register

Vol. 73, No. 73

Tuesday, April 15, 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

Forest Service

Ochoco National Forest, Paulina Ranger District; Oregon; Upper Beaver Creek Vegetation Management Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impactstatement.

SUMMARY: The USDA Forest Service is proposing to conduct timber harvest, noncommercial thinning, and fuels reduction activities in the Upper Beaver Creek Watershed. The project area covers approximately 37,000 acres.

DATES: Comments concerning the scope of the analysis must be received by May 16, 2008. The draft environmental impact statement is expected by September 2008 and the final environmental impact statement is expected in March 2009.

ADDRESSES: Send written comments to Mike Lawrence, District Ranger, Paulina Ranger District, Ochoco National Forest, 7803 Beaver Creek Road, Paulina, Oregon 97751. Alternately, electronic comments can be sent to *comments-pacificnorthwest-ochocopaulina@fs.fed.us*.

FOR FURTHER INFORMATION CONTACT: Janis Bouma, Project Leader, at the address listed above.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose and need for this proposal is to (1) Move vegetation seral/structural stages toward their historic range of variability and to increase large woody debris recruitment and hardwood plant composition within Riparian Habitat Conservation Areas (RHCAs); (2) Move Fire Regimes toward their historic range of variability by maintaining low intensity fire conditions and decreasing high intensity fire conditions across the project area; and (3) Provide wood products to contribute to the health of the local and regional economies, and provide opportunities for employment and income.

Proposed Action

The Paulina Ranger District is proposing to manage vegetation through commercial timber harvest, noncommercial thinning, and fuel reduction activities. The proposed action includes approximately 2,923 acres of commercial harvest and 8,337 acres of noncommercial thinning. Fuel reduction activities include approximately 11,259 acres of prescribed fire to reduce fuels from management activities in this project and past projects, 5,243 acres of fire to maintain low intensity fuel levels, and 1,341 acres of fire to reduce ladder and surface fuels in untreated vegetation areas. Approximately 2,500 acres of grapple piling would be completed. Construction of a shaded fuel break approximately 600 feet along each side of the Summit Trail (approximately 450 acres) is proposed in order to protect the historic value of the Summit Trail and to provide for future firefighter safety. Commercial harvest includes tractor, skyline, and helicopter logging systems. Areas identified as tractor logging are areas where heavy equipment, such as logging tractors/skidders, will be used to remove a commercial product. Approximately two miles of temporary roads would be constructed. No new roads would be constructed and roads that are reopened would be closed after harvest activities are complete.

Possible Alternatives

At this time, the Forest Service is considering at least three alternatives. The no action alternative is the baseline for comparison and will analyze the effects of natural processes along with ongoing activities such as road maintenance and recreation use. Ongoing activities, such as road maintenance, noxious weeds treatments, and recreational use, would continue. Access for public and administrative purposes would continue on the existing transportation system. Alternative 2, the proposed action, will analyze the effects of timber harvest, noncommercial thinning, and prescribed fire activities. A third alternative being considered at this time is similar to Alternative 2; however, it would analyze treatment of the maximum number of acres to meet the purpose and need while meeting Forest Plan standards and guidelines. The action alternatives will examine combinations and degrees of activities to meet the purpose of and need for action and concerns stated during the public scoping process.

Responsible Official

The responsible official for this project is Jeff Walter, Forest Supervisor, Ochoco National Forest, 3160 NE., Third Street, Prineville, Oregon 97754.

Nature of Decision To Be Made

The Forest Supervisor will decide whether to conduct timber harvest, noncommercial thinning, and prescribe fire treatments within the Upper Beaver Creek project area. The decision will be based on the information disclosed in the EIS, and the goals, objectives, and desired future conditions as stated in the Forest Plan as amended. The responsible official will consider significant issues, public comments, environmental consequences, and compliance with applicable laws, regulations, and policies in making his decision. The responsible official will also determine whether to amend the Forest Plan to allow: (1) Prescribed fire treatments in old growth areas and (2) moving designated old growth areas to areas more suited as old growth habitat. The rationale for the decision will be stated in the Record of Decision for the project.

Scoping Process

The Paulina Ranger District intends to scope for information by mailing letters to adjacent landowners, persons, and organizations interested or potentially affected by the proposed action. Meetings may be conducted with interested individuals and groups to further explain and clarify the proposal and project area resources and receive comments. This project will be included in the Ochoco National Forest Quarterly Schedule of Proposed Actions for the duration of the environmental analysis.

Preliminary Issues

The Paulina Ranger District has identified five preliminary issues related to the proposed action. They are: (1) Removal of trees would cause changes to connectivity corridors; (2)

Proposed activities could cause changes to goshawk nest stands; (3) Proposed activities in Riparian Habitat Conservation Areas could increase sediment and cause a decline in water quality. Commercial harvest and noncommercial thinning could also cause a reduction in shade on streams and cause an increase in stream temperatures; (4) Equipment use during harvest activities and connected actions could change soil productivity; and (5) Prescribed fire treatments would cause changes to ground nesting habitat for migratory and sensitive land birds.

Comment Requested

This notice of intent is part of the scoping process that will guide the development of the environmental impact statement. The primary purpose of scoping is to gather public comments, issues, and concerns regarding the proposed action. Comments, issues, and concerns may be used to formulate alternatives. Comments are most helpful if they are as specific as possible and relate to the proposed action. Comments should include the name, address, and, if possible, telephone number of the commenter. Electronic comments must be submitted as part of the actual e-mail message, or as an attachment in plain text (.txt), Microsoft Word (.doc), rich text format (.rtf), or portable document format (.pdf). Comments received in response to this solicitation, including the names and addresses of those who comment, will be considered part of the public record and will be available for public inspection.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared and made available for comment. The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Dated: April 8, 2008.

Jeff Walter,

Forest Supervisor, Ochoco National Forest.

[FR Doc. E8–7838 Filed 4–14–08; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Government Finance Forms.

Form Number(s): F–5, F–11, F–11(S), F–12, F–12(S), F–13, F–25, F–28, F–29, F–32, F–42.

OMB Control Number: 0607–0585.

Type of Request: Extension of a currently approved collection.

Burden Hours: 36,040.

Number of Respondents: 2,257.

Average Hours per Response: 3 hours.

Needs and Uses: This program is the only known comprehensive source of state and local government finance data collected on a nationwide scale using uniform definitions, concepts, and procedures.

The many different types and sizes of state and local governments require that the Census Bureau use a variety of questionnaires to collect government finance data. In both the Census and annual surveys, equivalent data are collected.

In 2007, the Census Bureau submitted a non-substantive change request to OMB seeking permission to add questions for the collection of defined contribution and post-employment health care plan data for state administered systems included in the 2007 Census of Publicly Administered Employee Retirement Systems. In addition, five questions related to the liabilities of these systems were added. The non-substantive change request was approved for the 2007 collection cycle only. The plan for 2008 and future data collections is to collect the defined contribution plan, post-employment health care plan, and the five liability questions, in addition to the defined benefit plan questions from all state administered retirement systems and the 12 locally administered systems whose total holdings and investments are five billion dollars or more. The universe of respondents receiving this questionnaire remains the same as in previous collection cycles.

The Census Bureau incorporates the data collected on these forms into its governmental finance program. This program has facilitated the dissemination of comprehensive and comparable governmental finance statistics on government revenue, expenditure, debt, and assets since 1902.

These statistics are widely used by Federal, state, and local legislators, policy makers, administrators, analysts, economists, and researchers to follow the changing characteristics of the government sector of the economy. Journalists, teachers, and students rely on these data as well.

The Census Bureau provides its governmental finance data annually to the Bureau of Economic Analysis (BEA) for use in measuring and developing estimates of the government sector of the economy in the National Income and Product Accounts. The Census Bureau also provides these data to the Federal Reserve Board for constructing the Flow of Funds Accounts.

If this information were not available, it would create a large gap in economic statistics for the government sector, making it impossible for the BEA to calculate the government sector of the National Income and Product Accounts. It would also eliminate a key source of

data needed by the Federal Reserve Board.

Affected Public: State, local or tribal government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, Sections 161 and 182.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: April 10, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–8007 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Office of the Secretary, Office of Civil Rights.

Title: Complaint of Employment Discrimination Used by Permanent Employees and Applicants for Employment at DOC and Complaint of Employment Discrimination for the Decennial Census.

OMB Control Number: 0690–0015.

Form Number(s): CD–498 and CD–498A.

Type of Request: Regular submission.

Burden Hours: 350.

Number of Respondents: 700.

Average Time Per Response: 30 minutes.

Needs and Uses: The Equal Employment Opportunity Commission (EEOC) regulations at 29 CFR 1614.106 requires that a person alleging discrimination treatment, based on race, color, religion, sex, national origin, age, disability, and/or reprisal for participation in equal employment opportunity activity, by a federal agency must submit a signed statement that is sufficiently precise to identify the general actions or practices that form the basis of the complaint. The proposed forms are used to collect the required information. The complaint form used by permanent employees and applicants for employment will be part of a regular complaint process. The Decennial Census complaint form, used only during a decennial census, is expected to be used until the end of 2011.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via e-mail at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent to David Rostker, OMB Desk Officer, fax number (202) 395–7258 or via e-mail at *David_Rostker@omb.eop.gov*.

Dated: April 10, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–8008 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–BP–P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Proposed Information Collection; Comment Request; Annual Retail Trade Survey

AGENCY: U.S. Census Bureau.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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)).

DATES: To ensure consideration, written comments must be submitted on or before June 16, 2008.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to John Trimble, U.S. Census Bureau, SSSD HQ–8K175, 4600 Silver Hill Road, Suitland, MD 20746 at (301) 763–7223 (or via the Internet at *John.R.Trimble@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Annual Retail Trade Survey (ARTS) provides a sound statistical basis for the formation of policy by other government agencies. It also provides continuing and timely national statistics on retail trade and accommodation and food services, augmenting the period between economic censuses, and is a continuation of similar retail trade surveys conducted each year since 1951. The data collected are applicable to a variety of public and business needs and include annual sales and other operating receipts, e-commerce sales and other operating receipts, purchases, end-of-year inventories, accounts receivables, and operating expenses. Data items collected for accommodation and food services are annual receipts and e-commerce receipts. The estimates of purchased merchandise will be used to estimate trade margins on commodities sold in calculating the personal consumption portion of the Gross Domestic Product (GDP) by the Bureau of Economic Analysis (BEA). Accounts receivable balances are used by the Federal Reserve Board in measuring consumer credit. Businesses use these estimates to determine market share and to perform other analysis.

The ARTS sampling frame consists of all firms operating retail or accommodations and food service establishments within the U.S. whose probability of selection is determined by sales size. Estimates developed in the ARTS are used to benchmark the monthly sales and inventories series. The firms canvassed in this survey are not required to maintain additional records since carefully prepared estimates are acceptable if book figures are not available.

Estimates produced from the ARTS are published on the North American Industry Classification System (NAICS) basis.

II. Method of Collection

ARTS data are collected through mail, fax, and telephone follow-up. In January 2006, we began offering the option to submit data over the Internet using the Census Taker system.

III. Data

OMB Control Number: 0607–0013.

Form Number: SA–44, SA–44A, SA–44C, SA–44E, SA–44N, SA–44S, SA–45, SA–45C, SA–721A, SA–721E, SA–722A, and SA–722E.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 21,635.

Estimated Time Per Response: 34 minutes.

Estimated Total Annual Burden Hours: 12,260.

Estimated Total Annual Cost: $0.

Respondents Obligation: Mandatory.

Legal Authority: Title 13 United States Code, Section 182, 224, and 225.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 10, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–8012 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Proposed Information Collection; Comment Request; Data Collection for Compliance With Government Performance and Results Act

AGENCY: Economic Development Administration.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before June 16, 2008.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to William P. Kittredge, PhD, Senior Program Analyst, Program Evaluation Division, Room 7009, Economic Development Administration, Washington, DC 20230, or at e-mail *wkittredge@eda.doc.gov* or telephone (202) 482–5442.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Economic Development Administration's mission is to lead the federal economic development agenda by promoting innovation and competitiveness, preparing American regions for growth and success in the worldwide economy. The Economic Development Administration (EDA) accomplishes its mission by helping our partners across the nation (states, regions, and communities) create wealth and minimize poverty by promoting a favorable business environment to attract private capital investment and jobs through world-class capacity building, planning, infrastructure, research grants, and strategic initiatives.

EDA's strategic investments in public infrastructure and local capital markets provide lasting benefits for economically disadvantaged areas. Acting as catalysts to mobilize public and private investments, EDA's investments address problems of high unemployment, low per capita income, and other forms of severe economic distress in local communities. EDA also provides special economic adjustment assistance to help communities and businesses respond to major layoffs, plant shutdowns, trade impacts, natural disasters, military facility closures, and other severe economic dislocations.

EDA must comply with the Government Performance and Results Act of 1993 which requires Federal agencies to develop performance measures, and report to Congress and stakeholders the results of the agency's performance. EDA needs to collect specific data from grant recipients to report on its performance in meeting its stated goals and objectives.

II. Method of Collection

The forms can be submitted electronically or in paper format.

III. Data

OMB Control Number: 0610–0098.

Form Number(s): ED–915, ED–916, ED–917, and ED–918.

Type of Review: Regular submission.

Affected Public: State, local, or tribal government; not-for-profit institutions; business or other for-profit organizations.

Estimated Number of Respondents: 1,529.

Estimated Time per Response: 7 hours 16 minutes.

Estimated Total Annual Burden Hours: 11,116.

Estimated Total Annual Cost to Public: $113,220.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 10, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–8011 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

(Docket 19–2008)

Foreign–Trade Zone 122 – Corpus Christi, Texas, Application for Subzone, Haliburton Energy Services, Inc., (Barite Grinding and Milling), Corpus Christi, Texas

An application has been submitted to the Foreign–Trade Zones Board (the Board) by the Port of Corpus Christi Authority, grantee of Foreign–Trade Zone (FTZ) 122, requesting special–purpose subzone status for the barite grinding and milling facility of Haliburton Energy Services, Inc. (HESI) located in Corpus Christi, Texas. The application was submitted pursuant to the provisions of the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on April 1, 2008.

The HESI facility (12 acres, 15 employees) is located at 2600 Navigation Boulevard, in Corpus Christi. The facility is used for the manufacturing, warehousing and distribution activities related to the processing of raw barite (HTSUS 2511.10.50) into ground barite (HTSUS 2511.10.10) (up to 160,000 tons annually). Ground barite is used in the production of drilling fluids (drilling mud) and various specialty chemicals for use by the oil and natural gas exploration industry. HESI sources the majority of its raw barite from abroad. The duty rate on the imported raw barite is $1.25 per metric ton.

This application requests authority for HESI to conduct the activity under FTZ procedures, which would exempt the company from customs duty payments on the imported barite used in export production. Less than one percent of production is exported. On domestic sales, the company could choose the duty rate (duty–free) for the imported raw barite used in manufacturing that applies to the finished product. The majority of FTZ–related savings will come from the elimination of the duty on the finished product. HESI will also realize additional savings on the elimination of duties on materials that become scrap/waste during manufacturing. The application indicates that the FTZ–related savings would improve the plant's international competitiveness.

In accordance with the Board's regulations, Christopher Kemp of the FTZ staff is designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address listed below. The closing period for their receipt is June 16, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15–day period (to June 30, 2008).

A copy of the application and accompanying exhibits will be available at each of the following addresses: Port of Corpus Christi Authority, 222 Power Street, Corpus Christi, Texas 78401; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Ave, NW, Washington, D.C. 20230. For further information contact Christopher Kemp at christopher__kemp@ita.doc.gov or (202) 482–0862.

Dated: April 1, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–8032 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

(Docket 22–2008)

Foreign–Trade Zone 2 New Orleans, Louisiana, Application for Subzone, Haliburton Energy Services, Inc.(Barite Grinding and Milling) New Orleans, Louisiana

An application has been submitted to the Foreign–Trade Zones Board (the Board) by the Port of New Orleans, grantee of Foreign–Trade Zone (FTZ) 2, requesting special–purpose subzone status for the barite grinding and milling facility of Haliburton Energy Services, Inc. (HESI) located in New Orleans, Louisiana. The application was submitted pursuant to the provisions of the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on April 1, 2008.

The HESI facility (12 acres, 18 employees) is located within the 14–acre Port of New Orleans property located at 8000 Jourdan Road, in New Orleans. The facility is used for the manufacturing, warehousing and distribution activities related to the processing of raw barite (HTSUS 2511.10.50) into ground barite (HTSUS 2511.10.10) (up to 480,000 tons annually). Ground barite is used in the production of drilling fluids (drilling mud) and various specialty chemicals for use by the oil and natural gas exploration industry. HESI sources the majority of its raw barite from abroad. The duty rate on the imported raw barite is $1.25 per metric ton.

This application requests authority for HESI to conduct the activity under FTZ procedures, which would exempt the company from customs duty payments on the imported barite used in export production. Less than one percent of production is exported. On domestic sales, the company could choose the duty rate (duty–free) for the imported raw barite used in manufacturing that applies to the finished product. The majority of FTZ–related savings will come from the elimination of the duty on the finished product. HESI will also realize additional savings on the elimination of duties on materials that become scrap/waste during manufacturing. The application indicates that the FTZ–related savings would improve the plant's international competitiveness.

In accordance with the Board's regulations, Christopher Kemp of the FTZ staff is designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address listed below. The closing period for their receipt is June 16, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to June 30, 2008).

A copy of the application and accompanying exhibits will be available at each of the following addresses: U.S. Department of Commerce Export Assistance Center, 2 Canal Street, Suite 2710, New Orleans, LA 70130; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Ave, NW, Washington, D.C. 20230. For further information contact Christopher Kemp at christopher__kemp@ita.doc.gov or (202) 482–0862.

Dated: April 1, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–8042 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

Docket 19–2008

Foreign–Trade Zone 26 Atlanta, GA, Application for Subzone Status, KIA Motors Manufacturing Georgia, Inc. (Motor Vehicles)

An application has been submitted to the Foreign–Trade Zones Board (the Board) by the Georgia Foreign–Trade Zone, Inc., grantee of FTZ 26, requesting special–purpose subzone status for the motor vehicle manufacturing plant of Kia Motors Manufacturing Georgia, Inc. (KMMG), located in West Point, Georgia. The application was submitted pursuant to the provisions of the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on March 28, 2008.

The KMMG plant (635 acres/2.4 million sq.ft.) is to be located at 700 Kia Parkway in West Point (Troup County), Georgia. The facility, currently under construction, will be used to produce light–duty passenger vehicles (sedans, sport utility vehicles, minivans) for export and the domestic market. At full capacity, the facility (about 2,500 employees) will manufacture up to approximately 350,000 vehicles annually. Components to be purchased from abroad (representing approximately 25% of total material inputs, by value) would include: oils, hydraulic fluids, pipe/tube of plastics, paint, plastic knobs, flexible rubber tubes/hoses, self–adhesive plastic or polyurethane sheets/foil/film, labels, tape, rubber belts, tires, gaskets, seals, floor mats, safety glass, mirrors, pipe fittings, stranded wire of steel and copper, pins, hangers, brake cables, body parts, trim parts, articles of base metals, doors, fasteners, cotter pins, helical springs, catalytic converters, locks and keys, spark–ignition and diesel engines, engine parts, pumps, compressors, air conditioner components, filters, valves, parts of steering systems, steering wheels, hubs and flanges, universal joints, clutches, half/drive shafts, transmissions and parts of transmissions, torque converters, differentials, bearings and parts thereof, compasses, thermostats, motors, batteries, ignition parts, electrical parts, lighting equipment, horns, windshield wipers, audio/video components, speakers, antennas, wiring harnesses, carpet sets, seats, seat belts, airbag modules/inflators, brake components, wheels, wheel locks, lug nuts, lug wrenches, suspension components, radiators, exhaust systems, hinges, pneumatic dampeners, speedometers, tachometers, voltmeters, flow meters, regulators/controllers, windshields, glass windows, resistors, relays, starters, clocks, spark plugs, and switches (duty rate range: free 9.0%).

FTZ procedures would exempt KMMG from customs duty payments on foreign components used in export production (estimated to be 10% of plant shipments). On its domestic sales, KMMG would be able to choose the duty rate that applies to finished passenger vehicles (2.5%) for the foreign inputs noted above that have higher rates. Customs duties also could possibly be deferred or reduced on foreign status production equipment. The application indicates that the savings from FTZ procedures would help improve the facility's international competitiveness.

In accordance with the Board's regulations, Pierre Duy of the FTZ Staff is designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 16, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to June 30, 2008.

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations: U.S. Department of Commerce Export Assistance Center, 75 Fifth Street, N.W., Suite 1055, Atlanta, Georgia 30308; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230–0002. For further information, contact Pierre Duy at pierre__duy@ita.doc.gov, or (202) 482–1378.

Dated: April 3, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–8034 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 23–2008]

Foreign–Trade Zone 26 Atlanta, Georgia, Application for Subzone, Noramco, Inc. (Pharmaceutical Intermediate Manufacturing), Athens, Georgia

An application has been submitted to the Foreign–Trade Zones (FTZ) Board (the Board) by the Georgia Foreign–Trade Zone, Inc., grantee of FTZ 26, requesting special–purpose subzone status with manufacturing authority at the pharmaceutical intermediate manufacturing facility of Noramco, Inc. (Noramco), located in Athens, Georgia. The application was submitted pursuant to the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on April 3, 2008.

Noramco, a wholly–owned subsidiary of Johnson & Johnson, Inc., produces intermediates for prescription and over–the-counter pharmaceutical products. Noramco has requested authority to manufacture under zone procedures an active ingredient (Tapentadol Hydrochloride) for a new prescription analgesic product at the facility (170 employees). The proposed subzone facility (130 acres, 121,300 sq. ft. within 3 buildings for the proposed activity) is located at 1440 Olympic Drive, Athens, Georgia.

Foreign–origin chemical ingredient inputs to be used in the manufacturing process (about half of finished product value) have duty rates ranging from 3.7 percent to 6.5 percent, ad valorem. The applicant is also requesting to import polyethylene bags and poly drums, duty rates 3 percent and 5.3 percent respectively, for use in processing of the active ingredient. FTZ procedures would exempt Noramco from customs duty payments on foreign materials used in export production. At this time, the final product will only be marketed in the United States; however, the plant may in the future support export of the final product to Canada and Japan. On its domestic shipments, Noramco could defer duty until the product is entered for consumption, and choose the duty–free rate that applies to the finished active ingredient for the foreign inputs used in production. The company may also realize certain logistical/procedural savings related to weekly entry and direct delivery procedures, as well as savings on materials that become scrap/waste during manufacturing. The application indicates that FTZ

procedures would help improve the plant's international competitiveness.

In accordance with the Board's regulations, Diane Finver of the FTZ staff is designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 16, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to June 30, 2008).

A copy of the application will be available for public inspection at each of the following locations: U.S. Department of Commerce Export Assistance Center, 75 Fifth Street, N.W, Suite 1055, Atlanta, Georgia 30308; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, D.C. 20230–0002.For further information, contact Diane Finver at Diane__Finver@ita.doc.gov or (202) 482–1367.

Dated: April 3, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–8030 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

(Docket 21–2008)

Foreign–Trade Zone 87 Lake Charles, Louisiana, Application for Subzone, Haliburton Energy Services, Inc.(Barite Grinding and Milling) Westlake, Louisiana

An application has been submitted to the Foreign–Trade Zones Board (the Board) by the Lake Charles Harbor & Terminal District, grantee of Foreign–Trade Zone (FTZ) 87, requesting special–purpose subzone status for the barite grinding and milling facility of Haliburton Energy Services, Inc. (HESI) located in Westlake, Louisiana. The application was submitted pursuant to the provisions of the Foreign–Trade Zones Act, as amended (19U.S.C. 81a–81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on April 1, 2008.

The HESI facility (17 acres, 48 employees) is located at 3500 Bayou D'Inde Road, in Westlake. The facility is used for the manufacturing, warehousing and distribution activities related to the processing of raw barite (HTSUS 2511.10.50) into ground barite (HTSUS 2511.10.10) (up to 540,000 tons annually). Ground barite is used in the production of drilling fluids (drilling mud) and various specialty chemicals for use by the oil and natural gas exploration industry. HESI sources the majority of its raw barite from abroad. The duty rate on the imported raw barite is $1.25 per metric ton.

This application requests authority for HESI to conduct the activity under FTZ procedures, which would exempt the company from customs duty payments on the imported barite used in export production. Less than one percent of production is exported. On domestic sales, the company could choose the duty rate (duty–free) for the imported raw barite used in manufacturing that applies to the finished product. The majority of FTZ–related savings will come from the elimination of the duty on the finished product. HESI will also realize additional savings on the elimination of duties on materials that become scrap/waste during manufacturing. The application indicates that the FTZ–related savings would improve the plant's international competitiveness.

In accordance with the Board's regulations, Christopher Kemp of the FTZ staff is designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be adressed to the Board's Executive Secretary at the address listed below. The closing period for their receipt is June 16, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to June 30, 2008.

A copy of the application and accompanying exhibits will be available at each of the following addresses: Lake Charles Harbor and Terminal District, 150 Marine Street, Lake Charles, Louisiana 70601; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Ave, NW, Washington, D.C. 20230. For further information contact Christopher Kemp at christopher__kemp@ita.doc.gov or (202) 482–0862.

Dated: April 1, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–8036 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting

The Sensors and Instrumentation Technical Advisory Committee (SITAC) will meet on April 29, 2008, 9:30 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology.

Agenda

Public Session

1. Welcome and Introductions.
2. Remarks from Bureau of Industry and Security Management.
3. Industry Presentations.
4. New Business.

Closed Session

5. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yspringer@bis.doc.gov* no later than April 22, 2008.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that the materials be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on April 8, 2008, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 10(d)), that the portion of this meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app.

2 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information contact Yvette Springer on (202) 482–2813.

Dated: April 9, 2008.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. E8–7909 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

(A–570–848)

Freshwater Crawfish Tail Meat From the People's Republic of China: Final Results and Partial Rescission of the 2005–2006 Antidumping Duty Administrative Review and Rescission of 2005–2006 New Shipper Reviews

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

EFFECTIVE DATE: April 15, 2008.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review and new shipper reviews of the antidumping duty order on freshwater crawfish tail meat (crawfish) from the People's Republic of China (PRC). The period of review (POR) is September 1, 2005, through August 31, 2006. The Department published the preliminary results of these reviews on October 9, 2007. *See Freshwater Crawfish Tail Meat From the People's Republic of China: Preliminary Results and Partial Rescission of the 2005–2006 Antidumping Duty Administrative Review and Preliminary Intent to Rescind 2005–2006 New Shipper Reviews*, 72 FR 57288 (October 9, 2007) (*Preliminary Results*). We invited interested parties to comment on the *Preliminary Results*. After reviewing interested parties' comments, we made no changes to our calculations for the final results of review. The final dumping margins for this review are listed in the ''Final Results of Review'' section below.

FOR FURTHER INFORMATION CONTACT: Melissa Blackledge or Jeff Pedersen; AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., N.W., Washington, DC 20230; telephone: (202) 482–3518 or (202) 482–2769, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Results* on October 9, 2007. On December 17, 2007, the petitioners[1], Xuzhou Jinjiang Foodstuffs Co., Ltd. (Xuzhou), Washington International Insurance Co. (WII), the surety company for the U.S. importer of Xuzhou's subject merchandise, and Jingdezhen Garay Foods Co., Ltd (Jingdezhen) submitted case briefs. On December 26, 2007, Xiping Opeck Food Co., Ltd. (Xiping Opeck), and the petitioners submitted rebuttal briefs. On February 22, 2008, WII and Xuzhou submitted comments in response to a memorandum the Department placed on the record regarding Xuzhou's shipments to the United States. *See* Memorandum from Jeff Pedersen to the File regarding ''Information Obtained from the Food and Drug Administration Regarding Shipments by Xuzhou Jinjiang Foodstuffs Co., Ltd.,'' dated February 7, 2008.

On February 1, 2008, the Department extended the time period for completion of the final results until April 7, 2008. *See Freshwater Crawfish Tail Meat From the People's Republic of China: Notice of Extension of Time Limit for the Final Results of the 2005–2006 Antidumping Duty Administrative Review and 2005–2006 New Shipper Reviews*, 73 FR 6127 (February 1, 2008).

Scope of the Order

The product covered by this antidumping duty order is freshwater crawfish tail meat, in all its forms (whether washed or with fat on, whether purged or unpurged), grades, and sizes; whether frozen, fresh, or chilled; and regardless of how it is packed, preserved, or prepared. Excluded from the scope of the order are live crawfish and other whole crawfish, whether boiled, frozen, fresh, or chilled. Also excluded are saltwater crawfish of any type, and parts thereof. Freshwater crawfish tail meat is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers 1605.40.10.10 and 1605.40.10.90, which are the new HTSUS numbers for prepared foodstuffs, indicating peeled crawfish tail meat and other, as introduced by CBP in 2000, and HTSUS numbers 0306.19.00.10 and 0306.29.00.00, which are reserved for fish and crustaceans in general. The HTSUS subheadings are provided for convenience and customs purposes only. The written description of the scope of this order is dispositive.

[1] The petitioners are the Crawfish Processors Alliance, the Louisiana Department of Agriculture and Forestry, and Bob Odom, Commissioner.

Final Rescission of New Shipper Reviews

In the *Preliminary Results*, the Department preliminarily rescinded the new shipper reviews of Anhui Tongxin Aquatic Product & Food Co., Ltd. (Anhui), Huoshan New Three–Gold Food Trade Co., Ltd. (Huoshan), and Jingdezhen because it found the companies' sales were not *bona fide*. *See Preliminary Results*; *see also*, separate memoranda for each of these companies to Stephen J. Claeys, Deputy Assistant Secretary For Import Administration from Abdelali Elouaradia, Director, Office 4 Import Administration, regarding *Bona Fide* Sales Analysis and Intent to Rescind the Review (dated October 1, 2007).

We received comments with respect to our preliminary decision to rescind the new shipper review for Jingdezhen. The Department continues to find sales by Anhui, Huoshan, and Jingdezhen to be non–*bona fide*. *See* Comment 2 of the ''Issues and Decision Memorandum for the Final Results and Partial Rescission of the 2005–2006 Antidumping Duty Administrative Review and Rescission of 2005–2006 New Shipper Reviews'' (Issues and Decision Memorandum) accompanying this notice for a detailed discussion of our decision with respect to Jingdezhen. Because these companies had no reviewable sales during the POR, the Department is rescinding these new shipper reviews. *See* 19 CFR 351.213(d)(3); *see also*, *Tianjin Tiancheng Pharmaceutical Co., Ltd. v. United States*, 366 F. Supp. 2d 1246, 1263 (CIT 2005) (the Court of International Trade affirmed that Commerce may exclude sales from the export price calculation where it finds the sales are not *bona fide*. In the case of new shipper reviews involving only one sale, exclusion of the new shipper sale as being non–*bona fide* must necessarily end the review).

Final Partial Rescission of Administrative Review

In the *Preliminary Results*, the Department preliminarily rescinded the administrative review of Yancheng Hi–King Agriculture Developing Co., Ltd. (Yancheng), which reported no shipments, and Anhui, whose single sale, which was covered by both the new shipper review and administrative review, the Department found to be non–*bona fide*. Interested parties did not comment on these preliminary rescissions. For the reasons stated in the *Preliminary Results*, we are rescinding the administrative review with respect to Yancheng and Anhui. *See* 19 CFR 351.213(d)(3).

Adverse Facts Available

In the *Preliminary Results*, the Department found that Xuzhou failed to report all of its U.S. sales of subject merchandise, and thus it was appropriate to base the company's dumping margin on total adverse facts available. For these final results, the Department continues to find that it is appropriate to base Xuzhou's dumping margin on total adverse facts available. *See* the accompanying Issues and Decision Memorandum at Comment 3.

Analysis of Comments Received

All issues raised in the case briefs are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues which parties raised and to which we responded in the Issues and Decision Memorandum is attached to this notice as an appendix. The Issues and Decision Memorandum is a public document which is on file in the Central Records Unit in room 1117 in the main Department building, and is accessible on the Web at http://www.ia.ita.doc.gov/frn. The paper copy and electronic version of the memorandum are identical in content.

Changes Since the Preliminary Results

There have been no changes since the *Preliminary Results*.

Final Results of Review

We determine that the following percentage margins exist for the period September 1, 2005, through August 31, 2006:

FRESHWATER CRAWFISH TAIL MEAT FROM THE PRC

Manufacturer/Exporter	Weighted–Average Margin (Percent)
Xiping Opeck Food Co., Ltd	13.61
Xuzhou Jinjiang Foodstuffs Co., Ltd.	223.01
PRC–wide Rate	223.01

Assessment Rates

Pursuant to 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of crawfish from the PRC entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) for Xiping Opeck and Xuxhou, which each have separate rates, the cash deposit rate will be the company–specific rate shown above; (2) for previously reviewed or investigated companies not listed above that have a separate rate, the cash deposit rate will continue to be the company–specific rate published for the most recent period; (3) the cash deposit rate for all other PRC exporters will be 223.01 percent, the current PRC–wide rate; and (4) the cash deposit rate for all non–PRC exporters will be the rate applicable to the PRC exporter that supplied that exporter. These cash deposit requirements shall remain in effect until further notice.

Notification of Interested Parties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. 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.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 7, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

Appendix – List of Issues

Comment 1: Whether the Department Should Assign a Combination Rate to Xiping Opeck

Comment 2: Whether Jingdezhen's Sale was *Bona Fide*

Comment 3: Whether Xuzhou's Dumping Margin Should be Based on Total Adverse Facts Available

A. Unreported POR Sales of Subject Merchandise

B. Application of Adverse Facts Available

C. The Appropriate AFA Rate

Comment 4: Whether the Department Should have Accepted New Factual Information Submitted by Washington International Insurance Company

Comment 5: Whether Certain Factual Information Should be Removed from the Record

[FR Doc. E8–8046 Filed 4–14–08; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–933]

Frontseating Service Valves From the People's Republic of China: Initiation of Antidumping Duty Investigation

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

EFFECTIVE DATE: April 15, 2008.

FOR FURTHER INFORMATION CONTACT: Hallie N. Zink, AD/CVD Operations, China/NME Group, SEC Office, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: 202–482–6907.

Initiation of Investigation

The Petition

On March 19, 2008, the Department of Commerce (''Department'') received a petition concerning imports of frontseating service valves (''FSVs'') from the People's Republic of China (''PRC''), filed in proper form by Parker-Hannifin Corporation (''Petitioner''). *See* Petition for the Imposition of Antidumping Duties on Frontseating Service Valves, filed March 19, 2008 (''Petition''). On March 25, 2008, the Department issued a request for

additional information and clarification of certain areas of the Petition. Based on the Department's request, Petitioner filed additional information on March 31, 2008 (''Supplement to the Petition''). The Department requested corrections to data filed in the Supplement to the Petition and the Petitioner filed the corrections on April 4, 2008. *See* Memorandum to the file dated April 3, 2008, from Meredith A. W. Rutherford, Import Policy Analyst.

In accordance with section 732(b) of the Tariff Act of 1930, as amended (''Act''), Petitioner alleges that imports of FSVs from the PRC are being, or are likely to be, sold in the United States at less-than-fair-value (''LTFV''), within the meaning of section 731 of the Act, and that the domestic industry is materially injured or threatened with material injury by reason of such imports.

The Department finds that Petitioner may file this Petition on behalf of the domestic industry because Petitioner is an interested party as defined in section 771(9)(C) of the Act, and has demonstrated sufficient industry support with respect to the antidumping duty investigation. *See* Determination of Industry Support for the Petition section, *infra.*

Period of Investigation

The period of investigation (''POI'') is July 1, 2007, through December 31, 2007. *See* 19 CFR 351.204(b)(1).

Scope of Investigation

The merchandise covered by this investigation is frontseating service valves, assembled or unassembled, complete or incomplete, and certain parts thereof. Frontseating service valves contain a sealing surface on the front side of the valve stem that allows the indoor unit or outdoor unit to be isolated from the refrigerant stream when the air conditioning or refrigeration unit is being serviced. Frontseating service valves rely on an elastomer seal when the stem cap is removed for servicing and the stem cap metal to metal seat to create this seal to the atmosphere during normal operation.[1]

For purposes of the scope, the term ''unassembled'' frontseating service valve means a brazed subassembly requiring any one or more of the following processes: the insertion of a valve core pin, the insertion of a valve stem and/or O ring, the application or installation of a stem cap, charge port cap or tube dust cap. The term ''complete'' frontseating service valve means a product sold ready for installation into an air conditioning or refrigeration unit. The term ''incomplete'' frontseating service valve means a product that when sold is in multiple pieces, sections, subassemblies or components and is incapable of being installed into an air conditioning or refrigeration unit as a single, unified valve without further assembly.

The major parts or components of frontseating service valves intended to be covered by the scope under the term ''certain parts thereof'' are any brazed subassembly consisting of any two or more of the following components: a valve body, field connection tube, factory connection tube or valve charge port. The valve body is a rectangular block, or brass forging, machined to be hollow in the interior, with a generally square shaped seat (bottom of body). The field connection tube and factory connection tube consist of copper or other metallic tubing, cut to length, shaped and brazed to the valve body in order to create two ports, the factory connection tube and the field connection tube, each on opposite sides of the valve assembly body. The valve charge port is a service port via which a hose connection can be used to charge or evacuate the refrigerant medium or to monitor the system pressure for diagnostic purposes.

The scope includes frontseating service valves of any size, configuration, material composition or connection type. Frontseating service valves are classified under subheading 8481.80.1095, and also have been classified under subheading 8415.90.80.85 of the Harmonized Tariff Schedule of the United States (''HTSUS''). It is possible for frontseating service valves to be manufactured out of primary materials other than copper and brass, in which case they would be classified under HTSUS subheadings 8481.80.3040, 8481.80.3090, or 8481.80.5090. In addition, if unassembled or incomplete frontseating service valves are imported, the various parts or components would be classified under HTSUS subheadings 8481.90.1000, 8481.90.3000, or 8481.90.5000. The HTSUS numbers are provided for convenience and customs purposes, but the written description of the scope is dispositive.

Comments on Scope of Investigation

During review of the Petition, the Department discussed the scope with Petitioner to ensure that it is an accurate reflection of the products for which the domestic industry is seeking relief. In addition, as discussed in the preamble to the Department's regulations, the Department is setting aside a period of time for interested parties to raise issues regarding product coverage. *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997). The Department encourages all interested parties to submit such comments to the Department by April 28, 2008. Comments should be addressed to Import Administration's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, Attention: Hallie N. Zink, room 4003. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determination.

Comments on Product Characteristics for Antidumping Duty Questionnaire

The Department is requesting comments from interested parties regarding the appropriate physical characteristics of FSVs to be reported in response to the Department's antidumping questionnaire. This information will be used to identify the key physical characteristics of the subject merchandise in order for any respondents to report more accurately the relevant factors of production, as well as develop appropriate product reporting criteria, in accordance with the Department's non-market economy (''NME'') methodology, as described in the ''Normal Value'' section, *infra.*

Interested parties may provide any information or comments that they believe are relevant to the development of an accurate listing of physical characteristics. Specifically, interested parties may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics; and (2) product reporting criteria. The Department notes that it is not always appropriate to use all product characteristics as product reporting criteria. While there may be some physical product characteristics that manufacturers use to describe FSVs, it may be that only a select few product characteristics take into account meaningful physical characteristics of FSVs.

[1] The frontseating service valve differs from a backseating service valve in that a backseating service valve has two sealing surfaces on the valve stem. This difference typically incorporates a valve stem on a backseating service valve to be machined of steel, where a frontseating service valve has a brass stem. The backseating service valve dual stem seal (on the back side of the stem), creates a metal to metal seal when the valve is in the open position, thus, sealing the stem from the atmosphere.

In order to consider the suggestions of interested parties in developing and issuing the antidumping duty questionnaire, the Department must receive non-proprietary comments at the above-referenced address by April 28, 2008, and receive rebuttal comments by May 8, 2008.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (''ITC''), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law. *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001), *citing Algoma Steel Corp. Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989), *cert. denied* 492 U.S. 919 (1989).

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this subtitle.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, Petitioner does not offer a definition of domestic like product distinct from the scope of the investigation. Based on the Department's analysis of the information submitted on the record, the Department has determined that FSVs constitutes a single domestic like product and the Department has analyzed industry support in terms of that domestic like product. For a discussion of the domestic like product analysis in this case, *see* ''Antidumping Duty Investigation Initiation Checklist: Frontseating Service Valves from the People's Republic of China'' (''Initiation Checklist''), at Attachment II (Industry Support), on file in the Central Records Unit, Room 1117 of the main Department of Commerce building.

The Department's review of the data provided in the Petition, supplemental submissions, and other information readily available to the Department indicates that Petitioner has established industry support. First, the Petition establishes support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling). *See* Section 732(c)(4)(D) of the Act. Second, the domestic producers have met the statutory criteria for industry support under 732(c)(4)(A)(i) because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product. Finally, the domestic producers have met the statutory criteria for industry support under 732(c)(4)(A)(ii) because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition. Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act. *See* Initiation Checklist, at Attachment II.

The Department finds that Petitioner filed the Petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act and it has demonstrated sufficient industry support with respect to the antidumping investigation that it is requesting the Department initiate. *See* Initiation Checklist, at Attachment II.

Allegations and Evidence of Material Injury and Causation

Petitioner alleges that the U.S. industry producing the domestic like product is being materially injured by reason of the imports of the subject merchandise sold at less than normal value (''NV''). Petitioner contends that the industry's injured condition is illustrated by the reduced market share, reduced production, and capacity utilization, reduced shipments, underselling and price depressing and suppressing effects, lost revenue and sales, reduced employment, a decline in financial performance, and an increase in import penetration. The Department has assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and the Department determines that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See* Initiation Checklist, at Attachment III.

Allegation of Sales at Less Than Fair Value

The following is a description of the allegation of sales at LTFV upon which the Department based its decision to initiate this investigation of imports of FSVs from the PRC. The sources of data for the deductions and adjustments relating to the U.S. price and the factors of production are also discussed in the checklist. *See* Initiation Checklist. Should the need arise to use any of this information as facts available under section 776 of the Act in the preliminary or final determinations, the Department will re-examine the information and revise the margin calculations, if appropriate.

Export Price

Petitioner obtained three price quotes for three different sized FSVs produced and exported by Zhejiang Sanhua Co., Ltd. (''Sanhua'') in the PRC and offered for sale to one of its U.S. customers during the POI. *See* Petition, at 23–24; Initiation Checklist. Petitioner deducted charges and expenses associated with exporting and delivering the product,

including the affiliated importer, Sanhua International Inc.'s (''Sanhua USA''), U.S. indirect selling expenses, U.S. credit expenses, U.S. inland freight, ocean freight and insurance charges, U.S. duties, U.S. port and wharfage fees, foreign inland freight costs, and foreign brokerage and handling. *See* Petition, at 26; Initiation Checklist. Petitioner calculated the affiliated U.S. importer's indirect selling expenses based on its own industry knowledge and experience. *See* Petition, at 29, 34, 40; Supplement to the Petition, at 15–17, and AD–Supp 6; and Initiation Checklist. Petitioner calculated U.S. inland freight, port to Sanhua USA's warehouse facility, based on its commercial experience and direct quotes for the specific U.S. importer's route. *See* Petition, at 27, 34, 41, and Exhibits AD 2A–AD 2C; Initiation Checklist. Because Petitioner obtained the U.S. inland freight quote after the POI, it provided a period deflator, moving the U.S. inland freight quote to the average of the POI. *See* Supplement to the Petition, at 17; I Exhibits AD–Supp 9, and AD–Supp 15A–15C; and Initiation Checklist.

Normal Value

Petitioner notes that the Department's long-standing treatment of the PRC as an NME country remains in effect until revoked by the Department, and notes that no such revocation determination has been made to date. *See* Petition, at 46–47. The Department has previously examined the PRC's market status and determined that NME status should continue for the PRC. *See* Memorandum from the Office of Policy to David M. Spooner, Assistant Secretary for Import Administration, regarding The People's Republic of China Status as a Non-Market Economy, dated May 15, 2006 (available online at *http://ia.ita.doc.gov/download/prc-nme-status/prc-nme-status-memo.pdf*). In addition, in recent investigations, the Department has continued to determine that the PRC is an NME country. *See Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007); *Final Determination of Sales at Less Than Fair Value: Certain Activated Carbon from the People's Republic of China,* 72 FR 9508 (March 2, 2007).

In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for the PRC has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the NV of the product is appropriately based on factors of production valued in a surrogate market economy country, in accordance with section 773(c) of the Act. In the course of this investigation, all parties will have the opportunity to provide relevant information related to the issues of the PRC's NME status and the granting of separate rates to individual exporters.

Petitioner asserts that, of the five countries normally considered as alternative surrogate market economies for the PRC, *i.e.*, India, Egypt, Indonesia, the Philippines and Sri Lanka, India is the appropriate surrogate country for the PRC because it is has a significant brass valve industry, including several producers of FSVs, is at a comparable level of economic development, and surrogate data from India are available and reliable. *See* Petition, at 47–48; Initiation Checklist. Further, Petitioner notes that the four other potential surrogate countries either have no FSVs production, or have FSVs production on a limited scale. *See* Petition, at 49–50, and Exhibit AD 3D; Initiation Checklist. Based on the information provided by Petitioner, the Department believes that the use of India as a surrogate country is appropriate for purposes of initiation. *See* Initiation Checklist. However, after initiation of the investigation, interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value factors of production within 40 days after the date of publication of the preliminary determination.

Petitioner calculated NVs and dumping margins for each of the three U.S. prices, discussed above, using the Department's NME methodology as required by 19 CFR 351.202(b)(7)(i)(C) and 19 CFR 351.408. Petitioner calculated NVs based on its own consumption rates for producing FSVs in 2007, with adjustments made for known differences, which included adjustments for labor and total material weight per piece. *See* Petition, at 51–56, and Exhibits AD11–AD11C; Supplement to the Petition, at 21–22, 27–28, and Exhibits AD—Supp 17–17C; and Initiation Checklist. Petitioner states that its production experience is representative of the production process used in the PRC because production of FSVs by large Chinese producers is based on similar, partly vertically integrated manufacturing starting with brass bar and copper tubing. *See* Petition, at 51; Supplement to the Petition, at 21–22; and Initiation Checklist.

Petitioner valued the factors of production on reasonably available, public surrogate country data, including official Indian government import statistics. *See* Petition, at 56; Initiation Checklist. Petitioner sourced the Indian statistics from the World Trade Atlas (''WTA''), excluding values from countries previously determined by the Department to be NME countries, as well as imports into India from Indonesia, the Republic of Korea, and Thailand because they maintain broadly available, non-industry specific, export subsidies. Specifically, Petitioner relied on WTA data for the following production inputs (*i.e.*, raw material metal inputs, semi-finished parts purchased, scrap as a production cost offset, chemical inputs, industrial gasses, and packing materials): Brass bar for valve bodies and valve stems; copper tubing to create a factory connection and field connection; valve stem caps; brass charge ports; check (gauge) valve cores; brass acorn charge port caps; plastic (neoprene) o-rings; copper scrap; brass scrap; coolant; solvent; hydraulic fluid; hydrogen; helium; compressed air; corrugated cartons; corrugated packing pads/cartons dividers; carton labels; wood pallets; and plastic pallet film. *See* Petition, at 59–81; Supplement to the Petition, at AD-Supp 17; and Initiation Checklist.

Petitioner used the US$ 0.83/hour labor rate for the PRC currently available for 2004 on the Department's Web site. *See* Petition, at 81, and Exhibit AD 22; Initiation Checklist. After noting that the WTA import value for the industrial gas input, nitrogen, appeared particularly high, Petitioner compared it against another source, a domestic Indian gas price. Subsequently, Petitioner determined to apply a more conservative surrogate value for nitrogen obtained from Bhoruka Gas Limited, an Indian manufacturer of industrial gases,[2] inflated from the 1997 source material, rather than the WTA value.[3] *See* Petition, at 84; Initiation Checklist. Petitioner valued electricity for industrial use in India in the fourth quarter of 2002, as published by the International Energy Agency (''IEA'') in its 2005 Key World Energy Statistics on-line. *See* Petition, at 82; Supplement to

[2] As previously used in the *Preliminary Determination of the Antidumping Duty Investigation of Carbon and Certain Alloy Steel Wire Rod from Moldova,* 67 FR 17401(April 2, 2002) (''*Steel Wire Rod from Moldova*'').

[3] *See Steel Wire Rod from Moldova,* Factors of Production Valuation/Analysis Memorandum dated, April 2, 2002, at 6.

the Petition, at 30; and Initiation Checklist. Petitioner valued natural gas based on the publication of non-subsidized Indian natural gas prices. Petitioner explains that, as noted in a May 28, 2005, *Financial Express* article, analysis must differentiate between the subsidized GAIL natural gas tariff and the Indian market-determined price for industrial users. *See* Petition, at 83, and Exhibit AD 23B; Supplement to the Petition, at 30.

Petitioner calculated water prices from publicly available information published by the Maharashtra Industrial Development Corporation on India. *See* Petition, at 83, and Exhibit AD 23C; Supplement to the Petition, at 30. Where Petitioner was unable to find input prices contemporaneous with the POI, it adjusted for inflation using the wholesale prices index for India, as published in ''International Financial Statistics'' by the International Monetary Fund. *See* Petition, at 57; Supplement to the Petition, at 29–30, and Exhibits AD-Supp 13 and 14; and Initiation Checklist. For exchange rates to convert Indian Rupees to U.S. Dollars, Petitioner averaged the foreign currency exchange rates, as provided on the Department's Web site, for each day of the POI. Monetary conversions were applied only after having first applied a Rupees-based inflator to the original source Rupee value, as necessary. *See* Petition, at 58, and Exhibit AD 5; Supplement to the Petition, at 29–30; and Initiation Checklist.

Petitioner was unable to provide a specific Indian Harmonized Tariff Schedule (''HTS'') category for brazing rings, one of the raw material inputs it purchased and used in the production of FSVs. Petitioner explains that brazing rings, which are made of copper, silver, zinc, phosphorus and tin, are used to connect various components of the valve assembly. *See* Petition, at 67; Initiation Checklist. Petitioner argues that because the finished brazing ring is a highly value-added component, the Department should value each element in the alloy composition (silver, zinc, phosphorus, and tin) and then attribute the value of each element to the proportion of each element. *See* Petition, at 67–68; Supplement to the Petition, at 30–32; and Initiation Checklist. Petitioner notes that it was similarly unable to locate an HTS category specific to brazing rings in one of the four other potential surrogate countries, *i.e.*, Egypt, Indonesia, the Philippines and Sri Lanka. *See* Supplement to the Petition, at 30–31; Initiation Checklist. While Petitioner did provide an Indian HTS basket subcategory, 8481.90.90 OTHER PARTS OF THE ITEMS UNDER HDG 8481, for valuing this raw material input, which it concedes would cover brazing rings, it argues that the average unit value (''AUV'') for this HTS is far lower than the actual U.S. market price paid by Petitioner. *See* Supplement to the Petition, at 31–32; Initiation Checklist. For initiation purposes, however, rather than attempting to account for the exact metal formulation in the alloy composition, we have determined to conservatively value brazing rings using the Indian HTS subcategory 8481.90.90. *See* Initiation Checklist, at Attachment V.

For the surrogate financial expenses for factory overhead, selling, general and administrative expenses (''SG&A''), and profit, Petitioner relied on the financial ratios of Brassomatic Pvt. Ltd. (''Brassomatic''), an Indian brass air-conditioning valve producer and Carbac Holdings Ltd. (''Carbac''), an Indian brass valve producer for the natural gas industry. Brassomatic, however, had no profit before taxes in 2006/2007, while Carbac recorded profits during that time. Therefore, Petitioner calculated factory overhead and SG&A expenses using Brassomatic's 2006/2007 financial statements, while calculating surrogate profit using Carbac's 2006/2007 financial statements. *See* Petition, at 85–86, and Exhibits AD 24–AD 25; Supplement to the Petition, at 24–26, and Exhibits AD–Supp 17A–17C; Initiation Checklist. Since Brassomatic's financial statement did not report a profit, we have determined not to use any of Brassomatic's data in our calculation of surrogate financial ratios for purposes of this initiation. It is the Department's practice to disregard financial statements with zero profit when there are financial statements of other surrogate companies that have earned profit on the record. *See Notice of Initiation of Antidumping Duty Investigations: Electrolytic Manganese Dioxide from Australia and the People's Republic of China,* 72 FR 52850 (September 17, 2007); *citing Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results of the First Antidumping Administrative Review and First New Shipper Review,* 72 FR 52052 (September 12, 2007) and accompanying Issues and Decision Memorandum at Comment 2, section B. Therefore, we have recalculated factory overhead, SG&A, and profit using Carbac's 2006/2007 reported financial ratios. Although Carbac is not as similar as Brassomatic is to the PRC producer, it is still a producer of comparable merchandise and therefore serves as a viable alternative source of surrogate financial ratios information. *See* Initiation Checklist, at Attachment V.

Fair Value Comparisons

Based on the data provided by Petitioner, as adjusted by the Department, there is reason to believe that imports of FSVs from the PRC are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of export price to NV, calculated in accordance with section 773(c) of the Act, the estimated dumping margins for FSVs range from 25.82 percent to 55.62 percent. *See* Initiation Checklist, at Attachment V.

Initiation of Antidumping Investigations

Based upon the examination of the Petition on FSVs from the PRC, the Department finds that the Petition meets the requirements of section 732 of the Act. Therefore, the Department is initiating an antidumping duty investigation to determine whether imports of FSVs from the PRC are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act, unless postponed, the Department will make its preliminary determination no later than 140 days after the date of this initiation.

Separate Rates

In order to obtain separate-rate status in NME investigations, exporters and producers must submit a separate-rate status application. *See* Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries (April 5, 2005) (''Separate Rates/Combination Rates Bulletin''), available on the Department's Web site at *http://ia.ita.doc.gov/policy/bull05–1.pdf.* The specific requirements for submitting the separate-rate application in this investigation are outlined in detail in the application itself, available on the Department's Web site at *http://ia.ita.doc.gov/ia-highlights-and-news.html* on the date of publication of this initiation notice in the **Federal Register**. The separate rate-application will be due sixty (60) days from the date of publication of this initiation notice in the **Federal Register**.

NME Respondent Selection and Quantity and Value Questionnaire

The Department will request quantity and value information from all known exporters and producers identified in the Petition and Supplement to the Petition. The quantity and value data

received from NME exporters/producers will be used as the basis to select the mandatory respondents.

The Department requires that the respondents submit a response to both the quantity and value questionnaire and the separate-rate application by the respective deadlines in order to receive consideration for separate-rate status. *See Circular Welded Austenitic Stainless Pressure Pipe from the People's Republic of China: Initiation of Antidumping Duty Investigation,* 73 FR 10221, 10225 (February 26, 2008); and *Initiation of Antidumping Duty Investigation: Certain Artist Canvas From the People's Republic of China,* 70 FR 21996, 21999 (April 28, 2005). Appendix I of this notice contains the quantity and value questionnaire that must be submitted by all NME exporters/producers no later than May 8, 2008. In addition, the Department will post the quantity and value questionnaire along with the filing instructions on the Import Administration Web site, at *http://ia.ita.doc.gov/ia-highlights-and-news.html.* The Department will send the quantity and value questionnaire to those PRC companies identified in the Petition, at 9; Supplement to Petition, at 1–2.

Use of Combination Rates in an NME Investigation

The Department will calculate combination rates for certain respondents that are eligible for a separate rate in this investigation. The Separate Rates/Combination Rates Bulletin states:

{w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME investigations will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of combination rates because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question *and* produced by a firm that supplied the exporter during the period of investigation.

See Separate Rates/Combination Rates Bulletin, at 6.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petition have been provided to the representatives of the Government of the PRC. The Department considers the service of the public version of the Petition to the foreign exporters/producers satisfied by the delivery of a public version to the Government of the PRC, consistent with 19 CFR 351.203(c)(2).

U.S. International Trade Commission Notification

The Department has notified the ITC of its initiation, as required by section 732(d) of the Act.

Preliminary Determination by the International Trade Commission

The ITC will preliminarily determine, no later than May 5, 2008, whether there is a reasonable indication that the U.S. industry is materially injured or threatened with material injury by imports of FSVs from the PRC. A negative ITC determination with respect to the investigation will result in the investigation being terminated; otherwise, this investigation will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: April 8, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

Appendix I

Where it is not practicable to examine all known exporters/producers of subject merchandise, section 777A(c)(2) of the Tariff Act of 1930, as amended, permits us to investigate (1) a sample of exporters, producers, or types of products that is statistically valid based on the information available at the time of selection, or (2) exporters and producers accounting for the largest volume and value of the subject merchandise that can reasonably be examined.

In the chart below, please provide the total quantity and total value of all your sales of merchandise covered by the scope of this investigation (*see* ''Scope of Investigation'' section of this notice), produced in the PRC, and exported/shipped to the United States during the period July 1, 2007, through December 31, 2007.

Market	Total quantity in pieces	Terms of sale	Total value
United States			
1. Export Price Sales			
2. a. Exporter Name			
b. Address			
c. Contact			
d. Phone No.			
e. Fax No.			
3. Constructed Export Price Sales			
4. Further Manufactured			
Total sales			

Total Quantity:

- Please report quantity on a metric ton basis. If any conversions were used, please provide the conversion formula and source.

Terms of Sales:

- Please report all sales on the same terms (*e.g.*, free on board at port of export).

Total Value:

- All sales values should be reported in U.S. dollars. Please indicate any exchange rates used and their respective dates and sources.

Export Price Sales:

- Generally, a U.S. sale is classified as an export price sale when the first sale to an unaffiliated customer occurs before importation into the United States.
- Please include any sales exported by your company directly to the United States.
- Please include any sales exported by your company to a third-country market economy reseller where you had knowledge that the merchandise was destined to be resold to the United States.
- If you are a producer of subject merchandise, please include any sales manufactured by your company that were subsequently exported by an affiliated exporter to the United States.
- Please do not include any sales of subject merchandise manufactured in Hong Kong in your figures.

Constructed Export Price Sales:

- Generally, a U.S. sale is classified as a constructed export price sale when the first sale to an unaffiliated customer occurs after importation. However, if the first sale to the unaffiliated customer is made by a person in the United States affiliated with the foreign exporter, constructed export price applies even if the sale occurs prior to importation.
- Please include any sales exported by your company directly to the United States;
- Please include any sales exported by your company to a third-country market economy reseller where you had knowledge that the merchandise was destined to be resold to the United States.
- If you are a producer of subject merchandise, please include any sales manufactured by your company that were subsequently exported by an affiliated exporter to the United States.
- Please do not include any sales of subject merchandise manufactured in Hong Kong in your figures.

Further Manufactured:

- Sales of further manufactured or assembled (including re-packaged) merchandise is merchandise that undergoes further manufacture or assembly in the United States before being sold to the first unaffiliated customer.
- Further manufacture or assembly costs include amounts incurred for direct materials, labor and overhead, plus amounts for general and administrative expense, interest expense, and additional packing expense incurred in the country of further manufacture, as well as all costs involved in moving the product from the U.S. port of entry to the further manufacturer.

[FR Doc. E8–8006 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; NOAA Customer Surveys

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before June 16, 2008.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Sarah Brabson, 301–713–3333 ext. 204 or *sarah.brabson@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for renewal of a generic clearance for voluntary customer surveys to be conducted by NOAA program offices, and is submitted following the guidelines contained in the OMB Resource Manual for Customer Surveys. In accordance with Executive Order 12862, the National Performance Review, and good management practices, NOAA offices seek approval to continue to gather customer feedback on services and/or products, which can be used in planning for service/product modification and prioritization.

Under this generic clearance, individual offices would use approved questionnaires and develop new questionnaires, as needed, by selecting subsets of the approved set of collection questions and tailoring those specific questions to be meaningful for their particular programs. These proposed questionnaires would then be submitted to OMB using a fast-track request for approval process. *The generic clearance will not be used to survey any bodies NOAA regulates unless precautions are taken to ensure that the respondents believe that they are not under any risk for not responding or for the contents of their responses; e.g., in no survey to such a population will the names and addresses of respondents be required. Currently there are no such surveys being submitted for approval.*

II. Method of Collection

Information is collected via e-mail or interactive Web sites.

III. Data

OMB Number: 0648–0342.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Individuals or households; not-for-profit institutions; business or other for-profit organizations; and state, local or tribal governments.

Estimated Number of Respondents: 20,800.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 1,800.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 10, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–8009 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2008–0015]

Grant of Interim Extension of the Term of U.S. Patent No. 4,650,787; Sanvar®

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a fourth one-year interim extension of the term of U.S. Patent No. 4,650,787.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755, or by e-mail to *Mary.Till@uspto.gov*.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of

up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On March 24, 2008, Debiovision Inc., the exclusive agent of Debiopharm S.A. and Debio Recherche Pharmaceutique S.A., who is the exclusive licensee of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, the patent owner, timely filed an application under 35 U.S.C. 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the human drug product Sanvar® (vapreotide acetate). The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2008), a fourth interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fourth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2009.

Dated: April 9, 2008.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E8–8058 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submissions Regarding Correspondence and Regarding Attorney Representation (Trademarks)

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before June 16, 2008.

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

E-mail: Susan.Fawcett@uspto.gov. Include ''0651–0056 comment'' in the subject line of the message.

Fax: 571–273–0112, marked to the attention of Susan K. Fawcett.

Mail: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450. *Federal e-Rulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Janis Long, Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–9573; or by e-mail at *janis.long@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) administers the Trademark Act, 15 U.S.C. 1051 *et seq.*, which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses that use, or intend to use such marks in commerce may file an application to register their marks with the USPTO. Registered marks remain on the register indefinitely so long as the owner of the registration files the necessary maintenance documents.

Such individuals and businesses may also submit various communications to the USPTO regarding their pending applications or registered trademarks, including providing additional information needed to process a pending application, filing amendments to the applications, or filing the papers necessary to keep a trademark in force. In the majority of circumstances, individuals and businesses retain attorneys to handle these matters. As such, these parties may also submit communications to the USPTO regarding the appointment of attorneys of record or domestic representatives to represent applicants in the application process, the revocation of an attorney 's appointment, and requests for permission to withdraw from representation. Applicants and registrants may also submit change of owner's address forms requesting that the USPTO amend the record of an application or registration by entering a new address for the applicant or registrant.

The rules implementing the Trademark Act are set forth in 37 CFR Part 2. In addition to governing the registration of trademarks, the Act and rules also govern the appointments and revocations of attorneys and domestic representatives. The trademark rules provide the specifics for filing requests for permission to withdraw as the attorney of record. The requirements for changes of the owner's address are not governed by the trademark rules, but are outlined in the USPTO's procedures. The information in this collection is available to the public.

The information in this collection can be submitted in paper format or electronically through the Trademark Electronic Application System (TEAS). However, there are no official paper forms for these items. Individuals and businesses can submit their own paper forms, following the USPTO's rules and guidelines to ensure that all of the necessary information is provided. This collection contains three electronic forms.

II. Method of Collection

Electronically if applicants submit the information using the TEAS forms. By mail or hand delivery if applicants choose to submit the information in paper form.

III. Data

OMB Number: 0651–0056.

Form Number(s): PTO Forms 2196, 2197, and 2201.

Type of Review: Extension of a currently approved collection.

Affected Public: Primarily business or other for-profit organizations.

Estimated Number of Respondents: 160,004 responses per year.

Estimated Time per Response: The USPTO estimates that it takes the public approximately 3 minutes (0.05 hours) to 15 minutes (0.25 hours) to complete this information, depending on the application. This includes the time to gather the necessary information, prepare the applications, and submit the completed application to the USPTO. The time estimates shown for the electronic forms in this collection are based on the average amount of time needed to complete and electronically file the associated form.

Estimated Total Annual Respondent Burden Hours: 12,491 hours.

Estimated Total Annual Respondent Cost Burden: $3,797,264. The USPTO believes that associate attorneys will complete these submissions. The professional hourly rate for associate attorneys in private firms is $304. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is $3,797,264.

Item	Estimated time for response (min)	Estimated annual responses	Estimated annual burden hours
Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative	6	13,128	1,313
TEAS Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative (PTO Form 2196)	5	105,023	8,402
Request for Permission to Withdraw as Attorney of Record	15	427	107
TEAS Request for Permission to Withdraw as Attorney of Record (PTO Form 2201)	12	3,419	684
Change of Owner's Address	4	4,223	296
TEAS Change of Owner's Address (PTO Form 2197)	3	33,784	1,689
Total	160,004	12,491	

Estimated Total Annual Non-hour Respondent Cost Burden: $7,317. There are postage costs associated with this information collection. This collection does not have any capital start-up, operating, maintenance, or recordkeeping costs, nor does it have filing fees.

Customers incur postage costs when submitting the non-electronic information to the USPTO by mail through the United States Postal Service. The USPTO estimates that the majority (98%) of the paper forms are submitted to the USPTO via first class mail. Out of 17,778 paper forms, the USPTO estimates that 17,422 forms will be mailed , with a first class postage cost of 42 cents (as of May 12, 2008). Therefore, the USPTO estimates that the total non-hour respondent cost burden for this collection, in the form of postage costs, is $7,317 per year.

Item	Responses (yr) (a)	Postage costs (b)	Total cost (yr) (a) × (b)
Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative	12,865	$0.42	$5,403.00
Request for Permission to Withdraw as Attorney of Record	418	0.42	176.00
Change of Owner's Address Form	4,139	0.42	1,738.00
Total	17,422		7,317.00

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 8, 2008.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E8–7980 Filed 4–14–08; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 08–40]

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 08–40 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: April 7, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–p

DEFENSE SECURITY COOPERATION AGENCY
WASHINGTON, DC 20301-2800

APR 02 2008
In reply refer to:
USP002356-08

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. 08-40, concerning the Department of the Navy's proposed Letters(s) of Offer and Acceptance to Turkey for defense articles and services estimated to cost $227 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

You will also find attached a certification as required by Section 620C(d) of the Foreign Assistance Act of 1961, as amended, that this action is consistent with the principles set forth in subsection 620C(b) of that Act as codified in section 2373 of title 22, United States Code.

Sincerely,

Jeffrey A. Wieringa
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Section 620C(d)

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. 08-40

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:** Turkey

(ii) **Total Estimated Value:**

Major Defense Equipment*	$ 50 million
Other	$ 177 million
TOTAL	$ 227 million

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:** six MK 41 Vertical Launch System (VLS) Baseline VII tactical modules and two sets of MK 41 VLS upgrade kits to modernize two MEKO Track IIA frigates, four ex-Perry Class FFG Frigates and to upgrade two MEKO Track IIB MK-41 VLS from baseline IV to baseline VII configuration. Included with the MK 41 VLS are the ship's fire control system upgrades to allow for Evolved Sea Sparrow Missile capability, installation and testing, U.S. Government and contractor engineering and logistics personnel services, equipment operation and maintenance, personnel training and training equipment, support and test equipment, spare and repair parts, publications and technical documentation, launch system software development and maintenance and other related elements of logistics support.

(iv) **Military Department:** Navy (SDA, Amendment 1)

(v) **Prior Related Cases, if any:**
FMS case LID - $32 million – 15Jul94
FMS case SDA - $62 million - 5Jul07

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:** none

(vii) **Sensitivity of Technology Contained in the Defense Articles or Defense Services Proposed to be Sold:** See Annex attached

(viii) **Date Report Delivered to Congress:** APR 02 2008

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Turkey – MK 41 Vertical Launch Systems

The Government of Turkey has requested a possible sale of six MK 41 Vertical Launch System (VLS) Baseline VII tactical modules and two sets of MK 41 VLS upgrade kits to modernize two MEKO Track IIA frigates, four ex-Perry Class FFG Frigates and to upgrade two MEKO Track IIB MK-41 VLS from baseline IV to baseline VII configuration. Included with the MK 41 VLS are the ship's fire control system upgrades to allow for Evolved Sea Sparrow Missile capability, installation and testing, U.S. Government and contractor engineering and logistics personnel services, equipment operation and maintenance, personnel training and training equipment, support and test equipment, spare and repair parts, publications and technical documentation, launch system software development and maintenance and other related elements of logistics support. The estimated cost is $227 million.

Turkey is a partner of the United States in ensuring peace and stability in the region. It is vital to the U.S. national interest to assist our North Atlantic Treaty Organization (NATO) Ally in developing and maintaining a strong and ready self-defense capability that will contribute to an acceptable military balance in the area. This proposed sale is consistent with those objectives.

The proposed sale of Vertical Launch Systems to Turkey will contribute to U.S. security objectives by improving the Turkish Navy's ability to contribute to coalition and NATO operations and the Global War on Terrorism, and coalition operations such as United Nations Interim Force in Lebanon and BLACKSEAFOR in the Black Sea and Eastern Mediterranean regions. The proven reliability and compatibility of like systems in association with numerous platforms will foster increased interoperability with U.S., NATO and coalition forces, and expand regional defenses to counter common threats to border and shipping assets in the region. The Turkish Navy can easily integrate this system capability into its concept of operations and will have no difficulty absorbing these systems into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principle contractor will be Lockheed Martin Maritime Systems and Sensors of Baltimore, Maryland, and Moorestown, New Jersey. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government representatives or contractor representatives to Turkey.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 08-40

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 MK-41 Vertical Launch Systems (VLS) contain sensitive technology and are Unclassified. The Launch Control Computer Program (LCCP), which also contains missile launch rates, is classified Confidential. The LCCP provides the control and processing to interface the Weapon Control System with the VLS. Sections of the MK-41 technical documentation, which disclose launcher vulnerabilities, are classified Confidential.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, 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 advanced capabilities.

[FR Doc. E8–7860 Filed 4–14–08; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Renewal of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Amendment of Federal Advisory Committee.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972, (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.65, the Department of Defense gives notice that it is amending the charter for the Board of Visitors National Defense University (hereafter referred to as the Board).

The Board is a discretionary federal advisory committee established by the Secretary of Defense to provide the Department of Defense independent advice and recommendations on organization management, curricula, instructional methods, facilities and other matters of interest to the National Defense University.

The Board shall be composed of approximately twenty-one members, who are eminent authorities in the fields of national defense, academia, business, national security affairs, and the defense industry. Three of the twenty-one Board members are Federal ex officio members: (a) The Under Secretary of Defense for Personnel and Readiness; (b) the Assistant Secretary of Defense for Networks and Information Integration; and (c) the Department of State Director General.

Board Members appointed by the Secretary of Defense, who are not federal officers or employees, shall serve as Special Government Employees under the authority of 5 U.S.C. 3109. With the exception of the federal ex officio members, Board members shall be appointed on an annual basis by the Secretary of Defense, and shall serve no more than fifteen years on the Board. Board members shall, with the exception of travel and per diem for official travel, serve without compensation.

The Board Membership shall select the Board's Chairperson and the Co-Chairperson from the total Board Membership, and this individual shall serve at the discretion of the Chairman of Joint Chiefs of Staff or designee. In addition, the Chairman of the Joint Chiefs of Staff or designated representative may invite other distinguished Government officers to serve as non-voting observers of the Board, and appoint consultants, with special expertise, to assist the Board on an ad hoc basis.

The Board shall be authorized to establish subcommittees, as necessary and consistent with its mission, and these subcommittees or working groups shall operate under the provisions of the Federal Advisory Committee Act of 1972, the Government in the Sunshine Act of 1976, and other appropriate Federal regulations.

Such subcommittees or workgroups shall not work independently of the chartered Board, and shall report all their recommendations and advice to the Board for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered Board nor can they report directly to the

Department of Defense or any federal officers or employees who are not Board Members.

SUPPLEMENTARY INFORMATION: The Board shall meet at the call of the Board's Designated Federal Officer, in consultation with the President, National Defense University. The Designated Federal Officer, pursuant to DoD policy, shall be a full-time or permanent part-time DoD employee, and shall be appointed in accordance with established DoD policies and procedures. The Designated Federal Officer or duly appointed Alternate Designated Federal Officer shall attend all committee meetings and subcommittee meetings.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to the Board of Visitors National Defense University membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board of Visitors National Defense University.

All written statements shall be submitted to the Designated Federal Officer for the Board of Visitors National Defense University, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Board of Visitors National Defense University Designated Federal Officer can be obtained from the GSA's FACA Database—*https://www.fido.gov/facadatabase/public.asp.*

The Designated Federal Officer, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Board of Visitors National Defense University. The Designated Federal Officer, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

FOR FURTHER INFORMATION CONTACT: Contact Jim Freeman, Deputy Committee Management Officer for the Department of Defense, 703–601–6128.

Dated: April 8, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–7988 Filed 4–14–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Closed Meeting of the Chief of Naval Operations (CNO) Executive Panel

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The CNO Executive Panel will report on the findings and recommendations of the Sea Basing and Forcible Entry Subcommittee to the Chief of Naval Operations. The meeting will consist of discussions of ongoing Navy, Marine Corps, and Joint/DoD sea basing and forcible entry policies, programs, and organizational concepts to find opportunities to increase compatibility, flexibility, and buttress the Maritime Strategy.

DATES: The meeting will be held on May 8, 2008 from 10 a.m. to 12 p.m.

ADDRESSES: The meeting will be held in Boardroom at CNA Corporation Building, 4825 Mark Center Drive, Alexandria, VA 22311.

FOR FURTHER INFORMATION CONTACT: LCDR Brown, CNO Executive Panel, 4825 Mark Center Drive, Alexandria, VA 22311, *telephone:* 703–681–4939.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), these matters constitute classified information that is specifically authorized by Executive Order to be kept secret in the interest of national defense and are, in fact, properly classified pursuant to such Executive Order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of this meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

Individuals or interested groups interested may submit written statements for consideration by the Chief of Naval Operations Executive Panel at any time or in response to the agenda of a scheduled meeting. All requests must be submitted to the Designated Federal Officer at the address detailed below. If the written statement is in response to the agenda mentioned in this meeting notice then the statement, if it is to considered by the Panel for this meeting, must be received at least five days prior to the meeting in question.

The Designated Federal Officer will review all timely submissions with the Chief of Naval Operations Executive Panel Chairperson, and ensure they are provided to members of the Chief of Naval Operations Executive Panel before the meeting that is the subject of this notice.

To contact the Designated Federal Officer, write to Executive Director, CNO Executive Panel (N00K), 4825 Mark Center Drive, 2nd Floor, Alexandria, VA 22311–1846.

Dated: April 9, 2008.

T. M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–7972 Filed 4–14–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to delete a System of Records.

SUMMARY: The Department of the Navy is deleting a system of records in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed actions will be effective without further notice on May 15, 2008, unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy 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 Department of Navy proposes to delete a system of records notices from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is 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 new or altered systems reports.

April 9, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N11101–4

Station Housing Records (February 22, 1993, 58 FR 10817).

REASON:

Program discontinued and all files deleted.

[FR Doc. E8–7982 Filed 4–14–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[USN–2008–0028]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to Amend a System of Records.

SUMMARY: The Department of the Navy 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 May 15, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy 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 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.

April 9, 2008.

L.M. Bynum

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N01070–9

SYSTEM NAME:

White House Support Program (February 22, 1993, 58 FR 10700).

CHANGES:

Delete ''N01070–9'' replace with ''NM01070–9''.

* * * * *

SYSTEM LOCATION:

At end of entry, add ''and Naval Support Facility (NSF), Thurmont, P.O. Box 1000, Thurmont, MD 21788–5100.''

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''White House Military Office Security Screening Questionnaire; personnel records; name, Social Security Number (SSN); photographs; fingerprint cards; interview sheet; correspondence, documents and records concerning classification, security clearances, assignment, training, and other qualifications relating to suitability for Presidential support duties.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; and E.O. 9397 (SSN).''

* * * * *

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Delete entry and replace with ''Paper and automated records/databases.''

RETRIEVABILITY:

Delete entry and replace with ''Name and/or Social Security Number (SSN).''

SAFEGUARDS:

Add new para 2 ''Access to automated information is password protected and only available to individuals with an official need to know.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Successful candidate's package is held for one year past period of tour. Unsuccessful candidate's package is destroyed within 1 year.''

* * * * *

NOTIFICATION PROCEDURE:

Add new para 2 ''Individual should sign their request and provide full name and Social Security Number.''

RECORD ACCESS PROCEDURES:

Add new para 2 ''Individual should sign their request and provide full name and Social Security Number.''

NM01070–9

SYSTEM NAME:

White House Support Program.

SYSTEM LOCATION:

White House Liaison Office, Office of the Secretary of the Navy, 1000 Navy Pentagon, Washington, DC 20350–1000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Navy and Marine Corps military and civilian personnel and contractor employees who had been nominated by their employing activities for assignment to Presidential support duties.

CATEGORIES OF RECORDS IN THE SYSTEM:

White House Military Office Security Screening Questionnaire; personnel records; name, Social Security Number (SSN); photographs; fingerprint cards; interview sheet; correspondence, documents and records concerning classification, security clearances, assignment, training, and other qualifications relating to suitability for Presidential support duties.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; and E.O. 9397 (SSN).

PURPOSE(S):

To evaluate and nominate individuals for assignment to Presidential support duties and to ensure that only those individuals most suitably qualified are assigned to duty in Presidential support activities.

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 officials and employees in the Executive Office of the President in the performance of their duties related to personnel administration, and evaluation and nomination of individuals for assignment to Presidential support duties.

To officials and employees of other federal agencies and offices, upon request, in the performance of their official duties related to the provision of Presidential support and protection.

The 'Blanket Routine Uses' that appear at the beginning of the Navy'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:

Paper and automated records/databases.

RETRIEVABILITY:

Name and/or Social Security Number (SSN).

SAFEGUARDS:

Records are afforded appropriate protection at all times, stored in locked rooms and locked file cabinets, and are accessible only to authorized personnel who have a definite need-to-know and who are properly screened, cleared, and trained. Access to automated information is password protected and only available to individuals with an official need-to-know.

RETENTION AND DISPOSAL:

Successful candidate's package held for one year past period of tour. Unsuccessful candidate's package destroyed within 1 year.

SYSTEM MANAGER(S) AND ADDRESS:

Administrative Aide to the Secretary of the Navy, 1000 Navy Pentagon, Washington, DC 20350–1000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Office of the Administrative Aide to the Secretary of the Navy, 1000 Navy Pentagon, Washington, DC 20350–1000.

Individuals should sign their request and provide full name and Social Security Number (SSN).

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Office of the Administrative Aide to the Secretary of the Navy, 1000 Navy Pentagon, Washington, DC 20350–1000.

Individuals should sign their request and provide full name and Social Security Number (SSN).

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Officials and employees of the Department of the Navy and other Department of Defense components; federal, state, and local court documents; civilian and military investigative reports; general correspondence concerning the individual; and federal and state agency records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k)(1), (k)(2), (k)(3) and (k)(5), as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b) (1), (2), and (3), (c) and (e) and published in 32 CFR part 701, subpart G. For additional information contact the system manager.

[FR Doc. E8–7984 Filed 4–14–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[USN–2008–0029]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to Amend a System of Records.

SUMMARY: The Department of the Navy 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 May 15, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy 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 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: April 9, 2008.

L.M. Bynum

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NM12610–1

SYSTEM NAME:

Hours of Duty Records (November 16, 2004, 69 FR 67128).

CHANGES:

* * * * *

SYSTEM LOCATION:

In para 1, delete ''*http://neds.daps.dla.mil/sndl.htm*'' and replace with ''*http://doni.daps.dla.mil/sndl.aspx*''.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Replace ''*http://neds.daps.dla.mil/sndl.htm*'' with ''*http://doni.daps.dla.mil/sndl.aspx*''.

NOTIFICATION PROCEDURE:

In para 1, replace ''*http://neds.daps.dla.mil/sndl.htm*'' with ''*http://doni.daps.dla.mil/sndl.aspx*''.

Add new second para that states ''The request should be signed and include full name and Social Security Number (SSN).''

RECORD ACCESS PROCEDURES:

In para 1, replace ''*http://neds.daps.dla.mil/sndl.htm*'' with ''*http://doni.daps.dla.mil/sndl.aspx*''.

Add new second para that states ''The request should be signed and include full name and Social Security Number (SSN).''

* * * * *

NM12610–1

SYSTEM NAME:

Hours of Duty Records.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

Commander, U.S. Joint Forces Command, 1562 Mitscher Avenue, Suite 200, Norfolk, VA 23551–2488.

Commander, U.S. Pacific Command, P.O. Box 64028, Camp H.M. Smith, HI 96861–4028.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military and civilian personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Record contains such information as name, grade/rate, Social Security Number, organizational code, work center code, grade code, pay rate, labor code, type transaction, hours assigned. Database includes scheduling and assignment of work; skill level; tools issued; leave; temporary assignments to other areas.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; and E.O. 9397 (SSN).

PURPOSE(S):

To effectively manage the work force.

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:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy'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:

Paper and computerized records.

RETRIEVABILITY:

Name, organization code, Social Security Number, and work center.

SAFEGUARDS:

Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.

RETENTION AND DISPOSAL:

Records are destroyed when three years old.

SYSTEM MANAGER(S) AND ADDRESS:

The commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the naval activity where currently employed. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

The request should be signed and include full name and Social Security Number (SSN).

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the naval activity where currently employed. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

The request should be signed and include full name and Social Security Number (SSN).

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual, correspondence, and personnel records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–7992 Filed 4–14–08; 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 May 15, 2008.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. 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: April 9, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Postsecondary Education

Type of Review: Extension.

Title: Financial Status and Program Performance Final Report for State and Partnership for the Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP).

Frequency: One time.

Affected Public: Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 175.

Burden Hours: 6,125.

Abstract: The purpose of this information collection is to determine whether recipients of GEAR UP have made substantial progress towards meeting the objectives of their respective projects, as outlined in their grant applications and/or subsequent work plans. In addition, the final report will enable the Department to evaluate each grant project's fiscal operations for the entire grant performance period, and compare total expenditures relative to federal funds awarded, and actual cost-share/matching relative to the total amount in the approved grant application. This report is a means for grantees to share the overall experience of their projects and document achievements and concerns, and describe effects of their projects on participants being served; project barriers and major accomplishments; and evidence of sustainability. The report will be GEAR UP's primary

method to collect/analyze data on students' high school graduation and immediate college enrollment rates.

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 3593. 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. E8–7943 Filed 4–14–08; 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: Wednesday, April 16, 2008, 1–5 p.m. (CDT).

PLACE: Millennium Hotel Minneapolis, Horizons, 14th Floor, 1313 Nicollet Mall, Minneapolis, Minnesota 55403–2697, (612) 332–6000.

AGENDA: The Commission will receive presentations on Successful Ballot Design. The presentations will focus on the following: The Ballot Design Process from Start to Finish; Ballot Design Accessibility, and Usability; and Successful Designs for Optical-scan Ballots, Direct Recording Device Ballots and Paper Ballots. The Commission will receive a status report on a first-time voter study. The Commission will consider and vote on the following items: consideration and vote on a voter information Web sites study; consideration and vote on policy proposal regarding the allowable uses of HAVA funds; consideration and vote on whether to modify Advisory Opinion 07–003–A regarding Maintenance of Effort (MOE) funding, Pursuant to HAVA Section 254 (a) (7). 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.

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. E8–7932 Filed 4–14–08; 8:45 am]

BILLING CODE 6820–KF–M

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada Test Site. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 14, 2008, 5 p.m.

ADDRESSES: Atomic Testing Museum, 755 East Flamingo Road, Las Vegas, Nevada 89119.

FOR FURTHER INFORMATION CONTACT: Rosemary Rehfeldt, Board Administrator, 232 Energy Way, M/S 505, North Las Vegas, Nevada 89030. Phone: (702) 657–9088; Fax (702) 295–5300 or E-mail: *ntscab@nv.doe.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Committee Reports

A. Environmental Management Public Information Review Effort Committee;
B. Outreach Committee;
C. Transportation/Waste Committee;
D. Underground Test Area Committee.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Rosemary Rehfeldt at the telephone number listed above. The request must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing to Rosemary Rehfeldt at the address listed above or at the following Web site: *http://www.ntscab.com/MeetingMinutes.htm.*

Issued at Washington, DC on April 10, 2008.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. E8–8072 Filed 4–14–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC08–520–000; FERC–520]

Commission Information Collection Activities, Proposed Collection; Comment Request; Extension

April 8, 2008.

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of proposed information collection and request for comments.

SUMMARY: In compliance with the requirements of section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), the Federal Energy Regulatory Commission (Commission) is soliciting public comment on the specific aspects of the information collection described below.

DATES: Comments in consideration of the collection of information are due June 9, 2008.

ADDRESSES: An example of this collection of information may be obtained from the Commission's Documents & Filing Web site (*http://www.ferc.gov/docs-filing/elibrary.asp*) or by contacting the Federal Energy Regulatory Commission, Attn: Michael Miller, Office of the Executive Director, ED–34 Rm. 42–39, 888 First Street, NE., Washington, DC 20426. Comments may be filed either in paper format or electronically. Those parties filing electronically do not need to make a paper filing. For paper filing, the original and 14 copies of such comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 and refer to Docket No. IC08–520–000.

Documents filed electronically via the Internet must be prepared in an acceptable filing format and in compliance with the Federal Energy Regulatory Commission submission guidelines. Complete filing instructions and acceptable filing formats are available at (*http://www.ferc.gov/help/submission-guide/electronic-media.asp*). To file the document electronically, access the Commission's website and click on Documents & Filing, E-Filing (*http://www.ferc.gov/docs-filing/efiling.asp*), and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgement to the sender's e-mail address upon receipt of comments.

All comments may be viewed, printed or downloaded remotely via the Internet through FERC's homepage using the ''eLibrary'' link. For user assistance, contact *fercolinesupport@ferc.gov* or toll-free at (866) 208–3676 or for TTY, contact (202) 502–8659.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202) 502–8415, by fax at (202) 273–0873, and by e-mail at *michael.miller@ferc.gov*.

SUPPLEMENTARY INFORMATION: The information collected under the requirements of FERC–520 ''Application for Authority to Hold Interlocking Directorate Positions'' (OMB No. 1902–0083) is used by the Commission to implement the statutory provisions of section 305 of the Federal Power Act (FPA) as amended by Title II, section 211 of the Public Utility Regulatory Policies Act of 1978 (PURPA) (16 U.S.C. 825d). Section 305(b) makes the holding of certain defined interlocking corporate positions unlawful unless the Commission has authorized the interlocks to be held and, requires the applicant to show in a form and manner as prescribed by the Commission, that neither public nor private interests will be adversely affected by the holding of the position.

The Commission implements these provisions through its filing requirements in the Code of Federal Regulations (CFR) 18 CFR part 45. The information required under part 45 generally identifies the applicant, describes the various interlocking positions the applicant seeks authorization to hold, provides information on the applicant's financial interests, other officers and directors of the firms involved, and the nature of the business relationships among the firms.

Two types of FERC–520 applications are provided for, that which is described in 18 CFR 45.8 as a ''full'' application and that which is described in 18 CFR 45.9 as an ''informational'' application for automatic authorization. Section 45.8 ''full'' applications are made by (1) An officer or director of more than one public utility; (2) an officer or director of a public utility and of a public utility securities underwriter; or (3) an officer or director of a public utility and of an electrical equipment supplier to that utility. Section 45.9 ''informational applications'' are made by (1) An officer or director of two or more public utilities where the same holding company owns, directly or indirectly, wholly or in part, the other public utility; (2) an officer or director of two public utilities, if one utility is owned, wholly or in part, by the other; or (3) an officer or director of more than one public utility, if such person is already authorized under Part 45 to hold different positions where the interlock involves affiliated public utilities.

Without this information collection, the Commission and the public would not be able to inquire into and determine whether public or private interests will be adversely affected by the holding of such positions.

Under the current OMB authorization, the Commission was allowing the filing of FERC–520 in hardcopy and/or diskette/CD. However, through RM07–16–000, implemented March 1, 2008, the electronic filing of FERC–520 filings is also accepted through the Commission's eFiling system.

Action: The Commission is requesting a three-year extension of the current expiration date.

Burden Statement: The two types of interlocking directorate applications, a ''full application'' pursuant to 18 CFR 45.8 and the much more abbreviated ''informational application'' pursuant to 18 CFR 45.9 are represented separately here. Public reporting burden for each is estimated as:

Type of application filed annually	Number of respondents annually (1)	Number of responses per respondent (2)	Average burden hours per response (3)	Total annual burden hours (1)×(2)×(3)
Full	17	1	51.8	881
Informational	911	1	29.5	23,595
Total				24,476

The estimated total cost to respondents is $1,487,199 [24,476 hours divided by 2080 hours [1] per year, times $126,384 [2] which equals $1,487,199]. The cost per respondent is $1,603. The increase in the estimated total cost over what was reported in 2005 is due to the informational filings not being included in earlier estimates. The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, using technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable filing instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The cost estimate for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Comments are invited on: (1) Whether the proposed information collection is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of

[1] Number of hours an employee works each year.

[2] Average annual salary per employee.

the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions used to calculate the reporting burden; and (3) ways to enhance the quality, utility and clarity of the information to be collected.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7919 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC08–73–001, FERC Form 73]

Commission Information Collection Activities, Proposed Collection; Comment Request; Submitted for OMB Review

April 9, 2008.

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice.

SUMMARY: In compliance with the requirements of section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507, the Federal Energy Regulatory Commission (Commission) has submitted the information collection described below to the Office of Management and Budget (OMB) for review of this information collection requirement. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission received one comment in response to an earlier **Federal Register** notice of January 14, 2008 (73 FR 2232) and has noted this fact in its submission to OMB.

DATES: Comments on the collection of information are due by May 15, 2008.

ADDRESSES: Address comments on the collection of information to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer. Comments to OMB should be filed electronically, c/o *oira_submission@omb.eop.gov* and include the OMB Control No. (1902–0019) as a point of reference. The Desk Officer may be reached by telephone at 202–395–7345. A copy of the comments should also be sent to the Federal Energy Regulatory Commission, Office of the Executive Director, ED–34, Attention: Michael Miller, 888 First Street, NE., Washington, DC 20426.

Comments may be filed either in paper format or electronically. Those persons filing electronically do not need to make a paper filing. For paper filings, such comments should be submitted to the Secretary of the Commission, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 and should refer to Docket No. IC08–73–001.

Documents filed electronically via the Internet must be prepared in an acceptable filing format and in compliance with the Federal Energy Regulatory Commission submission guidelines. Complete filing instructions and acceptable filing formats are available at (*http://www.ferc.gov/help/submission-guide/electronic-media.asp*). To file the document electronically, access the Commission's Web site and click on Documents & Filing, E-Filing (*http://www.ferc.gov/docs-filing/efiling.asp*), and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgement to the sender's e-mail address upon receipt of comments.

All comments may be viewed, printed or downloaded remotely via the Internet through FERC's homepage using the ''eLibrary'' link. For user assistance, contact *fercolinesupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202) 502–8415, by fax at (202) 273–0873, and by e-mail at *michael.miller@ferc.gov.*

SUPPLEMENTARY INFORMATION:

Description

The information collection submitted for OMB review contains the following:

1. *Collection of Information:* FERC Form 73 ''Oil Pipeline Service Life Data''.

2. *Sponsor:* Federal Energy Regulatory Commission.

3. Control No. 1902–0019.

The Commission is now requesting that OMB approve with a three-year extension of the expiration date, with no changes to the existing collection. The information filed with the Commission is mandatory.

4. *Necessity of the Collection of Information:* Submission of the information is necessary to enable the Commission to carry out its responsibilities in implementing the statutory provisions of the Department of Energy Organization Act, and Executive Order No. 12009, 42 FR (September 13, 1977). The Commission has authority over interstate pipelines as stated in the Interstate Commerce Act, 49 U.S.C. 6501 *et al.* As part of the information necessary for the subsequent investigation and review of an oil pipeline company's proposed depreciation rates, the pipeline companies are required to provide public service life data as part of their data submission if the proposed depreciation rates are based on the remaining physical life calculations. This service life data is submitted on FERC Form 73.

The scope of the Commission's jurisdiction over oil pipelines includes the authority to regulate their rates and charges for transportation of oil in interstate commerce, and the authority to establish valuations. Oil pipeline companies are required to submit depreciation information pursuant to 1–8(b)(2) and 1–8(b)(3) of the General Instructions found at 18 CFR Part 352 of the Commission's regulations. These instructions require oil pipeline carriers to compute percentage rate studies for their depreciable property accounts, and to maintain records as to the service life and net salvage value of their property and property retirements.

The Commission uses the information submitted on FERC Form 73 to conduct depreciation rate investigations of oil pipelines. The Commission also uses the information to determine appropriate oil pipeline service lives and book depreciation rates. Oil pipeline companies use book depreciation rates to compute the depreciation portion of their operating expenses when determining their cost of service. The Commission implements these requirements in 18 CFR 357.3 of its regulations.

5. *Respondent Description:* The respondent universe currently comprises on average 2 respondents subject to the Commission's jurisdiction. The Commission estimates that it will receive annually on average 2 filings per year.

6. *Estimated Burden:* 80 total hours, 2 respondents (average per year), 1 response per respondent, and 40 hours per response (average).

7. *Estimated Cost Burden to respondents:* The estimated total cost to respondents is $4861. (80 hours ÷ 2080 hours per year × $126,384)

Statutory Authority: Sections 306 and 402 of the Department of Energy Organization Act, Pub. L. 95–91, 42 7155 and 7172,

Interstate Commerce Act (ICA), 49 U.S.C. 6501 *et al.*, and Executive Order No. 12009.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7954 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM07–10–000]

Transparency Provisions of Section 23 of the Natural Gas Act; Second Notice and Agenda for Form No. 552 Technical Conference

April 8, 2008.

The staff technical conference in the above-referenced proceeding is scheduled for April 22, 2008, at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in the Commission Meeting Room (2–C) from 9:30 a.m. until 12:30 p.m. (EST).

As discussed in Order No. 704, Transparency Provisions of section 23 of the Natural Gas Act,[1] the conference will address issues associated with filing the Form No. 552. Order No. 704 requires certain natural gas buyers and sellers to identify themselves to the Commission and report summary information about their physical natural gas transactions for the previous calendar year in Form No. 552, established for that purpose. During the Technical Conference, Commission staff and conference participants will discuss, among other things, the following topics, with respect to Form No. 552:

1. Entities required to file the form;
2. Filing exclusions or exemptions;
3. Detail in reporting sales and purchases of natural gas;
4. Definitions of data elements; and
5. Publisher index point definitions and differences in reportable locations between publishers.

As stated in the March 6, 2008, Notice of Form No. 552, Technical Conference questions about the Form No. 552 were to be filed before March 31, 2008 under Docket No. RM07–10–000. Those filings are available at the Commission and may be viewed on the Commission's Web site at *http://www.ferc.gov,* using the ''eLibrary'' link. For assistance accessing documents on eLibrary, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or via phone at (866) 208–3676 (toll-free). For TTY, contact (202) 502–8659.

All interested persons are invited to attend in person or participate via teleconference for the Technical Conference, and there is no fee to register, participate via teleconference, or attend the conference. Those interested in participating by phone must register no later than April 18, 2008, on the FERC Web site at *https://www.ferc.gov/whats-new/registration/form-552-04-22-form.asp.* Those who will participate in person are encouraged, but not required, to register. Information for the conference call will be emailed to registered participants. For additional information, please contact Michelle Reaux of FERC's Office of Enforcement at (202) 502–6497 or by e-mail at *michelle.reaux@ferc.gov.*

Commission conferences and meetings are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or 202–502–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7926 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

[1] *Transparency Provisions of Section 23 of the Natural Gas Act,* Order No. 704, 73 Fed. Reg. 1014 (Jan. 4, 2008), FERC Stats. & Regs. ¶ 31,260 (2008).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13111–000]

Dan River Hydropower, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

April 8, 2008

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 13111–000.

c. *Date filed:* February 11, 2008.

d. *Applicant:* Dan River Hydropower, LLC.

e. *Name of Project:* Dan River Project.

f. *Location:* On the Dan River, in Rockingham County, North Carolina. The Dam is own by Duke Energy Corporation.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Kevin Edwards, Dan River Hydropower, LLC, P.O. Box 143, Mayodan, NC 27027, (336) 589–6138.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–13111–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) An existing 350-foot-long, 11-foot-high Steam Station Dam, (2) an existing impoundment having a surface area of 108 acres, with a storage capacity of 54 acre-feet and normal water surface elevation of 496.0 feet mean sea level, (3) a proposed power house containing three generating units having a total installed capacity of 1,200 kilowatts, (4) a proposed 4,000-foot-long, 12 kilovolt transmission line, and (5) appurtenant facilities. The proposed project would have an estimated average annual generation of 6.5 gigawatt-hours, which would be sold to a local utility.

l. *Location of Application:* This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCONLINESUPPORT@FERC.GOV.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should

so indicate by writing to the Secretary of the Commission.

n. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

o. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

p. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

q. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

r. *Comments, Protests, or Motions To Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', and ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7924 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12555–002]

Mahoning Creek Hydroelectric Company, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

April 8, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12555–002.

c. *Date filed:* March 3, 2008.

d. *Applicant:* Mahoning Creek Hydroelectric Company, LLC.

e. *Name of Project:* Mahoning Creek Project.

f. *Location:* On Mahoning Creek, in Armstrong County, Pennsylvania. The dam is administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Clifford Phillip, Mahoning Creek Hydroelectric Company, LLC, 150 North Miller Road, Suite 450C, Fairlawn, OH 44333, (330) 869–8451.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

j. Deadline for filing comments, protests, and motions to intervene: 60 days from the issuance date of this notice.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) Proposed intake, (2) a proposed 1,200-foot-long, 90-inch-diameter penstock (3) an existing powerhouse containing two generating units having a total installed capacity of 3 megawatts, (4) an existing 100-foot-long, 5-foot-wide, 7-foot-high concrete conduit tailrace, (5) a proposed 400-foot-long, 25-kilovolt transmission line, and (6) appurtenant facilities. The project would have an annual generation of 17 gigawatt-hours that would be sold to a local utility.

l. *Locations of Applications:* A copy of the application is available for

inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

o. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

p. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

q. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

r. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; See 18 C.F.R. 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under ''e-filing'' link. The Commission strongly encourages electronic filing.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7923 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12484–003]

Metro Hydroelectric Company, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

April 8, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12484–003.

c. *Date filed:* March 3, 2008.

d. *Applicant:* Metro Hydroelectric Company, LLC.

e. *Name of Project:* Metro Project.

f. *Location:* On the Cuahoga River, in Summit County, Ohio.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Clifford Phillips, Metro Hydroelectric Company, LLC, 150 North Miller Road, Suite 450C, Fairlawn, OH 44333, (330) 869–8451.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–12484–003) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an

issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) An existing 308-foot-long, 47-foot-high Ohio Edison Gorge Dam, (2) an existing reservoir having a surface area of 34 acres, having a storage capacity of 589 acre-feet and normal water surface elevation of 912 feet mean sea level, (3) a proposed 700-foot-long, 90-inch-diameter penstock, (4) a proposed powerhouse containing two generating units with a total installed capacity of 2.5 megawatts, (5) a proposed 0.5-mile-long 12.5 kilovolt transmission line, and (6) appurtenant facilities. The applicant estimates that the average annual generation would be 11 gigawatt-hours, which would be sold to a local utility.

l. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCONLINESUPPORT@FERC.GOV*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', and ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7921 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13138–000]

Stoughton Water Power Company, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

April 8, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 13138–000.

c. *Date filed:* March 3, 2008.

d. *Applicant:* Stoughton Water Power Company, LLC.

e. *Name of Project:* Stoughton Project.

f. *Location:* On the Yahara River, in Dane County, Wisconsin. The Dam is own by the City of Stoughton, WI.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Thomas J. Reiss, Stoughton Water Power Company, P.O. Box 553, 319 Hart Street, Watertown, WI 53094, (9206) 261–2139.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the

''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–13138–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) An existing 200-foot-long, 9-foot-high Stoughton Dam, (2) an existing impoundment having a surface area of 11 acres, with a storage capacity of 80 acre-feet and normal water surface elevation of 841.5 feet mean sea level, (3) an existing 200-foot-long power canal, (4) a proposed power house containing two generating units having a total installed capacity of 192 kilowatts, (5) a proposed 350-foot-long transmission line, and (6) appurtenant facilities. The proposed project would have an estimated average annual generation of 450 megawatt-hours, which would be sold to a local utility.

l. *Location of Application:* This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCONLINESUPPORT@FERC.GOV*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

o. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

p. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

q. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

r. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', and ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7925 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12486–002]

Twin Lakes Canal Company; Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

April 8, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12486–002.

c. *Date filed:* February 5, 2008.

d. *Applicant:* Twin Lakes Canal Company.

e. *Name of Project:* Bear River Narrows Project.

f. *Location:* On the Bear River, in Franklin County, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Nicholas Josten, Twin Lakes Canal Company Authority,

C/O GeoSense, 2742 Saint Charles Avenue, Idaho Falls, ID 83404, (208) 528–6152.

i. *FERC Contact:* Robert Bell, (202) 502–6062.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–12486–002) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) A proposed 700-foot-long, 108-foot-high embankment dam, (2) a proposed reservoir having a surface area of 420 acres, having a storage capacity of 17,300 acre-feet and normal water surface elevation of 4,734 feet above mean sea level, (3) a proposed powerhouse containing two generating units with a total installed capacity of 11 megawatts, (4) a proposed 0.8-mile-long transmission line, and (5) appurtenant facilities. The applicant estimates that the average annual generation would be 51 gigawatt-hours, which would be sold to a local utility.

l. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCONLINESUPPORT@FERC.GOV*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', and ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7922 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No.: 2232–522]

Duke Energy Carolinas, LLC; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

April 7, 2008.

Take notice that the following hydroelectric application has been filed

with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2232–522.

c. *Date filed:* August 29, 2006.

d. *Applicant:* Duke Energy Carolinas, LLC.

e. *Name of Project:* Catawba-Wateree Hydroelectric Project.

f. *Location:* On the Catawba River, in Alexander, Burke, Caldwell, Catawba, Gaston, Iredell, Lincoln, McDowell, and Mecklenburg counties, North Carolina, and on the Catawba and Wateree rivers in the counties of Chester, Fairfield, Kershaw, Lancaster, and York, South Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Jeffrey G. Lineberger, Catawba-Wateree Hydro Relicensing Manager; and E. Mark Oakley, Catawba-Wateree Relicensing Project Manager, Duke Energy, Mail Code EC12Y, P.O. Box 1006, Charlotte, NC 28201–1006.

i. *FERC Contact:* Sean Murphy at 202–502–6145; or at *Sean.Murphy@ferc.gov*.

j. The deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Comments, recommendations, terms and conditions, and prescriptions may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. This application has been accepted, and is ready for environmental analysis at this time.

l. The existing 831-megawatt (MW) Catawba-Wateree Project consists of the eleven reservoirs and thirteen developments described below, which span more than 225 River Miles (RM) and include approximately 1,795 miles of reservoir and island shoreline:

1. The Bridgewater development consists of the following existing facilities: (1) The Catawba dam consisting of: (a) A 1,650-foot-long, 125-foot-high earth embankment; (b) a 305-foot-long, 120-foot-high concrete gravity ogee spillway; and (c) a 850-foot-long, 125-foot-high earth embankment; (2) the Paddy Creek dam consisting of: A 1,610-foot-long, 165-foot-high earth embankment; (3) the Linville dam consisting of: A 1,325-foot-long, 160-foot-high earth embankment; (4) a 430-foot-long uncontrolled low overflow weir spillway situated between Paddy Creek dam and Linville dam; (5) a 6,754 acre reservoir formed by Catawba, Paddy Creek, and Linville with a normal water surface elevation of 1,200 feet above mean sea level (msl); (6) a 900-foot-long concrete-lined intake tunnel; (7) a powerhouse containing two vertical Francis-type turbines directly connected to two generators, each rated at 10,000 kilowatts (kW), for a total installed capacity of 20.0 MW; and (8) other appurtenances.

2. The Rhodhiss development consists of the following existing facilities: (1) The Rhodhiss dam consisting of: (a) A 119.58-foot-long concrete gravity bulkhead; (b) a 800-foot-long, 72-foot-high concrete gravity ogee spillway; (c) a 122.08-foot-long concrete gravity bulkhead with an additional 8-foot-high floodwall; and (d) a 283.92-foot-long rolled fill earth embankment; (2) a 2,724 acre reservoir with a normal water surface elevation of 995.1 feet above msl; (4) a powerhouse integral to the dam, situated between the bulkhead on the left bank and the ogee spillway section, containing three vertical Francis-type turbines directly connected to three generators, two rated at 12,350 kW, one rated at 8,500 kW for a total installed capacity of 28.4 MW; and (5) other appurtenances.

3. The Oxford development consists of the following existing facilities: (1) The Oxford dam consisting of: (a) A 74.75-foot-long soil nail wall; (b) a 193-foot-long emergency spillway; (c) a 550-foot-long gated concrete gravity spillway; (d) a 112-foot-long embankment wall situated above the powerhouse; and (e) a 429.25-foot-long earth embankment; (2) a 4,072 acre reservoir with a normal water surface elevation of 935 feet above msl; (4) a powerhouse integral to the dam, situated between the gated spillway and the earth embankment, containing two vertical Francis-type turbines directly connected to two generators, each rated at 18,000 kW for a total installed capacity of 35.7 MW; and (5) other appurtenances.

4. The Lookout Shoals development consists of the following existing facilities: (1) The Lookout Shoals dam consisting of: (a) A 282.08-foot-long concrete gravity bulkhead section; (b) a 933-foot-long uncontrolled concrete gravity ogee spillway; (c) a 65-foot-long gravity bulkhead section; and (d) a 1,287-foot-long, 88-foot-high earth embankment; (2) a 1,155 acre reservoir with a normal water surface elevation of 838.1 feet above msl; (3) a powerhouse integral to the dam, situated between the bulkhead on the left bank and the ogee spillway, containing three main vertical Francis-type turbines and two smaller vertical Francis-type turbines directly connected to five generators, the three main generators rated at 8,970 kW, and the two smaller rated at 450 kW for a total installed capacity of 25.7 MW; and (4) other appurtenances.

5. The Cowans Ford development consists of the following existing facilities: (1) The Cowans Ford dam consisting of: (a) A 3,535-foot-long embankment; (b) a 209.5-foot-long gravity bulkhead; (c) a 465-foot-long concrete ogee spillway with eleven Taintor gates, each 35-feet-wide by 28-feet-high; (d) a 276-foot-long bulkhead; and (e) a 3,924-foot-long earth embankment; (2) a 3,134-foot-long saddle dam (Hicks Crossroads); (3) a 32,339 acre reservoir with a normal water surface elevation of 760 feet above msl; (4) a powerhouse integral to the dam, situated between the spillway and the bulkhead near the right embankment, containing four vertical Kaplan-type turbines directly connected to four generators rated at 83,125 kW for a total installed capacity of 332.5 MW; and (5) other appurtenances.

6. The Mountain Island development consists of the following existing facilities: (1) The Mountain Island dam consisting of: (a) A 997-foot-long, 97-foot-high uncontrolled concrete gravity ogee spillway; (b) a 259-foot-long bulkhead on the left side of the powerhouse; (c) a 200-foot-long bulkhead on the right side of the powerhouse; (d) a 75-foot-long concrete core wall; and (e) a 670-foot-long, 140-foot-high earth embankment; (2) a 3,117 acre reservoir with a normal water surface elevation of 647.5 feet above msl; (3) a powerhouse integral to the dam, situated between the two bulkheads, containing four vertical Francis-type turbines directly connected to four generators rated at 15,000 kW for a total installed capacity of 55.1 MW; and (4) other appurtenances.

7. The Wylie development consists of the following existing facilities: (1) The

Wylie dam consisting of: (a) A 234-foot-long bulkhead; (b) a 790.92-foot-long ogee spillway section that contains 2 controlled sections with a total of eleven Stoney gates, each 45-feet-wide by 30-feet-high, separated by an uncontrolled section with no gates; (c) a 400.92-foot-long bulkhead; and (d) a 1,595-foot-long earth embankment; (2) a 12,177 acre reservoir with a normal water surface elevation of 569.4 feet above msl; (3) a powerhouse integral to the dam, situated between the bulkhead and the spillway near the left bank, containing four vertical Francis-type turbines directly connected to four generators rated at 18,000 kW for a total installed capacity of 69 MW; and (4) other appurtenances.

8. The Fishing Creek development consists of the following existing facilities: (1) The Fishing Creek dam consisting of: (a) A 114-foot-long, 97-foot-high uncontrolled concrete ogee spillway; (b) a 1,210-foot-long concrete gravity, ogee spillway with twenty-two Stoney gates, each 45-feet-widy by 25-feet-high; and (c) a 214-foot-long concrete gravity bulkhead structure; (2) a 3,431 acre reservoir with a normal water surface elevation of 417.2 feet above msl; (3) a powerhouse integral to the dam, situated between the gated spillway and the bulkhead structure near the right bank, containing five vertical Francis-type turbines directly connected to five generators two rated at 10,530 kW and three rated at 9,450 kW for a total installed capacity of 48.1 MW; and (4) other appurtenances.

9. The Great Falls-Dearborn development consists of the following existing facilities: (1) The Great Falls diversion dam consisting of a 1,557.6-foot-long concrete section; (2) the Dearborn dam consisting of: (a) A 160-foot-long, 103-foot-high, concrete embankment; (b) a 150-foot-long, 103-foot-high intake and bulkhead section; and (c) a 75-foot-long, 103-foot-high bulkhead section; (3) the Great Falls dam consisting of: (a) a 675-foot-long, 103-foot-high concrete embankment situated in front of the Great Falls Powerhouse (and joined to the Dearborn dam embankment); and (b) a 250-foot-long intake section (within the embankment); (4) the Great Falls bypassed spillway and headworks section consisting of: (a) A 446.7-foot-long short concrete bypassed reach uncontrolled spillway with a gated trashway (main spillway); (b) a 583.5-foot-long concrete headworks uncontrolled spillway with 4-foot-high flashboards (canal spillway); and (c) a 262-foot-long concrete headworks section situated perpendicular to the main spillway and the canal spillway, containing ten openings, each 16-feet-wide; (5) a 353 acre reservoir with a normal water surface elevation of 355.8 feet above msl; (6) two powerhouses separated by a retaining wall, consisting of: (a) Great Falls powerhouse: containing eight horizontal Francis-type turbines directly connected to eight generators rated at 3,000 kW for an installed capacity of 24.0 MW, and (b) Dearborn powerhouse: containing three vertical Francis-type turbines directly connected to three generators rated at 15,000 kW for an installed capacity of 42.0 MW, for a total installed capacity of 66.0 MW; and (7) other appurtenances.

10. The Rocky Creek-Cedar Creek development consists of the following existing facilities: (1) A U-shaped concrete gravity overflow spillway with (a) A 130-foot-long section (on the east side) that forms a forebay canal to the Cedar Creek powerhouse and contains two Stoney gate, each 45-feet-wide by 25-feet-high; (b) a 1,025-foot-long, 69-foot-high concrete gravity overflow spillway; and (c) a 213-foot-long section (on the west side) that forms the upper end of the forebay canal for the Rocky Creek powerhouse; (2) a 450-foot-long concrete gravity bulkhead section that completes the lower end of the Rocky Creek forebay canal; (3) a 748-acre reservoir with a normal water surface elevation of 284.4 feet above msl; (4) two powerhouses consisting of: (a) Cedar Creek powerhouse (on the east): containing three vertical Francis-type turbines directly connected to three generators, one rated at 15,000 kW, and two rated at 18,000 kW for an installed capacity of 43.0 MW; and (b) Rocky Creek powerhouse (on the west): containing eight horizontal twin-runner Francis-type turbines directly connected to eight generators, six rated at 3,000 kW and two rated at 4,500 kW for an installed capacity of 25.8 MW, for a total installed capacity of 68.8 MW; and (5) other appurtenances.

11. The Wateree development consists of the following existing facilities: (1) The Wateree dam consisting of: (a) A 1,450-foot-long uncontrolled concrete gravity ogee spillway; and (b) a 1,370-foot-long earth embankment; (2) a 13,025-acre reservoir with a normal water surface elevation of 225.5 feet above msl; (3) a powerhouse integral to the dam, situated between the spillway and the earth embankment, containing five vertical Francis-type turbines directly connected to five generators, two rated at 17,100 kW and three rated at 18,050 kW for a total installed capacity of 82.0 MW; and (4) other appurtenances.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov*, using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

All filings must (1) Bear in all capital letters the title ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. The revised schedule for the Catawba-Wateree Project relicensing follows:

Milestone	Target date
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions.	June 2008.
Issue Draft EIS	November 2008.
Comments filed on Draft EIS and Modified Terms and Conditions.	January 2009.
Issue Final EIS	April 2009.

o. A license applicant must file, no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying

agency received the request; or (3) evidence of waiver of water quality certification.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7913 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No.: 2210–169]

Appalachian Power Company; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

April 9, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2210–169.

c. *Date Filed:* March 27, 2008.

d. *Applicant:* Appalachian Power Company, dba American Electric Power.

e. *Name of Project:* Smith Mountain Hydroelectric Project.

f. *Location:* On the headwaters of the Roanoke River in south-central Virginia, within the counties of Bedford, Campbell, Franklin and Pittsylvania, and near the city of Roanoke, Virginia. No federal lands are occupied by the project works or otherwise located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Teresa P. Rogers, Environmental and Regulatory Affairs Supervisor, Appalachian Power Company, Hydro Generation, P.O. Box 2021, Roanoke, VA 24022–2121; (540) 985–2441; *tprogers@aep.com.*

i. *FERC Contact:* Allan Creamer, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; (202) 502–8365; *allan.creamer@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. *The Project Description:* The existing Smith Mountain Project consists of two developments; one used for pumped storage operation and the other conventional operation.

The upper, pumped storage development, known as Smith Mountain, consists of: (1) A 816-foot-long, 235-foot-high concrete arch dam, with a crest elevation of 812.0 feet National Geodetic Vertical Datum (NGVD); (2) two ogee-crest overflow spillways, each 100 feet long and having a crest elevation of 595.0 feet NGVD [passing 25,000 cubic feet per second (cfs)]; (3) a reservoir with a surface area of 20,260 acres at a normal operating level of 795.0 feet NGVD; (4) a pump station/powerhouse containing five generating units, with a total capacity of 586 megawatts (MW), a total hydraulic capacity of 46,000 cfs, and an average annual generation of 476,640 MWh (three of the units, which have a pumping capacity of 15,810 cfs, are reversible for pumping water from the Leesville's reservoir to Smith Mountain's reservoir); (5) a 600,000 KVA substation and a double-circuit 138-kV tie-in line to American Electric Power's (AEP) interconnected system; and (6) appurtenant facilities.

The lower, conventional development, known as Leesville, consists of: (1) A 980-foot-long, 94 foot-high concrete gravity dam, with a crest elevation of 615.67 feet NGVD; (2) a 224-foot-long gated spillway section, with (a) A crest elevation of 578.0 feet NGVD, (b) four taintor gates, and (c) a hydraulic capacity of 175,100 cfs; (3) a reservoir with a surface area of 3,260 acres at an elevation of 613.0 feet NGVD; (4) a powerhouse containing two generating units, with a total capacity of 50 MW, a total hydraulic capacity of 9,000 cfs, and an average annual generation of 59,376 MWh; (5) a 50,000 KVA substation and a double-circuit 138-kV tie-in line to AEP's interconnected system; and (6) appurtenant facilities.

The Smith Mountain development operates as a peaking/load-following facility, with generation occurring during peak demand periods and pump-back operation occurring during off-peak periods. Under normal operations, Smith Mountain Lake uses a 2-foot drawdown, which equates to a 13-foot fluctuation in Leesville Lake. Currently, Leesville is operated by auto-cycling the units, to provide a minimum average daily flow of 650 cfs to the Roanoke River downstream. Additional flow is provided during the spring spawning season for striped bass.

Appalachian Power does not propose to modify existing operations, except as described in its proposed *Water Management Plan.* Appalachian also proposes to implement numerous environmental enhancement measures that are contained in its proposed resource-specific management plans.

l. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov,* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. You may also register online at *http://www.ferc.gov/esubscribenow.htm* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Procedural Schedule:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate. For example, issuance of the Ready for Environmental Analysis Notice is based on the assumption that there will be no additional information.

Milestone	Target Date
Tendering Notice	(April 2008).
Notice of Acceptance/Notice of Ready for Environmental Analysis	(May 2008).
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	(July 2008).
Commission issues Draft EA or EIS	(January 2009).
Comments on Draft EA or EIS	(March 2009).
Modified Terms and Conditions	(May 2009).
Commission Issues Final EA or EIS	(August 2009).

o. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7955 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–110–000]

Gulf South Pipeline Company, LP; Notice of Application

April 9, 2008.

Take notice that on April 4, 2008, Gulf South Pipeline Company, LP (Gulf South), 9 Greenway Plaza, Houston, Texas 77046, filed in Docket No. CP08–110–000 an application pursuant to section 7(b) of the Natural Gas Act (NGA) requesting permission and approval to abandon by sale to Energy Partners, LTD. Approximately 11.8 miles of 12-inch diameter pipeline facilities and related appurtenances located in federal and state waters offshore in the Gulf of Mexico. In addition, Gulf South is requesting a determination that upon abandonment, Energy Partners ownership and operation of the facilities will be exempt from Commission jurisdiction under 1(b) of the NGA, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Any questions regarding this application should be directed to J. Kyle Stephens, Vice President, Regulatory Affairs, Gulf South Pipeline South Pipeline Company, LP, 9 Greenway Plaza, Houston, Texas 77046, or call (713) 479–8033, by fax (713) 479–1846, or by e-mail to *kyle.stephens@bwpmlp.com.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link at *http://www.ferc.gov.* The Commission strongly encourages intervenors to file electronically. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Comment Date: April 30, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7957 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–114–000]

Natural Gas Pipeline Company of America LLC; Notice of Application

April 9, 2008.

Take notice that on April 7, 2008, Natural Gas Pipeline Company of America LLC (Natural), 747 East 22nd Street, Lombard, Illinois 60148, filed an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity to construct and operate certain facilities, located in Cameron Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open for public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Specifically, Natural proposes to construct and operate approximately 900 feet of 16-inch diameter pipeline and operate an already constructed meter, consisting of ultrasonic meter runs, flow control valve, gas quality monitoring devices, and Electronic flow Measurement facilities. Natural states that the facilities are necessary to receive up to 300 MDth/day of re-vaporized liquefied natural gas from the Sabine Pass Segment of the Cheniere Creole Trail Pipeline (Cheniere), located in Cameron Parish, Louisiana. Natural estimates the cost of construction to be

$4,892,350, and all costs borne by Natural will be reimbursed by Cheniere.

Any questions regarding this Application should be directed to Bruce H. Newsome, Vice President, Regulatory, Natural Gas Pipeline Company of America, 747 East 22nd Street, Lombard, Illinois 60148–5072 or by telephone at (630) 691–3526 or e-mail at *bruce_newsome@kindermorgan.com*.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the below listed comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the Internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: April 21, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7952 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

April 8, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP96–320–084.

Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Company, LP submits an Amendment to a Negotiated Rate Letter Agreement executed by Gulf South and one of its customers in relation to the East Texas to Mississippi Expansion Project etc.

Filed Date: 03/28/2008.

Accession Number: 20080403–0255.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 9, 2008.

Docket Numbers: RP97–13–032.

Applicants: East Tennessee Natural Gas, LLC.

Description: East Tennessee Natural Gas LLC submits Original Sheet 30 *et al.* to FERC Gas Tariff, Third Revised Volume 1, to become effective 4/4/08.

Filed Date: 04/04/2008.

Accession Number: 20080407–0056.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP99–301–207.

Applicants: ANR Pipeline Company.

Description: ANR Pipeline Company submits Rate Schedule FTS–1 and Gathering negotiated rate agreement between ANR and Eagle Energy Partners I, LP.

Filed Date: 04/03/2008.

Accession Number: 20080404–0400.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 15, 2008.

Docket Numbers: RP99–480–020.

Applicants: Texas Eastern Transmission LP.

Description: Texas Eastern Transmission LP submits Original Sheet 118 *et al.* to FERC Gas Tariff, Seventh Revised Volume 1.

Filed Date: 04/01/2008.

Accession Number: 20080403–0044.

Comment Date: 5 p.m. Eastern Time on Monday, April 14, 2008.

Docket Numbers: RP02–534–007.

Applicants: Guardian Pipeline, L.L.C.

Description: Guardian Pipeline, LLC submits Original Sheet 8 *et al.* to its FERC Gas Tariff, Original Volume 1, to be effective April 4, 2008.

Filed Date: 04/03/2008.

Accession Number: 20080404–0399.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 15, 2008.

Docket Numbers: RP04–42–003.

Applicants: Southern Natural Gas Company.

Description: Southern Natural Gas Company submits Fifth Revised Sheet 107 *et al.* to FERC Gas Tariff, Seventh Revised Volume 1, to become effective 5/5/08.

Filed Date: 04/04/2008.

Accession Number: 20080407–0055.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP05–157–012.

Applicants: Saltville Gas Storage Company L.L.C.

Description: Saltville Gas Storage Company LLC submits Original Sheet 22 *et al.* as part of its FERC Gas Tariff, Original Volume 1, to become effective 4/4/08.

Filed Date: 04/04/2008.
Accession Number: 20080407–0054.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP07–666–002.
Applicants: Colorado Interstate Gas Company.
Description: Colorado Interstate Gas Company submits Fifth Revised Sheet 378 *et al.* to FERC Gas Tariff, First Revised Volume 1, to become effective 3/1/08.
Filed Date: 04/04/2008.
Accession Number: 20080407–0053.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP08–124–002.
Applicants: Columbia Gulf Transmission Company.
Description: Columbia Gulf Transmission Company submits Tenth Revised Sheet 130 to its FERC Gas Tariff, Second Revised Volume 1 to be effective date of June 1, 2008.
Filed Date: 04/04/2008.
Accession Number: 20080404–0243.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP08–127–002.
Applicants: Columbia Gas Transmission Corporation.
Description: Columbia Gas Transmission Corp submits Tenth Revised Sheet 268 *et al.* to its FERC Gas Tariff, Second Revised Volume 1 to be effective date of June 1, 2008.
Filed Date: 04/04/2008.
Accession Number: 20080404–0244.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP08–300–000.
Applicants: Kern River Gas Transmission Company.
Description: Kern River Gas Transmission Co submits a report supporting its gas compressor fuel factors and lost and unaccounted-for gas factors for calendar year 2007.
Filed Date: 03/31/2008.
Accession Number: 20080403–0211.
Comment Date: 5 p.m. Eastern Time on Monday, April 14, 2008.

Docket Numbers: RP08–304–001.
Applicants: Freebird Gas Storage, LLC.
Description: Freebird Gas Storage LLC submits Original Sheet 3 *et al.* to FERC Gas Tariff, First Revised Volume 1, to become effective 5/1/08.
Filed Date: 04/04/2008.
Accession Number: 20080407–0052.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: RP08–306–000.
Applicants: Portland Natural Gas Transmission System.
Description: Portland Natural Gas Transmission System's CD containing its notice of rate change.
Filed Date: 04/01/2008.
Accession Number: 20080401–4005.
Comment Date: 5 p.m. Eastern Time on Monday, April 14, 2008.

Docket Numbers: RP08–307–000.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company submits Original Sheet 55A *et al.* to FERC Gas Tariff, Fifth Revised Volume 1, to become effective 6/1/08.
Filed Date: 04/03/2008.
Accession Number: 20080407–0010.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 15, 2008.

Docket Numbers: RP08–308–000.
Applicants: Crossroads Pipeline Company.
Description: Cross Pipeline Company submits Third Revised Sheet 78 *et al.* to FERC Gas Tariff, First Revised Volume 1, to become effective 5/3/08.
Filed Date: 04/03/2008.
Accession Number: 20080407–0009.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 15, 2008.

Docket Numbers: RP08–309–000.
Applicants: Northern Border Pipeline Company.
Description: Northern Border Pipeline Company submits Fifth Revised Sheet 102A *et al.* to FERC Gas Tariff, First Revised Volume 1, to become effective 5/5/08.
Filed Date: 04/03/2008.
Accession Number: 20080407–0008.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 15, 2008.

Docket Numbers: RP08–310–000.
Applicants: Wyoming Interstate Company, Ltd.
Description: Wyoming Interstate Company Ltd submits Fifth Revised Sheet 11A *et al.* to Second Revised Volume 2, to become effective 11/17/07.
Filed Date: 04/04/2008.
Accession Number: 20080407–0051.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 16, 2008.

Docket Numbers: CP07–411–001.
Applicants: Texas Eastern Transmission, LP.
Description: Texas Eastern Transmission, LP submits Fourth Revised Sheet No. 51C to FERC Gas Tariff, Seventh Revised Volume No. 1, to become effective 5/1/08.
Filed Date: 04/01/2008.
Accession Number: 20080403–0252.
Comment Date: 5 p.m. Eastern Time on Monday, April 14, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,
Deputy Secretary.
[FR Doc. E8–7942 Filed 4–14–08; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

April 8, 2008.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG08–54–000.
Applicants: Airtricity Pyron Wind Farm, LLC.
Description: Notice of Self Certification of Exempt Wholesale Generator Status of Airtricity Pyron Wind Farm, LLC.
Filed Date: 04/07/2008.
Accession Number: 20080407–5124.
Comment Date: 5 p.m. Eastern Time on Monday, April 28, 2008.

Docket Numbers: EG08–55–000.
Applicants: Airtricity Inadale Wind Farm, LLC.
Description: Notice of Self Certification of Exempt Wholesale Generator Status of Airtricity Inadale Wind Farm, LLC.
Filed Date: 04/07/2008.
Accession Number: 20080407–5125.
Comment Date: 5 p.m. Eastern Time on Monday, April 28, 2008.

Docket Numbers: EG08–56–000.
Applicants: Airtricity Panther Creek Wind Farm, LLC.
Description: Notice of Self Certification of Exempt Wholesale Generator Status of Airtricity Panther Creek Wind Farm, LLC.
Filed Date: 04/07/2008.
Accession Number: 20080407–5150.
Comment Date: 5 p.m. Eastern Time on Monday, April 28, 2008.

Docket Numbers: EG08–57–000.
Applicants: Wolf Ridge Wind, LLC.
Description: Notice of Self Certification of Exempt Wholesale Generator Status of Wolf Ridge Wind, LLC.
Filed Date: 04/08/2008.
Accession Number: 20080408–5010.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 29, 2008.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER02–2042–004; ER99–2817–005; ER05–810–003.
Applicants: UGI Utilities, Inc.; UGI Development Company; UGI Energy Services, Inc.
Description: UGI Utilities Inc *et al.* submit an updated market power analysis.
Filed Date: 04/03/2008.
Accession Number: 20080407–0041.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER06–1399–005.
Applicants: Sunbury Generation LP.
Description: Notice of Change in Status of Sunbury Generation LP.
Filed Date: 04/03/2008.
Accession Number: 20080403–5078.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER07–1372–005.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Motion of Midwest Independent Transmission System Operator, Inc. for Temporary Waiver of Tariff Provision, and Request for Expedited Consideration and Shortened Notice Period.
Filed Date: 04/04/2008.
Accession Number: 20080408–5003.
Comment Date: 5 p.m. Eastern Time on Thursday, April 17, 2008.

Docket Numbers: ER07–1415–001.
Applicants: Xcel Energy Services Inc.
Description: Northern States Power Company *et al.* submits an supplement to the 1/22/08 Filing of Substitute Sheet 1365Z.16N to the Midwest ISO Tariff.
Filed Date: 04/02/2008.
Accession Number: 20080403–0208.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 23, 2008.

Docket Numbers: ER08–554–001.
Applicants: Allegheny Power.
Description: Allegheny Power submits a revised market-based rate tariff to replace the rate tariff that was included in the 2/12/08 application.
Filed Date: 03/31/2008.
Accession Number: 20080402–0109.
Comment Date: 5 p.m. Eastern Time on Monday, April 14, 2008.

Docket Numbers: ER08–622–001.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc submits proposed revisions to the Credit Policy in Attachment L of the Midwest ISO Open Access Transmission and Energy Markets Tariff, FERC Electric Tariff, Third Revised 1.
Filed Date: 03/31/2008.
Accession Number: 20080404–0218.
Comment Date: 5 p.m. Eastern Time on Monday, April 21, 2008.

Docket Numbers: ER08–636–001.
Applicants: Standard Binghamton LLC.
Description: Standard Binghamton LLC submits an amendment to their 3/4/08 filing of a Petition for Acceptance of Initial Rate Schedule, Waivers and Blanket Authority.
Filed Date: 04/03/2008.
Accession Number: 20080407–0001.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER08–693–000.
Applicants: NRG Southaven LLC, Southaven Power, LLC.
Description: Notice of withdrawal of application of NRG Southern LLC *et al.* for authorization of the disposition of jurisdictional facilities under section 203 of the Federal Power Act, request for waivers of Order 888 *et al.*
Filed Date: 04/04/2008.
Accession Number: 20080407–0047.
Comment Date: 5 p.m. Eastern Time on Friday, April 25, 2008.

Docket Numbers: ER08–778–001.
Applicants: New York Independent System Operator, Inc.
Description: New York Independent System Operator Inc submits an errata to the April 2 Filing and a clean version of the proposed Services Tariff sheet that was affected by the typographical error to the OATT.
Filed Date: 04/04/2008.
Accession Number: 20080407–0046.
Comment Date: 5 p.m. Eastern Time on Thursday, April 17, 2008.

Docket Numbers: ER08–779–000.
Applicants: Northwestern Corporation.
Description: NorthWestern Corp submits a revision to Rate Schedule 188.
Filed Date: 04/02/2008.
Accession Number: 20080404–0276.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 23, 2008.

Docket Numbers: ER08–780–001.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection LLC submits corrections to the 3/31/08 filing of revisions to the Open Access Transmission Tariff and the Amended and Restated Operating Agreement.
Filed Date: 04/03/2008.
Accession Number: 20080407–0002.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER08–781–000.
Applicants: Central Illinois Light Company.
Description: Central Illinois Light Co. *et al.* submit an Electric Resource Sharing Agreement for Capacity.
Filed Date: 04/02/2008.
Accession Number: 20080404–0275.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 23, 2008.

Docket Numbers: ER08–782–000.
Applicants: Union Electric Company.
Description: Union Electric Co. submits an application for approval to make power sales to its affiliates, Ameren Illinois Utilities.
Filed Date: 04/02/2008.
Accession Number: 20080404–0274.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 23, 2008.

Docket Numbers: ER08–783–000.
Applicants: Ameren Energy Marketing Company.
Description: Ameren Energy Marketing Co. submits their application to make power sales to its affiliates, Ameren Illinois Utilities.
Filed Date: 04/02/2008.
Accession Number: 20080404–0273.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 23, 2008.

Docket Numbers: ER08–784–000.
Applicants: West Valley Leasing Company, LLC.
Description: Application of West Valley Leasing Co., LLC for order accepting initial tariff (FERC Electric Tariff, Original Volume 1), waiving regulations, and granting blanket approvals.
Filed Date: 04/02/2008.
Accession Number: 20080404–0272.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 23, 2008.

Docket Numbers: ER08–785–000.
Applicants: Niagara Mohawk Power Corporation.
Description: Niagara Mohawk Power Corporation dba National Grid submits a Notice of Termination of Rate Schedule 255 with Ondondaga Cogeneration Limited Partnership.
Filed Date: 04/03/2008.
Accession Number: 20080407–0007.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER08–786–000.
Applicants: Avista Corporation.
Description: Avista Corporation submits an executed Letter Agreement with Clearwater Power Company etc.
Filed Date: 04/03/2008.
Accession Number: 20080407–0006.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER08–787–000.
Applicants: Avista Corporation.
Description: Avista Corporation submits an executed Letter Agreement with Clearwater Power Company.
Filed Date: 04/03/2008.
Accession Number: 20080407–0005.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER08–788–000.
Applicants: PacifiCorp.
Description: PacifiCorp submits Service Agreement 425 dated 3/7/08 for the installation of a new 230 kV substation on Bonneville Power Administration's Midway-Big Eddy 230 kV line.
Filed Date: 04/03/2008.
Accession Number: 20080407–0004.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: ER08–794–000.
Applicants: Ameren Services Company.
Description: Central Illinois Public Service Company submits a Letter Agreement with Wabash Valley Power Association Inc as agent for MJM Electric Cooperative Inc etc.
Filed Date: 04/04/2008.
Accession Number: 20080407–0045.
Comment Date: 5 p.m. Eastern Time on Friday, April 25, 2008.

Docket Numbers: ER08–795–000.
Applicants: Ameren Services Company.
Description: Ameren Services Company submits a Letter Agreement with Wayne-White Counties Electric Cooperative with an effective date of 3/7/08.
Filed Date: 04/04/2008.
Accession Number: 20080407–0044.
Comment Date: 5 p.m. Eastern Time on Friday, April 25, 2008.

Docket Numbers: ER08–800–000; ER96–1085–012; EL05–122–001.
Applicants: South Carolina Electric & Gas Company.
Description: South Carolina Electric & Gas Co. submits a refund report summarizing refund payments made.
Filed Date: 04/03/2008.
Accession Number: 20080408–0038.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Take notice that the Commission received the following electric securities filings:
Docket Numbers: ES08–42–000.
Applicants: Southern Indiana Gas & Electric Company.
Description: Application of Southern Indiana Gas and Electric Company for Authority to Issue Short-Term Debt under section 204 of the Federal Power Act.
Filed Date: 04/07/2008.
Accession Number: 20080408–5001.
Comment Date: 5 p.m. Eastern Time on Monday, April 28, 2008.

Take notice that the Commission received the following open access transmission tariff filings:
Docket Numbers: OA07–115–001; OA08–95–001.
Applicants: Alcoa Power Generating Inc.—Yadkin.
Description: Yadkin Division of Alcoa Power Generating, Inc submits its Open Access Transmission Tariff Sheets containing revised Attachment C.
Filed Date: 04/03/2008.
Accession Number: 20080404–0233.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: OA08–54–001; OA08–55–001; OA08–56–001; OA08–57–001; OA08–99–000.
Applicants: Deseret Generation & Transmission Co-op.; Idaho Power Company; NorthWestern Corporation; PacifiCorp; Black Hills Power, Inc.
Description: Deseret Generation & Transmission Co-operative, Inc *et al.* submit revised sheets & original sheets to Rate Schedule FERC 23 *et al.*
Filed Date: 04/03/2008.
Accession Number: 20080407–0003.
Comment Date: 5 p.m. Eastern Time on Thursday, April 24, 2008.

Docket Numbers: OA08–94–000.
Applicants: MATL LLP.
Description: MATL LLP submits Second Revised Sheet 7 *et al.* to Second Revised Volume 1 to its Open Access Transmission Tariff.
Filed Date: 03/17/2008.
Accession Number: 20080320–0052.
Comment Date: 5 p.m. Eastern Time on Monday, April 14, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or

call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–7961 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. DI08–5–000]

Loyalhanna Watershed Association, Inc.; Notice of Declaration of Intention and Soliciting Comments, Protests, and/or Motions To Intervene

April 8, 2008.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Declaration of Intention.

b. *Docket No.:* DI08–5–000.

c. *Date Filed:* April 1, 2008.

d. *Applicant:* Loyalhanna Watershed Association, Inc.

e. *Name of Project:* Saxman Run Mine Drainage Treatment and Hydroelectric Project.

f. *Location:* The proposed Saxman Run Drainage Treatment and Hydroelectric Project (Saxman) will be located on Saxman Run near the town of Latrobe, Unity Township, Westmoreland County, Pennsylvania.

g. *Filed Pursuant to:* Section 23(b)(1) of the Federal Power Act, 16 U.S.C. 817(b).

h. *Applicant Contact:* Susan L. Huba, Program Manager, Loyalhanna Watershed Association, 110 Andi Lane, Ligonier, PA 15658; telephone: (724) 238–7560; fax: (724) 238–7681; e-mail: *slhuba@verizon.net.*

i. *FERC Contact:* Any questions on this notice should be addressed to Henry Ecton, (202) 502–8768, or E-mail address: *henry.ecton@ferc.gov.*

j. *Deadline for filing comments, protests, and/or motions:* May 09, 2008. All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and/or interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing link.

Please include the docket number (DI08–5–000) on any comments, protests, and/or motions filed.

k. *Description of Project:* The proposed Saxman project will include: (1) An intake manifold at three free-flowing pipes discharging abandoned mine drainage; (2) a 2,200-foot-long, 14-inch-diameter transmission pipe, conveying water from the intake manifold to the Latrobe Municipal Authority Wastewater Treatment Plant (LMAWTP); (3) a proposed concrete foundation and simple enclosure containing a 10-kW turbine/generator, located at the LMAWTP; (4) a stone-and-grass-lined tailrace to Saxman Run; and (5) appurtenant facilities. The proposed project will not be connected to an interstate grid and will not occupy any tribal or federal lands.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) Would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Locations of the Application:* Copies of this filing are on file with the Commission and are available for public inspection. This filing may be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link, select ''Docket No.'' and follow the instructions. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTESTS'', AND/OR ''MOTIONS TO INTERVENE'', as applicable, and the Docket Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7927 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2835–026–NY]

New York State Electric and Gas Corporation; Notice of Availability of Environmental Assessment

April 9, 2008.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47879), the Office of Energy Projects has reviewed the proposed Whitewater Access Plan for the Rainbow Falls Project, located on the Ausable River in the Clinton and Essex Counties, New York, and has prepared an Environmental Assessment (EA).

A copy of the EA is on file with the Commission and is available for public inspection. The EA may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number (P–2835) excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659.

Any comments should be filed by May 27, 2008, and should be addressed to the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1–A, Washington, DC 20426. Please reference the project name and project number (P–2835) on all comments. Comments may be filed electronically via Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''eFiling'' link. For further information, contact Gina Krump at (202) 502–6704.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7956 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–72–005]

Dynegy Midwest Generation, Inc.; Notice of Filing

April 9, 2008.

Take notice that on March 31, 2008, Dynegy Midwest Generation, Inc. tendered for filing a refund report pursuant to Commission's Order issued October 12, 2007.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all the parties in this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on April 21, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7953 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM07–9–000]

Notice of Inquiry on Adequacy of FERC Financial Forms; Notice Requesting Comments

April 8, 2008.

On February 29, 2008, the Association of Oil Pipe Lines (AOPL) filed Supplemental Post-Workshop Comments (Supplemental Comments) in the above referenced proceeding, in which it proposes certain revisions to FERC Form No. 6, Annual Report of Oil Pipeline Companies. The Commission is noticing AOPL's filing for comment.

In its Supplemental Comments, AOPL proposes that the Commission further define the rate base figure in Line 5 of Page 700 by listing: (1) Net carrier property in service; (2) net AFUDC; (3) working capital; (4) net deferred return; (5) net starting rate base write-up; and (6) ADIT. AOPL also proposes that the Commission raise the annual interstate operating revenue reporting level from $500,000 to $1,000,000 and exempt all pipelines below $1,000,000 from filing the full FERC Form No. 6 (including Page 700).

The Commission encourages electronic submission of comments in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: May 8, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7918 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12693–001]

Sutton Hydroelectric Company, LLC; Notice of Intent To File License Application, Filing of Pre-Application Document, Commencement of Licensing Proceeding, Scoping Meetings, Solicitation of Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests

April 7, 2008.

a. *Type of Filing:* Notice of Intent to File License Application for an Original License and Commencing Licensing Proceeding.

b. *Project No.:* 12693–001.

c. *Date Filed:* February 6, 2008.

d. *Submitted By:* Sutton Hydroelectric Company, LLC.

e. *Name of Project:* Sutton Hydroelectric Project.

f. *Location:* On the Elk River, in Braxton County, West Virginia. The project would occupy federal lands administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to:* 18 CFR Part 5 of the Commission's Regulations.

h. *Potential Applicant Contact:* Ken Kemp, Project Manager, Sutton Hydroelectric Company LLC, Brookfield Power, 225 Greenfield Parkway, Suite 201, Liverpool, New York 13088, (315) 413–2769.

i. *FERC Contact:* Timothy Konnert, *timothy.konnert@ferc.gov,* (202) 502–6359.

j. We are asking Federal, State, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in paragraph o., below. Cooperating agencies should

note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. *With this notice, we are initiating informal consultation with:* (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; and (b) the State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Sutton Hydroelectric Company, LLC as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. Sutton Hydroelectric Company, LLC filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations. The Commission issued the Scoping Document for the proposed Sutton Project on April 7, 2008.

n. A copy of the PAD and the scoping document are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, of for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in paragraph h.

Register online at *http://ferc.gov/esubscribenow.htm* to be notified via e-mail of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. With this notice, we are setting the effective date for the commencement of the licensing proceeding as April 7, 2008, and soliciting comments on the PAD and the scoping document, as well as study requests. All comments on the PAD and the scoping document, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and the scoping document, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application (original and eight copies) must be filed with the Commission at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. All filings with the Commission must include on the first page, the project name (Sutton Project) and number (P–12693–001), and bear the heading ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or the scoping document, and any agency requesting cooperating status must do so by June 5, 2008.

Comments on the PAD and the scoping document, study requests, requests for cooperating agency status, and other permissible forms of communications with the Commission may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''efiling'' link.

p. Although our current intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. Nevertheless, this meeting will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

Scoping Meetings

Commission staff will hold two scoping meetings in the vicinity of the project at the time and place noted below. The daytime meeting will focus on resource agency, Indian tribes, and non-governmental organization concerns, while the evening meeting is primarily for receiving input from the public. We invite all interested individuals, organizations, and agencies to attend one or both of the meetings, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be addressed in the environmental document. The times and locations of these meetings are as follows:[1]

Evening Scoping Meeting

Date and Time: Monday, May 12, 2008, 6 p.m. (EST),

Location: Days Hotel Flatwoods, 2000 Sutton Lane, Sutton, WV 26601. (304) 765–5055.

Daytime Scoping Meeting

Date and Time: Tuesday, May 13, 2008, 10 a.m. (EST).

Location: Same location.

Sutton Hydroelectric Company, LLC will also host a site visit at the project on May 12, 2008, at 2 p.m. to describe the proposed project. Those wishing to participate will meet at the upstream recreation parking lot next to the dam.

The scoping document, which outlines the issues to be addressed in the environmental document, has been mailed to the individuals and entities on the Commission's mailing list. Copies of the scoping document will be available at the scoping meetings, and may be viewed on the Web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Depending on the extent of comments received, a revised Scoping Document may or may not be issued.

Scoping Meeting Objectives

At the scoping meetings, staff will: (1) Present the proposed list of issues to be addressed in the EA; (2) review and discuss existing conditions and resource agency management objectives; (3) review and discuss existing information and identify preliminary information and study needs; (4) review and discuss the process plan and schedule for pre-filing activity that incorporates the time frames provided for in Part 5 of the Commission's regulations and, to the extent possible, maximizes coordination of federal, state, and tribal permitting and certification processes; and (5) discuss requests by any federal or state agency or Indian tribe acting as a cooperating agency for development of an environmental document.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meetings. Directions on how to obtain a copy of the PAD and the scoping document are included in item n of this document.

Meeting Procedures

The meetings will be recorded by a stenographer and will become part of

[1] Pursuant to § 5.8(b)(3)(VIII) of the Commission's regulations, the scoping meeting and site visit is to be held within 30 days of this notice. However, due to facility unavailability, the scoping meetings have been rescheduled for one week later. To the extent necessary, therefore, § 5.8(b)(3)(VIII) is being waived. The updated process plan in the Commission's scoping document has been modified accordingly.

the formal record of the Commission proceeding on the project.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7914 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF08–2–000]

MarkWest Pioneer, LLC; Supplemental Notice of Intent To Prepare an Environmental Assessment for the Proposed Arkoma Connector Pipeline Project and Request for Comments on Environmental Issues

April 9, 2008.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Arkoma Connector Pipeline Project (Project) which involves the construction and operation of natural gas pipeline facilities in Coal, Atoka, and Bryan Counties, Oklahoma, proposed by MarkWest Pioneer, LLC (MarkWest).

On January 18, 2008 the FERC issued a ''Notice of Intent to Prepare an Environmental Assessment for the Proposed Arkoma Connector Pipeline Project and Request for Comments on Environmental Issues'' (NOI). The NOI was published in the **Federal Register** and was also mailed to interested parties, including federal, state and local officials, agency representatives, Native American groups; local libraries and newspapers; and property owners affected by the proposed facilities. This Supplemental Notice of Intent (NOI) discloses that on March 21, 2008, Markwest filed draft Resource Reports that identified the addition of various facilities to the Project, including a new compressor station, and substantially modified the proposed pipeline route at various locations. This NOI is being issued because the facility additions and proposed pipeline modifications were not identified in the original NOI, and landowners potentially affected by those facilities were therefore not included on the environmental mailing list for that correspondence. Please note that the scoping period for this NOI will close on May 12, 2008.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. MarkWest would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, MarkWest could initiate condemnation proceedings in accordance with State law.

This notice is being sent to previously unidentified affected landowners; federal, state, and local government representatives and agencies; elected officials; Native American tribes; other interested parties; and local libraries and newspapers. State and local government representatives are asked to notify their constituents of this proposed project and to encourage them to comment on their areas of concern.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is available for viewing on the FERC Internet Web site (*www.ferc.gov*).

Summary of the Proposed Project

MarkWest seeks authorization to construct new pipeline facilities in Coal, Atoka, and Bryan Counties, Oklahoma. As originally defined, the Arkoma Connector Pipeline Project would have consisted of about 50 miles of 24-inch-diameter pipeline, the 10,000-horsepower (hp) Arkoma Connector Compressor Station and associated facilities at milepost (MP) 0.0, and two meter stations. The pipeline project would have been designed to deliver a peak day capacity of 300,000 to 350,000 decatherms (Dth) of natural gas from producers in the Arkoma Basin area of southeastern Oklahoma to the Midcontinent Express Pipeline (MEP) that is currently proposed under Docket No. CP08–6–000.

This notice:

- Updates the name of the compressor station at MP 0.0 to the Origin Compressor Station, and its compression capacity of the from 10,000-hp to 14,200-hp;
- Identifies the addition of the 5,300-hp Mid-Line Compressor Station at MP 24.2 as the preferred site (with two alternative sites at MP 22.4 and MP 27.3;
- Identifies an increase in peak day deliverability to 625,000 Dth;
- Identifies Gulf Crossing Pipeline that is currently proposed under Docket No. CP07–398–000 as a second delivery point in addition to MEP;
- Reduces the number of interconnect meter stations from two to one;
- Identifies two contractor/pipe yards at MP 0.0 and MP 38.0; and
- Identifies several pipeline route modifications, primarily in the vicinity of MPs 9.0, 13.9 to 18.0, 23.2 to 26.5, 27.2 to 30.0, and 33.0.

The locations of the facility additions and pipeline route modifications are shown in Appendix 1.[1]

Land Requirements for Construction

Construction of the proposed project would affect a total of about 632 acres. Following construction, about 319 acres would be allowed to revert to its previous conditions. Disturbance associated with aboveground facilities would impact about 16 acres of land. The two compressor stations would each require about 8 and 7 acres, respectively, and the interconnect meter station would require about 1 acre of disturbance during and after construction. MarkWest would seek a 90-foot-wide construction right-of-way for the pipeline, and would maintain a 50-foot-wide permanent right-of-way for operation of the pipeline.

The EA Process

We[2] are preparing this EA to comply with the National Environmental Policy Act (NEPA) which requires the Commission to take into account the environmental impact that could result if it authorizes MarkWest's proposal. With this notice, we are also asking federal, state, and local agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. Agencies that would like to request cooperating status should follow the instructions for filing comments provided below.

NEPA also requires the FERC to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this

[1] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of all appendices are available on the Commission's Web site at the ''eLibrary'' link or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail. Requests for detailed maps of the proposed facilities should be made directly to MarkWest.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the FERC's Office of Energy Projects.

Notice of Intent, we are requesting public comments on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils
- Land use
- Water resources, fisheries, and wetlands
- Cultural resources
- Vegetation and wildlife
- Air quality and noise
- Endangered and threatened species
- Hazardous waste
- Public safety

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, the FERC staff has already initiated its NEPA review under its Pre-filing Process. The purpose of the Pre-filing Process is to encourage the early involvement of interested stakeholders and to identify and resolve issues before an application is filed with the FERC.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By filing comments, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, reasonable alternatives to the proposal including alternative locations and routes, and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.
- Label one copy of the comments for the attention of Gas Branch 3.
- Reference Docket No. PF08–2–000.
- Mail your comments so that they will be received in Washington, DC on or before May 12, 2008.

The Commission encourages electronic filing of comments. See Title 18 Code of Federal Regulations, Section 385.2001(a)(1)(iii) and the instructions on the Commission's Internet Web site at *http://www.ferc.gov* under the link to ''*Documents and Filings*'' and ''*eFiling.*'' eFiling is a file attachment process and requires that you prepare your submission in the same manner as you would if filing on paper, and save it to a file on your hard drive. New eFiling users must first create an account by clicking on ''*Sign up*'' or ''*eRegister.*'' You will be asked to select the type of filing you are making. This filing is considered a ''Comment on Filing.'' In addition, there is a ''*Quick Comment*'' option available, which is an easy method for interested persons to submit text only comments on a project. The *Quick-Comment* User Guide can be viewed at *http://www.ferc.gov/docs-filing/efiling/quick-comment-guide.pdf*. Quick Comment does not require a FERC eRegistration account; however, you will be asked to provide a valid e-mail address. All comments submitted under either eFiling or the Quick Comment option are placed in the public record for the specified docket or project number(s).

We might mail the EA for comment. If you are interested in receiving it, please return the Information Request (Appendix 3). If you do not return the Information Request, you will be taken off the mailing list.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*www.ferc.gov*) using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm.*

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7951 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER08–67–001]

Ameren Services Company; Notice Withdrawing Notice of Filing

April 9, 2008.

This notice withdraws a Notice of Filing that published in the **Federal Register** on Wednesday, March 5, 2008, in Commission Docket No. ER08–67–001 (73 FR 11905). The correct version of this notice was published in the **Federal Register** on March 6, 2008 (73 FR 12154).

Kimberly D. Bose,

Secretary.

[FR Doc. E8–7910 Filed 4–14–08; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 30, 2008.

A. Federal Reserve Bank of New York (Anne MacEwen, Bank

Applications Officer) 33 Liberty Street, New York, New York 10045-0001:

1. ICICI Bank Limited, Mumbai, India; to purchase certain assets of Global Investment Management, Princeton, New Jersey, and thereby engage in financial and investment advisory activities pursuant to Section 225.28(b) of Regulation Y.

Board of Governors of the Federal Reserve System, April 10, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–7994 Filed 4–14–08; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0200]

General Services Administration Acquisition Regulation; Information Collection; Sealed Bidding

AGENCY: Office of the Chief Acquisition Officer, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement regarding sealed bidding. A request for public comments was published at 72 FR 66176, November 27, 2007. No comments were received. This OMB clearance expires on July 31, 2008.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: May 15, 2008.

FOR FURTHER INFORMATION CONTACT: Michael Jackson, Procurement Analyst, Contract Policy Division, at telephone (202) 208–4949 or via e-mail to *michaelo.jackson@gsa.gov.*

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Ms. Jasmeet Seehra, GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to the Regulatory Secretariat (VPR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090–0200, Sealed Bidding, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration is requesting that the Office of Management and Budget (OMB) review and approve information collection, 3090–0200, Sealed Bidding. The information requested regarding an offeror's monthly production capability is needed to make progressive awards to ensure coverage of stock items.

B. Annual Reporting Burden

Respondents: 10.
Responses per Respondent: 1.
Hours per Response: .5.
Total Burden Hours: 5.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208–4755. Please cite OMB Control No. 3090–0200, Sealed Bidding, in all correspondence.

Dated: March 25, 2008.

Al Matera,

Director, Acquisition Policy.

[FR Doc. E8–8062 Filed 4–14–08; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the NTP Board of Scientific Counselors

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Meeting announcement and request for comments.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of a meeting of the NTP Board of Scientific Counselors (NTP BSC). The NTP BSC is composed of scientists from the public and private sectors and provides primary scientific oversight to the NTP Director and evaluates the scientific merit of the NTP's intramural and collaborative programs.

DATES: The NTP BSC meeting will be held on June 11–12, 2008. The deadline for submission of written comments is May 23, 2008, and for pre-registering to attend the meeting, including providing notice of intent to present oral comments, is June 4, 2008. Persons needing interpreting services in order to attend should contact 301–402–8180 (voice) or 301–435–1908 (TTY). For other accommodations, contact 919–541–2475 or e-mail *niehsoeeo@niehs.nih.gov.* Requests should be made at least 7 days in advance of the event.

ADDRESSES: The NTP BSC meeting will be held at the Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709. Public comments on all agenda topics and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP BSC, NTP Office of Liaison, Policy and Review, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709; telephone: 919–541–4253; fax: 919–541–0295; or e-mail: *shane@niehs.nih.gov.* Courier address: NIEHS, 111 T.W. Alexander Drive, Room A322, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Shane (telephone: 919–541–4253 or e-mail: *shane@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION:

Preliminary Agenda Topics and Availability of Meeting Materials

June 11–12, 2008

- Update of NTP activities.
- Center for the Evaluation of Risks to Human Reproduction: Peer review of the draft NTP Brief on Bisphenol A.
- Criteria for evaluating outcomes in reproductive, developmental, and immunotoxicology studies.
- Report on the NTP BSC Technical Reports Review Subcommittee meeting held February 27–28, 2008.
- NTP studies of DNA-based therapies.
- NTP testing program: Proposed research projects on dimorpholinodiethyl ether, 2-ethylhexyl-*p*-methoxycinnamate, furan, melamine and cyanuric acid, 4,7,10-trioxatridecane-1,13-diamine, and tetravalent and pentavalent vanadium compounds.
- Update on the High Throughput Screening Initiative.
- Update on the Host Susceptibility Program.

The preliminary agenda, roster of NTP BSC members and *ad hoc* reviewers, proposed NTP research projects, public comments, and any additional information, when available, will be posted on the NTP BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) or

may be requested in hardcopy from the Executive Secretary for the NTP BSC (see **ADDRESSES** above). Following the meeting, summary minutes will be prepared and made available on the NTP meeting Web site.

Peer Review of the Draft NTP Brief on Bisphenol A

The NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) conducts scientifically based assessments of the potential for chemicals to adversely affect human reproduction and development. CERHR follows a multi-step process for its evaluations (66 FR 37047). Currently, CERHR is conducting an evaluation of bisphenol A (CAS RN: 80–5–07), a high production volume chemical used primarily in the production of polycarbonate plastics and epoxy resins. Polycarbonate plastics have many applications including food and drink packaging, compact discs, and medical devices, while epoxy resins are used as lacquers to coat metal products such as food cans, bottle tops, and water supply pipes. CERHR selected bisphenol A for evaluation because of its (1) High production volume, (2) widespread human exposure, (3) evidence of reproductive toxicity in laboratory animals, and (4) public concern.

As part of its evaluation process, CERHR has prepared the draft NTP Brief on bisphenol A that contains the NTP's conclusions and scientific support on whether or not exposure to this chemical presents a concern for human reproduction or the development of children. The draft brief is based on the CERHR Expert Panel Report on Bisphenol A released November 30, 2007, public comments on that report (the report and comments are available at *http://cerhr.niehs.nih.gov/chemicals/bisphenol/pubcomm-bisphenol.html*), and new studies related to the toxicity or biological activity of bisphenol A published since the February 2007 cut-off date for literature for the expert panel's deliberations.

The draft brief will undergo peer review at the NTP BSC meeting. The NTP invites written public comments on the draft NTP Brief on Bisphenol A and/or presentation of oral comments at the NTP BSC meeting (see ''Request for Comments'' below). The draft brief will be available on the CERHR Web site (*http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.html*) and the NTP BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) on April 15, 2008.

NTP Testing Program: Proposed Research Projects

The NTP actively seeks to identify and select for study chemicals and other substances for which sufficient information is not available to adequately evaluate potential human health hazards. The NTP accomplishes this goal through a formal open nomination and selection process. Substances considered appropriate for study generally fall into two broad, yet overlapping categories: (1) Substances judged to have high concern as possible public health hazards based on the extent of human exposure and/or suspicion of toxicity and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, e.g., by facilitating cross-species extrapolation or evaluating dose-response relationships. Nominations are subject to a multi-step, formal process of review before selections for testing are made and toxicological studies are designed and implemented. The nomination review and selection process is accomplished through the participation of representatives from the NIEHS, other federal agencies represented on the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), the NTP BSC, the NTP Executive Committee—the NTP federal interagency policy body, and the public. The nomination review and selection process is described in further detail on the NTP Web site (*http://ntp.niehs.nih.gov;* select ''Nominations to the Testing Program'').

Table 1 lists new nominations to be reviewed at the NTP BSC meeting. Background documents for each nomination are available on the NTP Web site at *http://ntp.niehs.nih.gov/go/nom*. The NTP invites interested parties to submit written comments, provide supplementary information, and/or present oral comments at the NTP BSC meeting on the nominated substances and preliminary study recommendations that appear in Table 1 (see ''Request for Comments'' below). The NTP welcomes toxicology study information from completed, ongoing, or anticipated studies, as well as information on current U.S. production levels, use or consumption patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. The NTP is interested in identifying appropriate animal and non-animal experimental models for mechanistic-based research, including genetically modified rodents and high-throughput *in vitro* test methods, and as such, solicits comments regarding the use of specific *in vivo* and *in vitro* experimental approaches to address questions relevant to the nominated substances and issues under consideration. Although the deadline for submission of written comments to be considered at the NTP BSC meeting is May 23, 2008 (see ''Request for Comments'' below), the NTP welcomes comments or additional information on these study nominations at any time.

TABLE 1.—TESTING RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES

Substance [CAS No.]	Nominated by [1]	Nomination rationale	Preliminary study recommendations [2]
Dimorpholinodiethyl ether [6425–39–4].	NCI	High production volume; potential worker exposures; lack of adequate toxicological data; suspicion of toxicity based on structure.	—Initial toxicological characterization. —Studies to assess the potential for nitrosation.
2-Ethylhexyl *p*-methoxycinnamate [5466–77–3].	NCI	High production volume; widespread consumer exposure as a common sunscreen active ingredient; reported estrogenic and reproductive effects.	—Comprehensive toxicological characterization including carcinogenicity and developmental toxicity studies. —Characterization of photodecomposition products.
4,7,10-Trioxatridecane-1,13-diamine [4246–51–9].	NCI	High production volume; potential worker exposures; lack of adequate toxicological data; acutely toxic.	—Biomolecular screening studies. —Genotoxicity studies.

TABLE 1.—TESTING RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES—Continued

Substance [CAS No.]	Nominated by [1]	Nomination rationale	Preliminary study recommendations [2]
Vanadium, tetravalent and pentavalent forms.	NIEHS, U.S. Environmental Protection Agency.	Widespread occurrence as drinking water contaminant and use as a dietary supplement; EPA Drinking Water Contaminant Candidate List research need; pentavalent form is carcinogenic via the inhalation route; inadequate data to assess risk of oral exposures.	—Comprehensive toxicological characterization. —Chronic toxicity and carcinogenicity studies via oral route of administration. —Multi-generation reproductive and developmental toxicity studies.

[1] National Institute of Environmental Health Sciences (NIEHS); National Cancer Institute (NCI).

[2] The terms ''initial toxicological characterization'' and ''comprehensive toxicological characterization'' in this table refer to the approximate scope of a research program to address toxicological data needs. The types of toxicological studies that would be considered by NTP staff during the conceptualization and design of a research program for each are:

—Initial toxicological characterization: Biomolecular screening, *in vitro* mechanistic, *in vitro* and *in vivo* genotoxicity, absorption, disposition, metabolism, and elimination, and short-term repeat dose (2–4 weeks) *in vivo* studies.

—Comprehensive toxicological characterization: All of the aforementioned plus subchronic toxicity (13–26 weeks), chronic toxicity (1–2 years), carcinogenicity in conventional or genetically modified rodent models, organ systems toxicity (immunotoxicity, reproductive and developmental toxicity, neurotoxicity), *in vivo* mechanistic, toxicokinetics, and other special studies as appropriate (e.g., chemistry, toxicogenomics, phototoxicity).

To facilitate review of proposed research projects by the NTP BSC and the public, NTP staff developed a draft research concept document for each nomination recommended for study. A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program tailored for each nomination. The purpose of these research concepts is to outline the general elements of a program of study that would address the specific issues that prompted the nomination, but also encompass studies that may address larger public health issues, or topics in toxicology that could be appropriately addressed through studies on the nominated agent. Draft research concepts for the new nominations listed in Table 1 will be available on the NTP BSC meeting page (*http://ntp.niehs.nih.gov/go/165*) by May 7, 2008.

In addition to review of the new nominations in Table 1, the NTP BSC will review proposed research projects for (1) furan [CAS RN: 110–00–9]; and (2) melamine [CAS RN: 108–78–1] and cyanuric acid [CAS RN: 108–80–5]. Draft research concepts for these proposed projects will be available on the NTP BSC meeting page (*http://ntp.niehs.nih.gov/go/165*) by May 7, 2008.

Attendance and Registration

The meeting is scheduled for June 11–12, 2008, beginning at 8:30 a.m. on each day and continuing to 5 p.m. on June 1 and on June 12 until adjournment. The meeting is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) by June 4, 2008, to facilitate planning for the meeting. The NTP is making plans to videocast the meeting through the Internet at *http://www.niehs.nih.gov/news/video/live.*

Request for Comments

Written comments submitted in response to this notice should be received by May 23, 2008. Comments will be posted on the NTP BSC meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, e-mail, and sponsoring organization (if any) with the document.

Time will be allotted during the meeting for the public to present oral comments to the NTP BSC on the agenda topics. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the NTP BSC chair. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP BSC (see **ADDRESSES** above) by June 4, 2008, to enable review by the NTP BSC prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the NTP BSC and NIEHS/NTP staff and to supplement the record.

Background Information on the NTP Board of Scientific Counselors

The NTP BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the overall program and its centers. Specifically, the NTP BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. NTP BSC meetings are held annually or biannually.

Dated: April 4, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–7831 Filed 4–11–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Advisory Committee on Blood Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Office of Public Health and Science (OPHS) is seeking nominations of qualified individuals to be considered for appointment as members of the Advisory Committee on Blood Safety and Availability (ACBSA). ACBSA is a Federal advisory committee in the Department of Health and Human Services. Management support for the activities of this Committee is the responsibility of the OPHS.

The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration of appointment as members of the ACBSA. Members of the Committee, including the Chair, are appointed by the Secretary. Members are invited to serve on the Committee for overlapping four-year terms.

DATES: All nominations must be received no later than 4 p.m. EDT on June 30, 2008, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Dr. Jerry Holmberg, Executive Secretary, Advisory Committee on Blood Safety and Availability; Office of Public Health and Science; Department of Health and Human Services; 1101 Wootton Parkway, Suite 250; Rockville, MD 20852. *Telephone:* (240) 453–8803.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry Holmberg, Executive Secretary, Advisory Committee on Blood Safety and Availability. *Contact information for Dr. Holmberg is the same as previously provided.*

A copy of the Committee charter and roster of the current membership can be obtained by contacting Dr. Holmberg or by accessing the ACBSA Web site at *http://www.hhs.gov/bloodsafety.*

SUPPLEMENTARY INFORMATION: The Advisory Committee on Blood Safety and Availability provides advice to the Secretary and to the Assistant Secretary for Health. The Committee provides advice on a range of policy issues to include: (1) Definition of public health parameters around safety and availability of the blood and blood products, (2) broad public health, ethical and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and availability of various economic factors affecting product cost and supply.

The ACBSA consists of 18 voting members. The Committee is composed of 12 public members, including the Chair, and six (6) representative members. The public members are selected from State and local organizations, advocacy groups, provider organizations, academic researchers, ethicists, private physicians, scientists, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products. The six individuals who are appointed as official representative members are selected to serve the interests of the blood and blood products industry or professional organizations associated with transfusion or transplantation safety. The representative members are selected from the following groups: the AABB, the Plasma Protein Therapeutic Association (PPTA), one of the two major distributors of blood on a rotating basis, a trade organization or manufacturer of blood, plasma, or other tissue test kits or equipment, and a purchaser of blood and blood products from a major hospital organization.

All ACBSA members are authorized to receive the prescribed per diem allowance and reimbursement for travel expenses that are incurred to attend meetings and conduct Committee-related business, in accordance with Standard Government Travel Regulations. Individuals who are appointed to serve as public members are authorized also to receive a stipend for attending Committee meetings and to carry out other Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive a stipend for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to fill positions on the ACBSA that are scheduled to be vacated in the public member category. The positions are scheduled to be vacated on December 31, 2008.

Nominations

In accordance with the charter, persons nominated for appointment as members of the ACBSA should be among authorities knowledgeable in blood banking, transfusion medicine, plasma therapies, transfusion and transplantation safety, bioethics, and/or related disciplines. Nominations should be typewritten. The following information should be included in the package of materials submitted for each individual being nominated for consideration of appointment: (a) The name, return address, daytime telephone number and affiliation(s) of the individual being nominated, the basis for the individual's nomination, the category for which the individual is being nominated, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the Committee; (b) the name, return address, and daytime telephone number at which the nominator may be contacted. Organizational nominators must identify a principal contact person in addition to the contact; and (c) a copy of a current curriculum vitae or resume for the nominated individual.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department of Health and Human Services is committed to ensuring that women, minority groups, and physically challenged individuals are adequately represented on the Committee. Nominations of qualified candidates from these categories are encouraged. The Department also seeks to have geographic diversity reflected in the composition of the Committee.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special Government employees (SGEs). SGEs are Government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of the ACBSA are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: April 9, 2008.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. E8–7986 Filed 4–14–08; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Statement of Organization, Functions and Delegations of Authority

Part J (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 71 FR 58396–5 8397, dated October 3, 2006) is amended to reflect the reorganization of the Office of the Director, Agency for Toxic Substances and Disease Registry.

Section J–B, Organization and Functions, is hereby amended as follows:

After item (9) of the functional statement for the *Office of the Director (JAA), Agency for Toxic Substances and Disease Registry* (J), add the following: (10) serves as primary liaison between ATSDR and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

Delete in their entirety the title and functional statement for the *Office of Communications (JAA4)*.

Dated: April 2, 2008.

Joseph Henderson,

Acting Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. E8–7855 Filed 4–14–08; 8:45 am]

BILLING CODE 4160–70–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–08AW]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. Alternatively, to obtain a copy of the data collection plans and instrument, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to *omb@cdc.gov.*

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarify of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Quarantine Station Illness Response Forms—Airline, Maritime, Land/Border Crossing—New—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

CDC proposes to collect patient-level clinical, epidemiologic, and demographic data from ill travelers and their possible contacts in order to fulfill its regulatory responsibility to prevent the importation of communicable diseases from foreign countries (42 CFR Part 71) and interstate control of communicable diseases in humans (42 CFR Part 70).

Background and Brief Description

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. The regulations that implement this law, 42 CFR Parts 70 and 71, authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances (*e.g.*, airplanes, cruise ships, trucks, etc.), persons, and shipments of animals and etiologic agents in order to protect the public health. The regulations also require conveyances to immediately report an ''ill person'' or any death on board to the Quarantine Station prior to arrival in the United States. An ''ill person'' is defined in statute by:

—Fever (≥100 °F or 38 °C) persisting ≥48 hours

—Fever (≥100 °F or 38 °C) AND rash, glandular swelling, or jaundice

—Diarrhea (≥3 stools in 24 hours or greater than normal amount)

The SARS situation and concern about pandemic influenza and other communicable diseases have prompted CDC Quarantine Stations to recommend that *all* illnesses be reported prior to arrival.

CDC Quarantine Stations are currently located at 20 international U.S. Ports of Entry. When a suspected illness is reported to the Quarantine Station, officers promptly respond to this report by meeting the incoming conveyance (when possible), collecting information and evaluating the patient(s), and determining whether an ill person can safely be admitted into the U.S. If Quarantine Station staff are unable to meet the conveyance, the crew or medical staff of the conveyance are trained to complete the required documentation and forward it (using a secure system) to the Quarantine Station for review and follow-up.

To perform these tasks in a streamlined manner and ensure that all relevant information is collected in the most efficient and timely manner possible, Quarantine Stations use a number of forms—the Airline Screening and Illness Response Form, the Ship Illness/Death Reporting Form, and the Land/Border Crossing Form—to collect data on passengers with suspected illness and other travelers/crew who may have been exposed to an illness. These forms are also used to respond to a report of a death aboard a conveyance.

The purpose of all three forms is the same: to collect information that helps quarantine officials detect and respond to potential public health communicable disease threats. All three forms collect the following categories of information: Demographics and mode of transportation, clinical and medical history, and any other relevant facts (*e.g.*, travel history, traveling companions, etc.). As part of this documentation, quarantine public health officers look for specific signs and symptoms common to the nine quarantinable diseases (Pandemic influenza; SARS; Cholera; Plague; Diphtheria; Infectious Tuberculosis; Smallpox; Yellow fever; and Viral Hemorrhagic Fevers), as well as most communicable diseases in general. These signs and symptoms include fever, difficulty breathing, shortness of breath, cough, diarrhea, jaundice, or

signs of a neurological infection. The forms also collect data specific to the traveler's conveyance.

These data are used by Quarantine Stations to make decisions about a passenger's suspected illness as well as its communicability. This in turn enables Quarantine Station staff to assist conveyances in the public health management of passengers and crew.

The estimated total burden on the public, included in the chart below, can vary a great deal depending on the severity of the illness being reported, the number of contacts, the number of follow-up inquiries required, and who is recording the information (*e.g.*, Quarantine Station staff versus the conveyance medical authority). In all cases, Quarantine Stations have implemented practices and procedures that balance the health and safety of the American public against the public's desire for minimal interference with their travel and trade. Whenever possible, Quarantine Station staff obtain information from other documentation (*e.g.*, manifest order, other airline documents) to reduce the amount of the public burden.

There is no cost to respondents other than their time to complete the survey. The annualized burden for this data collection is 172 hours.

ESTIMATE OF ANNUALIZED BURDEN

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Airline Illness or Death Investigation Form	1320	1	6/60	132
International Maritime Illness or Death Report	200	1	3/60	10
International Maritime Illness or Death Investigation Form	200	1	7/60	24
Land Border Illness or Death Investigation Form	60	1	6/60	6
Total				172

Dated: April 8, 2008.

Maryam I. Daneshvar,

Acting Reports and Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–7969 Filed 4–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–0621]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960, send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

2009 and 2011 National Youth Tobacco Surveys (NYTS)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to renew OMB clearance of the National Youth Tobacco Survey (NYTS) (OMB No. 0920–0621; exp. date December 31, 2008), a national school-based study to be conducted in 2009 and 2011. The NYTS was previously funded by the American Legacy Foundation in 1999, 2000, and 2002. The NYTS was funded by CDC in 2004 and additional surveys were conducted in 2004 and 2006. The proposed revision will incorporate minor changes to the burden estimate and the survey instrument.

The NYTS is the most comprehensive source of nationally representative tobacco data among students in grades 9–12, moreover, the NYTS is the only source of such national data for students in grades 6–8. The NYTS covers the following topics related to youth tobacco use: use of cigarettes, smokeless tobacco, cigars, pipes, bidis, and kreteks; knowledge and attitudes; media and advertising; access to tobacco products and enforcement of restrictions on access; school curriculum; environmental tobacco smoke exposure; and cessation. The NYTS provides national estimates of tobacco use behaviors, information about exposure to pro- and anti-tobacco influences, and information about racial and ethnic disparities in tobacco-related topics. Information collected through the NYTS is used to identify trends over time, to inform the development of tobacco cessation programs for youth, and to evaluate the effectiveness of existing interventions and programs.

Tobacco use is a major preventable cause of morbidity and mortality in the U.S. and is one of the 28 focus areas in Healthy People 2010. Within the Healthy People 2010 focus area of tobacco use, the NYTS provides data relevant to six health objectives. The survey also provides data to monitor one of the 10 leading health indicators for Healthy People 2010 that addresses tobacco use.

In Spring 2009 and Spring 2011, the NYTS will be conducted among nationally representative samples of students attending public and private schools in grades 6–12. The NYTS is administered to students as an optically scannable, eight-page booklet of multiple-choice questions. Information supporting the NYTS also will be collected from state-, district-, and school-level administrators and

teachers. The table below reports the combined total number of respondents for the 2009 and 2011 NYTS annualized over the 3-year project period.

There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Administrators	State-level Recruitment Script for the National Youth Tobacco Survey.	17	1	30/60	9
District Administrators	District-level Recruitment Script for the National Youth Tobacco Survey.	80	1	30/60	40.0
School Administrators	School-level Recruitment Script for the National Youth Tobacco Survey.	133	1	30/60	67
Teachers	Data Collection Checklist for the National Youth Tobacco Survey.	595	1	15/60	149
Students	National Youth Tobacco Survey	12,659	1	45/60	9,494
Total					9,759

Dated: April 8, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–7970 Filed 4–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–08–08AB]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

All Age Influenza Hospitalization Surveillance (Flu Hosp)—New—National Center for Immunization and Respiratory Diseases (NCIRD) Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The data collection network is an established CDC-state-academic institution collaborative network, the Emerging Infections Program (EIP) which includes defined catchment areas in the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. From October 1 through April 30 (flu season), Flu Hosp sites will collect data in selected catchment areas using case report forms. Participating sites will also complete discharge audit forms following flu season.

A standardized case report form will be completed for all persons meeting the case definition and inclusion criteria in the selected catchment areas. Most of the case report forms can be completed using data obtained from the laboratory and medical chart review. If the medical chart is not available, or the necessary information is not included in the medical record, the patient or their proxy may be interviewed.

To address any limitation in completeness of case identification, a retrospective discharge audit will be conducted by each participating site following flu season. Based on a range of discharge diagnoses, persons aged 18 years or older who are residents of a geographically-defined area and who were admitted to hospitals during October 1, 2007 through April 30, 2008, will have their medical chart examined to identify whether they had an influenza positive test result at the beginning of their hospitalization. The discharge audit will determine if cases were missed by usual case ascertainment methods. The completeness evaluation is a matching (or linking) project, followed by chart abstraction of missed cases.

The need for the information and proposed use(s) of the information are necessary because currently there is no national surveillance system in place that is able to estimate the burden of laboratory-confirmed adult hospitalizations during seasonal or pandemic influenza within a given season. Additionally, because influenza is often underreported, including a retrospective discharge audit in addition to conducting prospective surveillance is needed to identify limitations in current surveillance efforts.

The respondents for each of the forms are the 10 state health departments who submit biweekly case report forms for pediatric and adult influenza surveillance, and who submit discharge audit forms to CDC. Responses for the case report forms indicate the number of cases that are identified. The number of responses for all case report forms must be estimated as we do not know before hand how many cases will occur. Respondents are required to submit data for the Adult Flu Hosp project and the Pediatric Influenza Project to the CDC bi-weekly during flu season. Responses for Discharge Audit forms A–D indicate the number of times each site is required to fill out the respective form. Data for the Discharge audit will be a one-time data collection for each case. Although 10 states participate in Flu Hosp, because New York includes two functionally and geographically different catchment areas, those two areas will submit individual discharge audit data, to make a total of 11 respondents.

There are no costs to respondents other than their time. The total estimated annualized burden is 508 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pediatric Influenza Hospitalization Surveillance Project Case Report Form.	Health Department	10	75	15/60
Adult Influenza Hospitalization Surveillance Project Case Report Form.	Health Department	10	120	15/60
Adult Discharge Audit Case Report Form	Health Department	11	3	15/60
Adult Discharge Audit Form A: Description of Matching Method	Health Department	11	1	15/60
Adult Discharge Audit Form B: Sampling Strategy	Health Department	11	1	15/60
Adult Discharge Audit Form C: Summary	Health Department	11	1	15/60
Adult Discharge Audit Form D: Future	Health Department	11	1	15/60

Dated: April 8, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–7971 Filed 4–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–0572]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Health Message Testing System, 0920—0572—Revision—National Center for Health Marketing (NCHM), Coordinating Center for Health Information and Service (CCHIS), Centers for Disease Control and Prevention CDC).

Background and Brief Description

The National Center for Health Marketing (NCHM) was established as part of the Centers for Disease Control and Prevention's Futures Initiative to help ensure that health information, interventions, and programs at CDC are based on sound science, objectivity, and continuous customer input.

Before CDC disseminates a health message to the public, the message always undergoes scientific review. However, reflecting the current state of scientific knowledge accurately provides no guarantee that the public will understand a health message or that the message will move people to take recommended action. Communication theorists and researchers agree that for health messages to be as clear and influential as possible, target audience members or representatives must be involved in developing the messages and provisional versions of the messages must be tested with members of the target audience.

However, increasingly there are circumstances when CDC must move swiftly to protect life, prevent disease, or calm public anxiety. Health message testing is even more important in these instances, because of the critical nature of the information need. Consider the following situations:

CDC must communicate about a hazard, outbreak, or other emergency that presents an urgent threat to one or more segments of the public. The national crisis in which anthrax spores contaminated mail, postal facilities, and congressional buildings is a striking example.

CDC receives a mandate from Congress with a tight deadline for communicating with the public about a specific topic. For example, in 1998 Congress gave CDC 120 days to develop and test messages for a public information campaign about *Helicobacter pylori,* a bacterium that can cause stomach ulcers and increase cancer risk if an infected individual is not treated with antibiotics.

Emerging lifestyle or technological trends create an ephemeral opportunity to leverage the attention or behavior of the public to increase the reach and/or salience of prevention messages. For example, media monitoring reveals a partnership between Napster, a music-based web site, and the Pennsylvania State University. This partnership creates an ample opportunity for CDC to join in the collaboration to reach students with a salient health promotion message. For instance, a ticker found on the top of the Napster homepage screen might contain an informational URL followed by a message encouraging students, especially those residing in dormitories, to receive the meningitis inoculation series at their campus health center. This message would be tailored prior to the beginning of each academic year and would need to be posted in a timely manner before the arrival of the incoming freshman class.

Of equal importance, this communication mechanism can be effectively used in emergency ''rapid response'' situations such as the campus shooting incidents at Virginia Tech and North Illinois University.

In the interest of timely health message dissemination, many programs forgo the important step of testing messages on dimensions such as clarity, salience, appeal, and persuasiveness (i.e., the ability to influence behavioral intention). Skipping this step avoids the delay involved in the standard OMB review process, but at a high potential

cost. Untested messages can waste communication resources and opportunities because the messages can be perceived as unclear or irrelevant. Untested messages can also have unintended consequences, such as jeopardizing the credibility of Federal health officials.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Central Location Intercept Interviews	300	12	5/60	300
Telephone Interviews	300	12	4/60	240
Individual In-depth Interview (Cognitive Interviews)	200	10	6/60	200
Focus Group Screenings	900	10	3/60	450
Focus Groups	300	20	8/60	.....
Online Surveys	400	12	6/60	480
Total	2,400	.....	.....	2,470

Dated: April 8, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–7973 Filed 4–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention, (ACD, CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC, announces the following meeting of the aforementioned committee:

Time and Date: 8 a.m.—4 p.m., May 1, 2008.

Place: CDC, Tom Harkin Global Communications Center, Auditorium B, 1600 Clifton Road, Atlanta, GA 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 150 people.

Purpose: The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

Matters To Be Discussed: Agenda items will include discussions on health systems transformation.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Brad Perkins, M.D., M.B.A., Executive Officer, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE., M/S D–14, Atlanta, Georgia 30333; Telephone (404) 639–7000.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–8039 Filed 4–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control/Initial Review Group, (NCIPC/IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned review group:

Time and Date: 1 p.m.–3 p.m., May 9, 2008 (closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct research on environmental exposures to hazardous substances.

Matters to be Discused: The meeting will include the review, discussion, and evaluation of cooperative agreement applications submitted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcement: TS08–001, Program on Exposure-Dose Reconstruction and Computational Methods to Quantify Exposures to Hazardous Substances.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: J. Felix Rogers, Ph.D., M.P.H., NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, Georgia 30341, Telephone (770) 488–4334.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–7975 Filed 4–14–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services 45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 73 FR 6728, dated February 2, 2008, is amended to reflect the reorganization of the National Center for Health Marketing, Coordinating Center for Health Information and Service,

Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows: Delete in their entirety the functional statements for the *National Center for Health Marketing (CPB),* and insert the following:

National Center for Health Marketing (CPB). The mission of the National Center for Health Marketing (NCHM) is to protect and promote the public's health through collaborative and innovative health marketing programs, products, and services that are customer-centered, science-based, and high-impact.

In carrying out its mission, NCHM: (1) Ensures the Centers for Disease Control and Prevention (CDC) has the necessary marketing and prevention research data to develop information, interventions, and programs that respond to customers' needs, values, and uses; (2) develops and evaluates rigorous research-based strategies for providing information, programs, and services; (3) develops and tests communication messages and programs for public and professional audiences; (4) ensures that CDC risk and emergency communication messages are effectively delivered to targeted audiences; (5) works collaboratively to manage the CDC brand and ensures the CDC brand/identity is promoted throughout all CDC marketing/communication channels; (6) provides value added cross-cutting scientific support to ensure the best available public health science is rapidly and reliably translated into effective practice and policy; (7) ensures efficient, focused use of CDC's expertise and mechanisms for delivering health information and services; (8) ensures customers have effective, real-time access to needed health and safety information, interventions, and programs through communication channels they prefer; (9) delivers CDC information and services to the public; (10) ensures effective strategic partnerships and alliances to extend CDC's reach; (11) increases public awareness and partner actions to enhance the public health infrastructure; (12) helps people understand public health and its relevance and value to people across all life stages; (13) fosters the development and/or improvement of methods by which the partnership of federal, state, and local public health agencies can assure the coordinated and effective establishment of priorities and responses to public health problems; (14) maintains a forum for communication, coordination, collaboration, and consensus among the National Centers (NC) of CDC, public agencies, and private organizations concerned with ensuring the quality of public health practice; (15) works collaboratively with academic institutions, especially schools of public health and departments of preventive medicine, to develop and evaluate all aspects of marketing and communication elements; (16) provides a central service for consultation, design, production, and evaluation of media and instructional services to support CDC's delivery of public health messages; (17) manages marketing-related shared services and in carrying out the above functions, collaborates, as appropriate, with other Coordinating Centers/Coordinating Offices (CC/CO), NCs, and Staff Offices (SO) of CDC; (18) oversees the management, development, implementation, and evaluation of CDC's primary Web site, *http://www.cdc.gov* and serves as a CDC-wide resource for communication technologies design, usability, and maintenance; (19) leads CDC's e-health marketing/communication efforts; and (20) leads NCHM efforts to apply new technologies, social networks, virtual worlds, and other new/emerging technologies to develop, enhance, maintain and deliver CDC information.

Office of the Director (CPB1). (1) Manages, directs, coordinates, and evaluates the activities of NCHM; (2) develops goals and objectives and provides leadership, policy formation, scientific oversight, and guidance in program planning, development, and integration; (3) coordinates assistance and oversight provided by NCHM to other CDC components, federal, state, and local government agencies, and the private sector; (4) chairs the CDC Excellence in Marketing Committee; (5) provides leadership and coordination for NCHM crosscutting programs including Global Health Marketing, Emergency Preparedness, Client and Collaborator Relations, and other center and agency-wide priority programs; (6) establishes, administers, and coordinates CDC's health communication and marketing policies to ensure communication efforts reflect the scientific integrity of all CDC research, programs, and activities, and information is factual, accurate, and targeted toward improving public health; (7) oversees NCHM-wide administrative and program services, and coordinates or assures coordination with the appropriate CDC offices on administrative and program matters; (8) promotes, stimulates, conducts, and supports research on health communication topics of CDC-wide interest; (9) maintains liaison with officials from the Department of Health and Human Services (HHS), other federal and state public health agencies, and non-profit and voluntary health agencies to coordinate health communication programs of mutual interest and concern; (10) manages and coordinates staff professional development trainings related to health marketing and health communication; (11) provides leadership and coordination for NCHM client and collaborator relationship activities; (12) manages and coordinates HHS clearance for CDC communications and marketing programs and related products, and Office of Management and Budget (OMB) clearance submissions for marketing and communication research; (13) develops new mechanisms for agency-level communications with the public including the CDC-INFO hotline and e-mail response systems, CDC publications system, electronic journals and newsletters, and subscription e-mail systems; and (14) establishes and manages a unified, comprehensive, high-quality CDC presence at selected public health conferences and health expositions.

Business Services Office (CPB13). (1) Provides leadership, oversight, and guidance in the management and operations of NCHM's programs; (2) plans, coordinates, and provides administrative management support, advice, and guidance to NCHM, in the areas of fiscal management, personnel, travel, and other administrative services; (3) coordinates the development of the NCHM annual budget submission and spending plans; (4) directs and coordinates the activities of the office; (5) conducts management analyses of NCHM programs, resources, and staff to ensure optimal utilization of resources and accomplishment of program objectives; (6) plans, allocates, and monitors NCHM resources; (7) maintains liaison and collaborates with other CDC components and external organizations in support of NCHM management and operations; (8) plans, allocates, and monitors NCHM-wide administrative resources; (9) works closely with other federal agencies involved with NCHM interagency agreements; (10) coordinates NCHM requirements relating to procurement, materiel management, and interagency agreements; (11) develops and implements administrative policies, procedures, and operations, as appropriate for NCHM, and prepares special reports and studies, as required, in the administrative management areas; (12) provides coordinated services to

NCHM for all internal conference/meeting management; and (13) collaborates, as appropriate, with the CDC Office of the Director, other CDC offices, domestic and international agencies and organizations in carrying out the above functions.

Extramural Services Activity (CPB132). (1) Performs administrative management functions for extramural programs which are linked to research and non-research activities of NCI–IM and other CC/COs that utilize NCHM's and/or CCHIS's extramural mechanisms; (2) provides expertise in the funding and administration of extramural activities, including grants, cooperative agreements and contracts; (3) triages linked research projects and solicits peer review services from the Office of the Chief Science Officer; (4) conducts annual program planning activities and plans the award process cycle with NCHM, other CC/CO/NCs and PGO staff, (5) serves as the primary point of contact with PGO; (6) provides technical consultation on HHS and CDC/PGO grant and cooperative agreement policy and regulations; (7) provides fiscal management and stewardship of selected grants, contracts, and cooperative agreements; and (8) coordinates NCHM requirements relating to selected contracts, grants, cooperative agreements, and reimbursable agreements.

MMWR Office (CPB14). (1) Manages the *MMWR* series of publications including the MMWR Recommendations and Reports, *CDC Surveillance Summaries,* and *Annual Summary of Notifiable Diseases;* and (2) develops, plans, coordinates, edits, and produces the *MMWR* series, including the *MMWR Recommendations and Reports, CDC Surveillance Summaries,* and *Annual Summary of Notifiable Diseases.*

Health Communication Science Office (CPB15). The Health Communication Science Office (HCSO): (1) Serves as the principal advisor to the CO/NC director on communication and marketing science, research and practice, (2) leads respective CO/NC strategic planning for communication and marketing science programs and projects; (3) serves as key focal point for integrating CO/NC communications/health messages into cohesive marketing campaigns targeted to defined audiences to advance CDC's health protection goals; (4) collaborates with other CO/NC in the development of marketing communications targeted to populations within certain life stages or who would otherwise benefit from a cross-functional approach; (5) ensures use of scientifically sound research for marketing and communication programs and projects; (6) serves as liaison to internal and external groups (this function does not apply to the National Center for Health Statistics [NCHS]); (7) develops and manages relationships with internal and external partners and customers (this function does not apply to the National Center for Environmental Health Agency for Toxic Substances and Disease Registry nor to the NCHS); (8) ensures accurate, accessible, timely, and effective translation of science for use by multiple audiences (this function does not apply to NCHS); (9) leads identification and implementation of information dissemination channels (this function does not apply to NCHS); (10) supervises and manages HCSO activities, programs, and staff; (11) leads audience segmentation research; (12) analyzing context, situation, and environment to inform Center-wide communication and marketing programs and projects; (13) develops and manages clearance systems (this function does not apply to NCHS); (14) provides training and technical assistance; (15) collaborates on health media production, including graphics and broadcast production; (16) provides project management expertise (this function does not apply to NCHS); (17) collaborates on CDC brand management activities; (18) collaborates with CDC media relations staff to ensure consistent and timely translation of center-specific health information to multiple audiences (this function does not apply to NCHS).

The following functions (19–21) apply only to the National Center for Environmental Health Agency for Toxic Substances and Disease Registry: (19) collaborates with external organizations and the news, public service, and entertainment and other media to ensure that effective findings and their implications for public health reach the public; (20) collaborates closely with Divisions to produce materials designed for use by the news media, including press releases, letters to the editor, public service announcements, television programming, video news releases, and other electronic and printed materials; (21) coordinates the development and maintenance of center/agency-wide information systems through an internet home page.

The following functions (22–23) apply only to the National Center for Health Statistics: (22) serves as the liaison to internal and external groups for health marketing activities; and (23) provides project management expertise for health marketing activities.

Division of Health Communication and Marketing (CPBC). (1) Provides leadership in the development of CDC's priorities, strategies and practices for effective health communication and marketing to a wide range of target audiences; (2) provides a CDC-wide forum for the sharing of health communication and marketing information; collaboration across programs; and discussion, development and implementation of health marketing policies and practices; (3) assists the CC/CO/NC/SOs of CDC in conducting formative, process and outcome research, and evaluation of specific applications of health communication and marketing in program areas; (4) assists the CC/CO/NC/SOs in identifying appropriate target audiences and messages; (5) assists the CC/CO/NC/SOs and their constituents in identifying and building expertise and state-of-the-art technology, logistical support, and other capacities required for effective health communication and marketing; (6) systematically conducts, collects, assesses and disseminates health communication and marketing research, evaluation results, and information on trends and emerging issues; (7) provides leadership for and ensuring coordination of risk, emergency, and terrorism communication; and (8) conducts evidence-based reviews of effective community health interventions.

Office of the Director (CPBC1). (1) Develops, manages, directs, and coordinates the implementation of strategic priorities and programmatic activities for the division; (2) establishes division goals and objectives; (3) provides oversight and coordination for division activities including personnel, budget, and administrative functions; (4) advises the directors of NCHM, CCHIS, CDC, and other CC/CO/NC/SOs on all matters related to health communication and marketing; (5) ensures CDC health marketing and communication activities follow policy directions established by the HHS Assistant Secretary for Public Affairs; (6) provides leadership in the development of CDC's priorities, strategies, and practices for effective health communication and marketing activities; (7) establishes strategy and oversight for emergency and risk communication efforts; (8) produces periodic reports and publications; (9) serves as point of contact and is responsible for agency and CC/CO/NC coordination for established programmatic activities as well as new initiatives; and (10) provides scientific leadership and guidance to the division.

Marketing and Communication Strategy Branch (CPBCB). (1) Provides a broad range of support for consultation,

coordination, and development of health communication and marketing program efforts across the agency; (2) identifies and pursues opportunities for bundling, embedding, and joint dissemination of CDC information to more effectively reach audiences; (3) monitors and refines strategies and messages based on evaluation and feedback mechanisms; (4) consults on conceptualizing, developing, planning, executing, and evaluating CDC health marketing and communication activities and campaigns, media buys, Public Service Announcements (PSA), and other CDC information; (5) establishes measures of success/effectiveness of CDC communication efforts and provides guidance to CDC programs on applying these measures; (6) ensures analytic function for interpretation of data from centralized marketing databases, sources of environmental scanning, and communication literature for use in development and implementation of strategies for communication activities; (7) provides an integrated marketing perspective to data collection and CDC data resources, using data from various sources to develop a more complete picture of the public and its health concerns/interests and to address cross cutting issues; (8) provides for efficient, agency-wide access to consumer-oriented databases that can help support public health marketing; (9) sponsors/initiates original health communication and marketing research; (10) manages a repository of CDC and external research on the effectiveness of programs and interventions (both for public and sector audiences), and promotes the use of such evidence throughout CDC; (11) ensures that the content of CDC scientific communications is accessible (available, understandable, actionable) to audiences that may have specific health literacy needs; (12) identifies and implements strategies for health literacy and multilingual translation and delivery of CDC information tailored to specific audiences for maximum health impact; (13) tailors science-based information to specific audiences based on the knowledge, literacy levels, and language, culture, interests, and level of scientific sophistication of those audiences; (14) identifies and implements strategies for translation and delivery of CDC information to key targeted audiences for maximum health impact; (15) directs, develops, and/or collaborates on channels for reaching the public with health messages that positively impact health; and (16) provides for systematic mechanisms for gaining public input on health issues and priorities (e.g., advisory mechanisms, focus groups, polling, legislative and media tracking) and for the systematic application of knowledge gained from such input into agency decision making.

Emergency and Risk Communication Branch (CPBCC). (1) Identifies and implements strategies for translation and delivery of CDC's risk and emergency communication messages to key targeted audiences for maximum health impact; (2) monitors, evaluates, and refines risk and emergency communication messages and channel selection, content, and use based on feedback mechanisms; (3) evaluates the reach and effectiveness of CDC's risk and emergency communication messages and products; (4) ensures the content of CDC's risk and emergency communication messages are accessible (available, understandable, actionable) and disseminated to the public and target audiences; (5) tailors science based information related to risk and emergency communication messages for key sector audiences using knowledge of the interests and level of scientific sophistication of those audiences; (6) manages, evaluates, and coordinates with selected/major channels CDC uses to push risk and emergency communication messages outward (e.g., media, distance learning, broadcast/satellite capability, messaging through Health Alert Network and the clinician registry, postings on the CDC website, and community and partner outreach); (7) manages and evaluates the content during national emergencies or terrorism events on selected/major channels the public uses to contact CDC (e.g., Internet, phone hotlines, public exhibition areas); (8) provides an integrated marketing perspective to risk emergency communication messages data collection and CDC data resources, using data from various sources to develop a more complete picture of the public and its health concerns/interests; (9) provides for systematic mechanisms for gaining public input on risk and emergency communication messages (e.g., advisory mechanisms, focus groups, polling, legislative inquiries, and media tracking), for getting customer feedback on CDC programs (Web site and 800 number feedback, user surveys, feedback from partners, media tracking), and for the systematic application of knowledge gained from such input into agency decision making; (10) sponsors/initiates original research related to risk and emergency communication messages on customer needs and interests; needs and interests of key sectors and partners; audience segmentation; and approaches to bundling and packaging of CDC offerings; and (11) develops and manages selected channels to deliver national emergency and terrorism-related messages.

Community Guide Branch (CPBCD). (1) Convenes and supports the independent Task Force on Community Preventive Services, which develops evidence-based recommendations for the use or non-use of population-based health interventions; (2) produces and promotes the use of the *Guide to Community Preventive Services* (aka *Community Guide*) which is a compilation of the systematic reviews, evidence-based recommendations, and research needs related to best public health practices; (3) performs evidence reviews of the efficacy and effectiveness of prevention activities not associated with the *Community Guide*; (4) assists CDC and other federal and non-federal partners in understanding, using, refining, and communicating methods for conducting systematic reviews; (5) assists CDC and other federal and non-federal partners in linking reviews of evidence to guidelines development and/or program implementation; (6) coordinates and manages large and diverse teams of internal and external partners in the systematic review process; (7) coordinates and manages a working group of CDC, HHS, and nongovernmental partners to develop and/or refine methods for conducting systematic reviews; (8) provides consultations for implementing *Community Guide* recommended strategies; (9) coordinates and manages a working group of CDC, HHS and nongovernmental partners to diffuse *Community Guide* reviews, recommendations, and research needs to appropriate audiences throughout the U.S. health care and public health systems; (10) participates in the development of national and regional public/private partnerships to enhance prevention research and the translation of evidence into policy and action; (11) conducts selected scientific evaluation of the center or division-related prevention activities; (12) communicates the *Community Guide* reviews, recommendations, and research needs beyond the *Morbidity and Mortality Weekly Report (MMWR)* and the *American Journal of Preventive Medicine/AJPM,* publications via other journals, books, the world wide Web, and other media; (13) designs and conducts programmatic, process and outcome evaluation strategies for all stages of development and diffusion of the *Community Guide;* and (14) assists

in making recommendations for prevention and policy decisions.

Division of Partnerships and Strategic Alliances (CPBD). (1) Provides leadership in the development and coordination of high-priority partnerships and sets strategy and goals for working with private and public partnership sectors including business, health care, education, federal agencies, and faith and community organizations, the public health community, especially state and local health organizations and their regional and national affiliate organizations, and emergency planning, preparedness, and response partners; (2) identifies critical cross-CDC relationships to maximize CDC's success in achieving priority health goals; (3) develops protocols for partnership ''triage'' to ensure timely and effective coordination; (4) serves as the agency-level contact on significant issues for major partners, or priority target partners; (5) provides leadership in building strategic relationships with new partners and extending the range of existing partnerships; (6) develops and maintains a database for high-priority, cross-cutting relationships; (7) provides leadership in developing systematic mechanisms for gaining public and private sectors and public health systems' input on health issues and priorities; identifies and pursues opportunities for broadening the range of approaches used by programs; (8) provides leadership in identifying and implementing strategies for effective delivery of CDC information to key sector and public health systems' audiences; (9) provides targeted, science-based information for key sector audiences; (10) provides leadership in the development of new mechanisms for agency-level communications with specific sectors; (11) leads partner teams in Director's Emergency Operations Center (DEOC) for emergency planning, response, and recovery; (12) coordinates field assignees for public health systems and partnerships; and (13) manages program management and project officer coordination for all partnership cooperative agreements including those applications submitted under cross-cutting CDC umbrella cooperative agreements.

Office of the Director (CPBD 1). (1) Manages, directs, and coordinates the research agenda and activities of the division; (2) maintains partnership coordination database and directory; (3) develops strategy and planning, and provides leadership and guidance on strategic planning, policy, program and project priority planning and setting, program management and operations for agency-wide CDC partnerships; (4) identifies and prioritizes partnership sectors; (5) establishes division goals, objectives, and priorities; (6) monitors progress in implementation of projects and achievement of objectives; (7) provides management, administrative, and support services, and coordinates with the NCHM OD on program and administrative matters; (8) leads and supports the Excellence in Partnership Committee, representing the various CDC Centers and coordinating agency-wide partnership activities; (9) provides liaison on partnerships with other CDC organizations, other governmental agencies, private organizations, and other outside groups; (10) provides scientific leadership and guidance to the division; (11) leverages partner relationships to improve CDC's translation of science and research to practice; (12) leads activities to improve partner engagement as a means of informing CDC's science and practice; (13) collaborates with the CDC Foundation in its activities with businesses and business organizations; (14) assesses partners' needs and opportunities to enhance health protection; (15) coordinates and/or collaborates on CDC representation on HHS Healthy People 2010 and 2020; and (16) provides oversight for program management and project officer coordination for all partnership cooperative agreements including those applications submitted under cross-cutting CDC umbrella cooperative agreements.

Public Health Partners and Coordination Branch (CPBDB). (1) Provides leadership within CDC, with national public health organizations, and with governmental public health agencies to promote and support effective national partnerships for health promotion and disease prevention; (2) supports program management and project officers for all partnership cooperative agreements including those applications submitted under cross-cutting CDC umbrella cooperative agreements; (3) advises CC/CO/NC/SOs on program activities that strengthen the nation's public health system through effective linkages with governmental public health agencies and national public health organizations; (4) supports and encourages public health systems research aimed at strengthening the public health system with particular emphasis on optimizing performance of governmental public health agencies; (5) monitors and evaluates the nation's public health system with regard to emerging issues, system effectiveness and progress on achieving CDC's and the nation's public health goals; (6) provides knowledge and science based information critical to the effectiveness of the governmental public health systems to public health agencies; (7) provides leadership to CDC field staff in encouraging strong public health system capacity and partnerships; (8) establishes and maintains program linkages with the Office of Workforce and Career Development and the Office of the Chief of Public Health Practice to facilitate systems development; and (9) staffs the partner teams in the DEOC partner desk.

Private/Public Partner Sectors Branch (CPBDC). (1) Assures private and public sector, and state and local health organization management support in the selection, prioritization and implementation of CDC goals; (2) leverages partner relationships to improve CDC' s translation of science and research to practice; (3) supports activities to improve partner engagement as a means of informing CDC's science and practice; (4) provides leadership to CDC and other organizations to promote and support effective partnerships for health promotion and disease prevention in all partnership sectors; (5) provides leadership and supports CDC's activities related to business and worker organizations, public and private purchasers of health care, consumers, health care consultants, academic institutions, and others; (6) assists in coordinating support for CDC's interactions with business collaboration partners; (7) directs, coordinates, and evaluates critical CDC activities with major components of the health care sectors; (8) serves as a focal point for developing public and private sector communications on health care issues relevant to CDC's goals; (9) supports the collaboration with the CDC Foundation in its activities with businesses and business organizations; (10) establishes data systems and knowledge required to support public private alliances; (11) coordinates collaborative activities of the branch with other NCs, federal agencies, professional societies, and private health organizations; (12) assures ongoing, effective communication between the CDC and key educational organizations on issues related to the nation's health; (13) represents CDC to private sector organizations such as the Joint Commission on Accreditation of Healthcare Organizations, the National Quality Forum, the National Committee for Quality Assurance, the Quality Interagency Coordinating Task Force, the National Quality Report, the

Institute for Healthcare Improvement, and others; (14) assists educational organizations in implementing health interventions to reduce high-priority health risks among student populations; (15) collaborates with other components of CDC, Public Health Service, and HHS, the U.S. Department of Education and other federal agencies; national professional, voluntary, and philanthropic organizations; and international agencies and other organizations as appropriate; (16) provides a federal partner interface with CDC; (17) builds networks and partner relationships; (18) provides leadership and support to CDC's activities related to foundations, faith, and community organizations, their constituencies, and others; and (19) provides access for faith- and-community-based organizations to compete for federal funds supporting delivery of public services, including health-related services.

Division of Electronic Health Marketing (CPBG). (1) Supports NCHM and CDC through the creation, design, development, and evaluation of effective communication technologies that enhance the presentation and distribution of CDC's products and services; (2) assists CDC information developers in planning, designing, usability testing, and maintaining Web sites, mobile applications/devices, and other communication technologies; (3) provides leadership and management for CDC's Web site (*http://www.cdc.gov*) and provides overall management, guidance, and direction for CDC Web sites and other communication technologies; (4) develops a common user interface for CDC Web sites and ensures CDC branding across CDC's sites and other electronic products/services; (5) provides leadership for CDC–INFO, CDC's telephone, e-mail, and fulfillment services center; (6) conducts and supports research in user experience and communication technology areas in collaboration with other CDC/HHS organizations; (7) creates and distributes tools, standards/guidelines, and other resources to assist CDC information developers in designing usable, useful, and accessible Web sites and other communication technologies; (8) leads, coordinates, and/or supports the identification, evaluation, and implementation of new communication technologies that are relevant to CDC's mission and goals; (9) stays abreast of emerging and new communications technologies and identifies appropriate ones to adopt; (10) provides in-depth professional development in e-health and communication technologies research, design, and evaluation to CDC staff/contractors; (11) provides agency-wide leadership, coordination, and/or support of CDC's presence in online social networks; and (12) leads, coordinates, and/or supports online collaborations with partners.

Office of the Director (CPBG1). (1) Develops, manages, directs, and coordinates the implementation of strategic priorities and programmatic activities of the division; (2) establishes division goals and objectives; (3) provides oversight and coordination for division activities including personnel, budget and administrative functions; (4) advises the directors of NCHM, CCHIS, CDC, and the CC/CO/NC/SOs on all matters related to e-health marketing, new media, social networks, and user experience; (5) ensures CDC's e-health activities follow policy directions established by the HHS Assistant Secretary for Public Affairs, OMB, and others; (6) provides leadership in the development of CDC's priorities, strategies, and practices for effective e-health marketing, new media, social networks, and user experience activities; (7) produces periodic reports and publications; (8) serves as point of contact and is responsible for agency, CC/CO/NC/SOs coordination for established c-Health programmatic activities as well as new initiatives; (9) provides scientific leadership and guidance to the division; (10) serves as NCHIM liaison with the National Center for Public Health Informatics and other CDC CC/CO/NC/SOs for e-health-related activities; (11) collaborates with the Office of Workforce and Career Development and others to provide in-depth training and professional development in research-based communication technologies design and development; (12) leads and coordinates CDC.gov's governance bodies (CDC.gov Council, CDC.gov Executive Board, CDC.gov Executive Committee, and related workgroups), and e-Health-related Communities of Practice and work groups; and (13) provides oversight to CDC.gov and CDC-de web efforts.

Digital Content and Marketing Branch (CPBGB). (1) Develops policies, guidance, and best practices to improve the quality of CDC.gov content and marketing activities; (2) coordinates CDC.gov content and marketing activities with CDC NCs and other internal and external organizations; (3) assists with planning, development, deployment, and maintenance of a Content Management System for CDC.gov and other CDC sites; (4) assesses CDC marketing priorities and ensures those priorities are reflected on CDC.gov; (5) coordinates CDC's risk and emergency communications via e-health communication channels; (6) assists CDC CC/CO/NC/SOs with planning, designing, and evaluating content and marketing efforts for CDC Web sites and other communication technologies using research-based approaches/methodologies; (7) manages CDC's primary Web site, *http://www.cdc.gov*, and provides overall management, content coordination, technology coordination, site maintenance and operations; (8) manages CDC–INFO, CDC's call center, e-mail responses, and fulfillment contracts; (9) identifies gaps in CDC.gov content and works with NCs to fill those gaps; and (10) markets CDC's e-health products, services, and tools and reporting the results of those marketing efforts.

Interactive Media and User Experience Branch (CPBGC). (1) Creates/provides data collection tools to assess the broad range of user needs, requirements, limitations, and satisfaction levels for CDC Web sites and other communication technologies; (2) develops evidence-based guidelines, templates, and tools to guide CDC information developers in design/developing effective e-Health efforts; (3) identifies potential communication technologies (hardware, software, and applications) and determines their feasibility for application to CDC products and services; (4) assists CDC CC/CO/NC/SOs in implementing relevant emerging technologies and aiding in diffusing new technologies; (5) evaluates emerging communication technologies; (6) provides user centered design services (user data collection, prototype development, iterative usability testing); (7) collects/analyzes user data/metrics from communication technologies (Web usage statistics, online user performance tools, user satisfaction tools, search logs, and other sources) to assess system performance, usability, accessibility, and usefulness; (8) oversees the development and management of a state-of-the-art research/testing lab and training facility designed to research and test new communication technologies, design ideas, and the accessibility of older and newer software and technologies; (9) leads, coordinates, and/or supports NCHM efforts to identify, evaluate the feasibility of, and implement new and emerging communication technologies that are relevant to CDC's mission and goals; and (10) conducts and supports research in user experience, social networks, and new media and interactive communication technologies

in collaboration with other CDC/HHS organizations.

Division of Creative Services (CPBH). (1) Manages and utilizes production facilities and resources to create effective programs for delivery of CDC information to key target audiences; (2) collaborates on development and production of communication campaigns, PSAs, and other CDC information and services that are a high priority for the agency and/or cross-cutting; (3) provides and manages CDC-wide services including graphic design and production (e.g., documents, posters, displays, visual presentations, etc.), writer editor services, scientific and event photographic services, and mechanisms to reach primary broadcast channels (e.g. broadcast, audio, and video); (4) collects and/or facilitates distribution of graphic, digital, and broadcast materials; (5) produces and collaborates on new broadcast communication mechanisms (e.g. HHS TV, CDC TV, radio/TV broadcasting, pod casting, web casting, and video-on-demand) for agency-level communications with the public and partners to include selection and promotion of content on selected channels and evaluation of its reach; (6) provides oversight for broadcast delivery mechanisms for inbound and outbound broadcast communications (e.g., press conferences, interviews); and (7) researches and works with other agency programs to develop new mechanisms to communicate with the public.

Office of the Director (CPBH1). (1) Develops, manages, directs, and coordinates the implementation of strategic priorities and programmatic activities of the division; (2) establishes division goals and objectives; (3) provides oversight and coordination for division activities including personnel, budget and administrative functions; (4) sets up and implements tracking and triage system for managing incoming requests for creative services as well as tracking progress in accomplishing task objectives and overall division performance measures; (5) develops and implements performance management measures for the division; (6) establishes and maintains quality assurance editing to ensure service and product quality are consistent with outside industry; (7) overseas customer service performance for CDC-wide service offerings; (8) manages project and information archives to facilitate knowledge management and organizational efficiency; (9) serves as point of contact for agency graphics and broadcast capabilities and is responsible for agency wide coordination for established graphics and broadcast programmatic activities and new initiatives; (10) provides scientific leadership and guidance to the division; and (11) manages the Global Health Odyssey, CDC's scientific museum and learning center.

Client Services Branch (CPBHB). (1) Accepts, tracks, and triages client requests for division services; (2) assigns all creative service requests from across the agency to appropriate division branches or teams; (3) manages and maintains an online request, work flow tracking, and program service indicator system; (4) manages large or multidisciplinary projects through a team of client service staff who serve as the division's creative project coordinators with other organizations within CDC; (5) gathers and monitors customer satisfaction information and addresses concerns as necessary; (6) monitors and manages performance, and evaluates and communicates findings to the division leadership, CC/COs, and Chief Management Officials for follow-up and potential action; (7) analyzes data about services being provided to be used to determine budget, equipment, staffing and training needs; (8) collaborates on the maintenance of the Public Health Image Library, an internet archive of CDC's scientific and historical photographs; and (9) provides scientific and event photography.

Graphic Services Branch (CPBHC). (1) Coordinates agency-wide graphics activities; (2) designs, develops, and produces graphic illustrations, scientific posters, desktop presentations, conference materials, brochures, newsletters, and exhibits; (3) provides high-end medical illustration and art design for CDC products and services; and (4) provides creative direction/leadership for graphics products to ensure consistency with established agency guidelines and quality standards set within the division.

Broadcast Branch (CPBHD). (1) Develops, produces and manages audio, video, and multimedia health media; (2) provides agency-wide and global communication capacity using state-of-the-art high-definition broadcast, Webcast and emerging health media delivery channels on a real time and/or recorded basis; (3) responsible for media asset management of all broadcast video and audio programming developed within CDC; (4) supports the communication needs of the CDC's DEOC to assure response capacity and capability for emergency broadcasts; (5) manages all CDC broadcast-grade audio and video production requirements; (6) develops and delivers television programming, in coordination with HITS, to deliver timely and accurate information to improve health and safety for the U.S. public and around the world; (7) provides in-house creation, duplication and format conversion of products including VHS, S–VHS, DVD, CD–R, DAT, Mini-Dy, Betacam-SP, Digital-Betacam, DVC Pro-HD and international formats such as PAL, SECAM, SECAM–Il; (8) keeps abreast of changing video formats to ensure CDC keeps pace; (9) provides audio-only production services including: broadcast-grade, in-house audio production, audio-for-video, audio sweetening, mixing and editing to picture, voice-over, narration, format-conversions and delivery; (10) provides professional consultation and support in the creation and production of emerging health media transmission technologies; (11) develops and collaborates on agency-wide communication products and processes through multimedia and digital/electronic methods; (12) produces graphic elements for national and international television broadcast programs, Web sites, and interactive CD–Rom and DVDs using state-of-the-art or leading edge technologies and expertise; (13) collaborates with other areas of NCHM, particularly the Division of Electronic Health Marketing, in reviewing potential communication technology; (14) provides audio/video engineering design, installation, setup and maintenance for the Division of Creative Services' facilities, CDC Director's press room, DEOC and the Continuity of Operations Site as required; (15) manages and provides leadership for the Public Health Training Network; (16) manages and coordinates the Public Health Grand Rounds, a program to disseminate the best practices in implementing public health activities; and (17) develops and manages distance education and health communication products to reach public health partners and professionals in support of health priorities.

Writer Editor Services Branch (CPBHE). (1) Provides production editing services for CDC's information products; (2) provides production editing services for *Morbidity and Mortality Weekly Report (MMWR)* publications, *Emerging Infectious Diseases (EID) Journal*, and *Preventing Chronic Disease (PCD) Journal*; (3) provides substantive editing services for CDC-authored written material; (4) provides copy editing services; (5) provides proofreading services; (6) provides Web editing services; (7) provides writing services, including research; and (8) provides editorial

consulting services, and training in writing and editing.

After item (11) of the functional statement for the *Office of the Director (CPC 1), National Center for Health Statistics (CPC),* add the following: (12) serves as primary liaison between NCHS and the National Center for Health Marketing on communications and marketing science, and its associated research and practice; and (13) releases and disseminates all NCHS statistical products and related activities in a mariner consistent with OMB Federal Statistical Agency Directive No. 4.

After item (17) of the functional statement for the *Office of the Director (CPE 1), National Center for Public Health Informatics (CPE)*, add the following: (18) serves as primary liaison between NCPHI and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

After item (9) of the functional statement for the *Office of the Director (CTB 1), National Center for Environmental Health (CTB)*, add the following: (10) serves as primary liaison between NCEH and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

Delete in their entirety the title and function statement for the *Office of Communications (CTB 12).*

After item (9) of the functional statement for the *Office of the Director (CTC 1), National Center for Injury Prevention and Control (CTC)*, add the following: (10) serves as primary liaison between NCIPC and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

Delete in their entirety the title and function statement for the *Office of Communication Resources (CTC 14).*

After item (6) of the functional statement for the *Office of the Director (CUB 1), National Center on Birth Defects and Developmental Disabilities (CUB)*, add the following: (7) serves as primary liaison between NCBDDD and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

After item (10) of the functional statement for the *Office of the Director (CUC1), National Center for Chronic Disease Prevention and Health Promotion (CUC),* add the following: (11) serves as primary liaison between NCCDPHP and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

After item (16) of the functional statement for the *Office of the Director (CVG1), National Center for Immunization and Respiratory Diseases (CVG),* add the following: (17) serves as primary liaison between NCIRD and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

After item (14) of the functional statement for the *Office of the Director (CVH 1), National Center for Zoonotic, Vector-borne, and Enteric Diseases (CVH),* add the following: (15) serves as primary liaison between NCZVED and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

After item (23) of the functional statement for the *Office of the Director (CVJ 1), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CVJ),* add the following: (24) serves as primary liaison between NCHHSTP and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

After item (10) of the functional statement for the *Office of the Director (CVK1), National Center for Preparedness, Detection, and Control of Infectious Diseases (CVK),* add the following: (11) serves as primary liaison between NCPDCID and the National Center for Health Marketing on communications and marketing science, and its associated research and practice.

Dated: April 2, 2008.

Joseph Henderson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. E8–7823 Filed 4–14–08; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Family Violence Prevention and Services: Grants to States; Native American Tribes and Alaskan Native Villages; and State Domestic Violence Coalitions.

OMB No.: 0970–0280.

Description: The Family Violence Prevention and Services Act (FVPSA), as amended, authorizes the Department of Health and Human Services to award grants to States, Tribes—and Tribal Organizations, and State Domestic Violence Coalitions for family violence prevention and intervention activities. The proposed information collection activities will be used to make grant award decisions and to monitor grant performance.

Respondents: State Agencies Administering FVPSA Grants; Tribal Governments and Tribal Organizations; and State Domestic Violence Coalitions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Grant Application	53	1	10	530
Tribal Grant Application	200	1	5	1,000
State Domestic Violence Coalition Application	52	1	10	520
State FVPSA Grant Performance Progress Report	53	1	10	530
Tribal FVPSA Grant Performance Progress Report	200	1	10	2,000
State Domestic Violence Coalition FVPSA Grant Performance Progress Report	52	1	10	520
Estimated Total Annual Burden Hours:				3,700

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 7, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–7817 Filed 4–14–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payment in Excess of the Poverty Income Level From a State Program Funded Under Part A of Title IV of the Social Security Act.

OMB No. : 0970–0004.

Description: The Department of Health and Human Services is required to collect these data under section 1124 of Title I of the Elementary and Secondary Education Act, as amended by Public Law 103–382. The data are used by the U.S. Department of Education for allocation of funds for programs to aid disadvantaged elementary and secondary students. Respondents include various components of State Human Service agencies.

Respondents: The 52 respondents include the 50 States, the District of Columbia, and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Annual Statistical Report on Children in Foster Homes and Children Receiving Payments in Excess of the Poverty Level From a State Program Funded Under Part A of Title IV of the Social Security Act	52	1	264.35	13,746

Estimated Total Annual Burden Hours: 13,746.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 9, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–7946 Filed 4–14–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Progress Report—University Centers for Excellence in Developmental Disabilities Education, Research, and Service.

OMB No.: 0970–0289.

Description: Section 104 (42 U.S.C. 15004) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act of 2000) directs the Secretary of Health and Human Services to develop and implement a system of program accountability to monitor the grantees funded under the DD Act of 2000. The program accountability system shall include the National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDDs) authorized under Part D of the DD Act of 2000. In addition to

the accountability system, Section 154 (e) (42 U.S.C. 15064) of the DD Act of 2000 includes requirements for a UCEDD Annual Report.

Respondents: 67.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UCEDD Annual Report Template	67	1	200	

Estimated Total Annual Burden Hours: 13,400.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: April 9, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–7947 Filed 4–14–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration for Children and Families (ACF)

Office of Child Support Enforcement (OCSE); Privacy Act of 1974; Amended System of Records

AGENCY: Office of Child Support Enforcement, ACF, HHS.

ACTION: Notice of Amended System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), the Office of Child Support Enforcement (OCSE) is publishing notice of amendment of its system of records, entitled ''Federal Case Registry of Child Support Orders'' (FCR), 09–80–0202, last published at 69 FR 46550 on August 3, 2004. The amendment adds four routine uses; new categories of records; and clarifying information and technical amendments.

DATES: Department of Health and Human Services (HHS) invites interested parties to submit written comments on the proposed notice until May 15, 2008. As required by the Privacy Act (5 U.S.C. 552a(r)), HHS on April 8, 2008 sent a report of an Amended System of Records to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB). The amendments described in this notice are effective on May 15, 2008, unless HHS receives comments that would result in a contrary determination.

ADDRESSES: Interested parties may submit written comment on this notice by writing to Linda Deimeke, Director, Division of Federal Systems, Office of Automation and Program Operations, Office of Child Support Enforcement, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447. Comments received will be available for public inspection at this address from 9 a.m. to 5 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Linda Deimeke, Director, Division of Federal Systems, Office of Child Support Enforcement, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone Number (202) 401–5439.

SUPPLEMENTARY INFORMATION: The Office of Child Support Enforcement (OCSE) is amending one of its systems of records, ''Federal Case Registry of Child Support Orders'' (FCR), 09–80–0202, last published at 69 FR 46550 on August 3, 2004.

First, OCSE is adding a routine use (15) to facilitate international child support enforcement in cases involving residents of the United States and residents of foreign countries that are the subject of a declaration under section 459A of the Social Security Act, by providing to foreign reciprocating countries notification of the state of residence of individuals sought for support enforcement.

Second, OCSE is adding a routine use (16) for the disclosure to authorized OCSE users and the HHS Office of Inspector General, Office of Investigations, in accordance with established procedures for the purpose of Federal criminal nonsupport prosecution.

Third, in accordance with a memorandum issued by the Office of Management and Budget, OCSE is adding a routine use (17) for the FCR pertaining to the disclosure of information to appropriate persons and entities for purposes of response and remedial efforts in the event of a breach of data maintained in the FCR. This routine use will facilitate an effective response to a confirmed or suspected breach by allowing for disclosure to those individuals affected by the breach, as well as to others who are in a position to assist in response efforts.

Fourth, OCSE is adding a routine use (18) for disclosures to authorized agency contractors for the purpose of accomplishing an agency function.

Fifth, OCSE is adding a category of records that will be maintained within the FCR, records from locate requests, which are disseminated through the FCR. Note: OCSE assists State child support agencies and other authorized persons in locating individuals who are involved in child support cases and to locate employment and asset information maintained in OCSE's National Directory of New Hires (NDNH) database, and within other Federal agencies' records. Records from locate requests are included in this Notice as a category of records within the system of records because they are disseminated through the FCR. However, because the records are collected and maintained within the NDNH prior to disclosure through the FCR, the routine uses under which they

are disclosed are published in the system of record notice for the Location and Collection System.

Sixth, OCSE is adding a category of records that will be maintained within the FCR, records from locate requests, which are retained within the FCR as a result of a computer system enhancement to electronically filter and suppress redundant information that would have been transmitted to State child support agencies or other authorized persons. This new filtering, suppressing process will also reduce State child support agencies' staff and computer processing unit costs.

Seventh, OCSE is adding a category of records maintained in the FCR, transaction audit logs.

The amendment also revises and expands upon the language of the previous system of records Notice and adds other clarifying information and technical amendments.

Dated: March 21, 2008.

Margot Bean,

Commissioner, Office of Child Support Enforcement.

09–80–0202

SYSTEM NAME:

Federal Case Registry of Child Support Orders (FCR).

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Computer Center, Social Security Administration, Baltimore, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals whose records are maintained within this system are: (1) Individuals involved in child support cases being enforced by the State child support agencies, and (2) individuals who are parties to child support orders established or modified after October 1, 1998. The individuals include custodial parties, non-custodial parents, putative fathers (individuals whose parentage is alleged but not established), and children. The information is obtained from the State Case Registries.

CATEGORIES OF RECORDS IN THE SYSTEM:

The FCR maintains, collects, and disseminates several categories of records. The FCR collects records provided by State Child Support Registries. These records are information from child support cases and support orders being enforced by the State child support agencies. The records may include the following information: name, Social Security number (SSN), State case identification number, State Federal Information Processing Standard (FIPS) code, county code, case type (IV–D, non-IV–D), sex, date of birth, mother's maiden name, father's name, participant type (custodial party, non-custodial parent, putative father, child), family violence indicator (domestic violence or child abuse), order indicator, locate request type, and requested locate source. These records are maintained within the FCR and are regularly compared (matched) to the National Directory of New Hires (NDNH) and other Federal agencies' databases to locate information for the State child support agencies or other authorized persons.

State child support agencies and other authorized persons can directly request locate information (locate requests) from Federal Parent Locator Service (FPLS), which includes the FCR system of records, and the ''Location and Collection System'' (LCS), 09–90–0074. The Notice for the LCS lists the authority and routine uses of disclosures from the LCS. The FPLS must also seek the requested locate information from other Federal agencies. When State child support agencies, or other authorized persons, make locate requests to the FPLS, the request is transmitted to the FPLS via the FCR. Upon receipt of such requests, or as a result of the regular comparisons of the FCR with the NDNH and other agencies' databases, the records located pertaining to the requests are disseminated to the requestor via the FCR. The records disseminated, depending upon the requestor's specific authority, may include information retrieved from the FCR, from the NDNH, or from other Federal agencies. Records from the NDNH and other agencies disseminated through the FCR may include categories of information such as name, SSN, address, phone number, employer, employment status and wages, retirement status and pay, assets, military status and pay, Federal benefits status and amount, representative payees, unemployment status and amount, children's health insurance, incarceration status, financial institution accounts, assets, and date of death. The FCR also contains information related to those categories of records; for example, the date of receipt of Federal benefits.

The FCR maintains records (logs) of transactions involving the receipt of locate requests and the dissemination of requested information and copies of the disseminated locate information for the purpose of electronically filtering and suppressing the transmission of redundant locate information.

AUTHORITY OF MAINTENANCE OF THE SYSTEM:

The Social Security Act (the Act), Section 453(a)(1) requires HHS to establish and conduct a FPLS pursuant to 42 U.S.C. 653(a)(1). Section 452(a)(9) of the Act placed the operation of the FPLS under the direction of the Office of Child Support Enforcement (OCSE) pursuant to 42 U.S.C. 652(a)(9). Section 456(h) requires OCSE to maintain within the FPLS an automated registry, the ''Federal Case Registry of Child Support Orders'' (FCR), containing abstracts of support cases and orders as furnished and regularly updated by State child support agencies pursuant to 42 U.S.C § 653(h).

PURPOSES:

The primary purpose of the FCR is to assist States in establishing parentage or establishing, setting the amount of, modifying, or enforcing child support obligations. OCSE is required to compare records transmitted to or maintained within the FCR to records maintained within the NDNH and other Federal agencies' databases and discloses information about the individuals within the records to State child support agencies or other authorized persons. The information assists State child support agencies or other authorized persons by locating individuals and their employment and asset information who are involved in child support cases. The FCR also conducts FCR to FCR comparisons to locate information about individuals who are involved in child support cases in more than one State and provides the information to those States. Other purposes of the FCR are: to provide locate information (state of residence) pertaining to individuals sought pursuant to the Convention on the Civil Aspects of International Child Abduction to authorized persons in a Central Authority; to assist the Attorney General of the United States in locating any parent or child for the purpose of enforcing State or Federal law with respect to the unlawful taking or restraint of a child, or making or enforcing a child custody or visitation determination; and to assist the Secretary of the Treasury in administering the sections of the Internal Revenue Code of 1986 which grant tax benefits based on support or residence of children. FCR records, without personal identifiers, are also available for research purposes likely to contribute to achieving the purposes of the Temporary Assistance for Needy

Families (TANF) or the Federal/State child support program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

The routine uses for the FCR are compatible with the stated purpose of the system. Records maintained within the FCR may be disclosed to the following categories of users for the purposes listed. If any record contains a ''family violence indicator'' associated to the record by State child support agencies if there is reasonable evidence of domestic violence or child abuse, and that disclosure could be harmful to the party or the child, the record will not be disclosed from the FCR. However, disclosure of any information defined as ''return or return information'' under 26 U.S.C. 6103 of the Internal Revenue Code will not be disclosed unless authorized by a statute, the Internal Revenue Service (IRS), or IRS regulations.

ROUTINE USES INCLUDING FURNISHING INFORMATION TO THE FOLLOWING CATEGORIES OR USERS:

(1) Agents and attorneys of a State which has in effect an approved plan under Title IV–D of the Act who have duty or authority to collect child and spousal support for the purpose of establishing parentage or establishing, setting the amount of, modifying, or enforcing child support obligations pursuant to 42 U.S.C. 653(c)(1); (2) the court which has authority to issue an order against a non-custodial parent for the support and maintenance of a child, or to issue an order against a resident parent for child custody or visitation rights, or any agent of such court for the purpose of establishing parentage or establishing, setting the amount of, modifying, or enforcing child support obligations pursuant to 42 U.S.C 653(c)(2); (3) the resident parent, legal guardian, attorney, or agent of a child (other than a child receiving TANF assistance) for the purpose of establishing parentage or establishing, setting the amount of, modifying, or enforcing child support obligations. 42 U.S.C. 653(c)(3); (4) a State agency that is administering a program operated under a State plan under subpart 1 of part B of the Act (Child Welfare Services) or a State plan approved under subpart 2 of part B (Promoting Safe and Stable Families) or under part E (Foster Care and Adoption Assistance), for the purpose of locating or facilitating the discovery of an individual who is or may be a child's parent pursuant to 42 U.S.C. 653(c)(4). Only information as to the name, SSN, address or location, and employment wages, benefits or income of the parent shall be provided under this section. Requests must be made through the State child support agency; (5) the Social Security Administration for verification of name, SSN, and birth dates pursuant to 42 U.S.C. 653(j)(1); (6) State agencies for the purpose of locating individuals in a paternity establishment case or a case involving the establishment, modification, or enforcement of a support order pursuant to 42 U.S.C. 653(j)(2)(B); (7) State agencies for the purpose of assisting States to carry out their responsibilities under programs operated under Titles IV–D (child support programs) and IV–A (TANF) of the Act pursuant to 42 U.S.C 653(j)(3)(B); (8) agents or attorneys of States having an agreement under this section who have the duty or authority to enforce child custody or visitation determinations. Requests may be made for the purpose of determining the whereabouts of any parent or child when such information is to be used to locate such parent or child for the purpose of making or enforcing a child custody or visitation determination. Only information as to the most recent address and place of employment of any parent or child shall be provided under this section pursuant to 42 U.S.C. 663(d)(2)(A); (9) courts or their agents having jurisdiction to make or enforce a child custody or visitation determination. Requests may be made for the purpose of determining the whereabouts of any parent or child when such information is to be used to locate such parent or child for the purpose of making or enforcing a child custody or visitation determination. Only information as to the most recent address and place of employment of any parent or child shall be provided under this section pursuant to 42 U.S.C. 663(d)(2)(B); (10) agents or attorneys of the United States having an agreement under this section with the U.S. Attorney, or of a State, who have the authority or duty to investigate, enforce, or prosecute the unlawful taking or restraint of a child. The request may be made for the purpose of determining the whereabouts of any parent or child when such information is to be used to locate such parent or child for the purpose of enforcing any State or Federal law with respect to the unlawful taking or restraint of a child. Only information as to the most recent address and place of employment of any parent or child shall be provided under this section pursuant to 42 U.S.C. 663(d)(2)(C) and 42 U.S.C. 663(f); (11) the U.S. Central Authority (U.S. Department of State) designated in accordance with the International Child Abduction Act, for the purpose of locating any parent or child on behalf of an applicant to that Central Authority. Only information as to the state of residence shall be provided under this section pursuant to 42 U.S.C. 663(e); (12) the Secretary of Treasury for the purpose of administering sections of the Internal Revenue Code which grant tax benefits based on support or residence of children pursuant to 42 U.S.C. 653(h)(3); (13) researchers for approved research purposes found by the Secretary to be likely to contribute to achieving the purposes of part A or part B of title IV of the Act, but without personal identifiers pursuant to 42 U.S.C. 653(j)(5); (14) any of the departments, agencies, or instrumentalities of the United States or of any State for the purpose of locating the individual, information on the individual's location, wages (or other income) from, and benefits of, employment (including rights to or enrollment in group health care coverage) and information on the type, status, location, and amount of any assets of, or debts owed by or to, any such individual pursuant to 42 U.S.C. 653(e); (15) a foreign reciprocating country in cases involving residents of the United States and residents of foreign countries that are the subject of a declaration under section 459A of the Social Security Act. Information disclosed is the State of residence of individuals sought for support enforcement purposes pursuant to 42 U.S.C.659A(c)(2); (16) OCSE and HHS Office of Inspector General, Office of Investigations, to identify, investigate, and, where warranted, to a U.S. Attorney for Federal nonsupport prosecution under 18 U.S.C. 228; (17) in the event of a breach of FCR data, an authorized individual or entity for response and remedial efforts related to such breach; and (18) an entity under contract to operate the records in the FCR for the purpose of accomplishing an agency function.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in the FCR are stored electronically at the Social Security Administration's National Computer Center. Historical logs and system backups are stored offsite at an alternate location.

RETRIEVABILITY:

System records can be retrieved by an identification number assigned to a child support case by the State child support agency or an SSN of the individuals whose records are maintained in the FCR.

SAFEGUARDS:

OCSE has established appropriate administrative, technical and physical safeguards to ensure the security and confidentiality of records maintained in the FCR. These safeguards include, but are not limited to, the following:

(1) Administrative Safeguards. On an annual basis, a risk assessment and a security assessment are conducted. Personnel are required to undergo background checks and must participate annually in security awareness training. (2) Technical Safeguards. Identification and authentication controls for access to the system and for access to the datasets are used, with audit logging for accountability. Records are encrypted prior to transmission. Firewalls and intrusion detection equipment are in place. (3) Physical Safeguards: Policies and procedures limit physical access to the system and the facility in which it is housed, while ensuring that authorized access is allowed. Guards, electronic monitoring, access keys, personal badges and physical barriers all contribute to the physical safeguarding of the system and the records maintained therein.

Records maintained in the FCR are secured in full compliance with Federal requirements, including the Federal Information Security Management Act and the HHS Security Program Policy, and in accordance with requirements governing a FIPS 199 categorized system. The FCR is fully certified and accredited in accordance with HHS requirements and guidance issued by the National Institute of Standards and Technology.

RETENTION AND DISPOSAL:

(1) Records provided from State child support agencies. (a) Electronic records furnished by the State child support agency containing child support case and order information (input files) are retained for 60 days and then deleted. (b) State agency records (as posted to the FCR) remain within the FCR until removed, upon notification by the State agency that the case is closed and notifies OCSE to remove it from the FCR, provided that, upon request, a sample may be retained for research purposes found by OCSE to be likely to contribute to achieving the purposes of child support programs or the TANF program, but without personal identifiers. (c) Records pertaining to closed cases are archived on the fiscal year basis and retained for two years. Family violence indicators are removed from the individual's record, upon request by the State that initiated the indicator. (2) Locate requests and match results. (a) Locate requests submitted by State child support agencies and other authorized persons are retained for 60 days and are then deleted. (b) Audit trail records of locate requests and disclosures of match results pursuant to those requests, which include indications of which Federal agencies were contacted for locate information, whether information was located, and the type(s) of information returned to the requesting entity. These records are archived once a year based on the fiscal year. The records are retained for two completed fiscal years and then destroyed. These records indicate the type of information located for the authorized user, not the information itself. (c) Copies of records containing information from the NDNH or other agencies obtained pursuant to locate requests are provided to authorized persons through the FCR. They are maintained within the FCR for one year for the purpose of electronically filtering and suppressing redundant information from being transmitted. After one year, the records are deleted. (3) Match results generated as a result of FCR to FCR comparisons which locate individuals who are participants in child support cases or orders in more than one state are transmitted to the relevant States. Copies of FCR to FCR match results are retained for 60 days and then deleted. (4) Any record relating or potentially relating to a fraud or abuse investigation or a pending or ongoing legal action including a class action, is retained until conclusion of the investigation or legal action. (5) Copies of the FCR records transmitted annually to the IRS for the purpose of administering the earned income tax credit (routine use 12) are retained for one year and then deleted.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Federal Systems, Office of Automation and Program Operations, Office of Child Support Enforcement, Administration for Children and Families, 370 L'Enfant Promenade, SW., 4th Floor East, Washington, DC 20447.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the Systems Manager at the address listed above. The Privacy Act requires that, except under certain conditions specified in the law, only the subject of the records may have access to them. All requests must be submitted in the following manner: Identify the system of records to be searched, have the request notarized to verify requestor's identity, and requestor should indicate awareness that the knowing and willful request for or acquisition of a Privacy Act record under false pretenses is a criminal offense subject to a $10,000 fine. The requestor's letter must also provide sufficient particulars to enable OCSE to distinguish between records on subject individuals with the same name.

RECORD ACCESS PROCEDURES:

Write to the Systems Manager specified above to attain access to records. Requestors should provide a detailed description of the record content they are seeking.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under the Systems Manager above, and identify the record and specify the information to be contested and corrective action sought with supporting justification to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Records maintained within the FCR are furnished by State child support agencies. Records disseminated from the FCR for the purpose of providing locate information from the NDNH and other Federal agencies are furnished by departments, agencies, or instrumentalities of the United States or any State, employers, financial institutions, and insurers or their agents. Records maintained for the purpose of filtering redundant data are also furnished by these sources.

EXEMPTIONS CLAIMED FROM THE SYSTEM:

None.

[FR Doc. E8–7944 Filed 4–14–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0225]

Antimicrobial Resistance; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a

public hearing on antimicrobial resistance. FDA is seeking general information about the problem of antimicrobial resistance, recommendations as to possible approaches to contain the problem of antimicrobial resistance, responses to specific questions (see section III of this document), and other pertinent information from interested parties. In addition, interested parties may provide views on which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antimicrobial-resistant bacteria, potentially qualify for available grants and contracts or other development incentives.

DATES: The public hearing will be held April 28, 2008, from 8 a.m. to 5 p.m. Submit written or electronic notices of participation by close of business on April 21, 2008. Written or electronic comments will be accepted until May 26, 2008.

ADDRESSES: The public hearing will be held at the University System of Maryland Shady Grove Center, 9630 Gudelsky Dr., Rockville, MD 20850.

See **REGISTRATION TO ATTEND AND/OR PARTICIPATE IN THE PUBLIC HEARING** for instructions on how to submit electronic notices of participation.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nancy Stanisic, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660, FAX 301–443–9718, *nancy.stanisic@fda.hhs.gov*.

REGISTRATION TO ATTEND AND/OR PARTICIPATE IN THE PUBLIC HEARING: To ensure there is sufficient room we ask that you pre-register. If you wish to make an oral presentation during the open public comment period of the hearing, state your intention to present on your registration submission. To register, please send an electronic mail message to *nancy.stansic@fda.hhs.gov* by April 21, 2008. Your e-mail should include the following information:

- Your name,
- Title,
- Business affiliation,
- Address,
- Telephone and fax numbers, and e-mail address.

Please submit a written statement at the time of registration, identifying by number each discussion question you wish to address and the approximate time requested to make your presentation. Organizations should provide this information as well as the names and addresses of all participants. Registered individuals will be notified of the scheduled time for their presentation prior to the hearing. Depending on the number of presentations, FDA may need to limit the time allotted for presentations. However, the administrative record of the hearing will remain open after the hearing, and written comments may be submitted to the docket as described in section V of this document. Presentations will be limited to the subject matter identified in section III of this document.

FDA will accept walk-in registration at the site, but space is limited. FDA will try to accommodate all persons who wish to make a public comment at the hearing, including those who register at the site. Registration is on a first-come, first-served basis.

Additionally, please notify FDA (see **FOR FURTHER INFORMATION CONTACT**) if you need any special accommodations (such as wheelchair access) at the time of registration.

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial drug resistance is a major public health concern and a threat to the effectiveness of existing antimicrobial drugs. Antimicrobial resistant pathogens continue to emerge that are very difficult to treat and that may cause serious or life-threatening diseases. Emerging antimicrobial resistance among many bacteria (e.g., *Pseudomonas* species, *Acinetobacter* species, *Enterococcus* species, *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Mycobacterium tuberculosis*) and changes in virulence (e.g., *Clostridium difficile*, group A *Streptococci*, *Escherichia coli* O157:H7, and *Staphylococcus aureus*) are major public health concerns. Timely development of new therapeutic agents is essential and use of existing therapies to treat infections caused by these organisms should be optimized to preserve their utility in treating infections and reduce the rate at which resistance develops.

FDA has been working closely with other Government agencies and organizations to address the issue of antimicrobial resistance. An interagency Task Force began looking at antimicrobial resistance in 1999, and developed and published the *Public Health Action Plan to Combat Antimicrobial Resistance (Action Plan)* (available at *http://www.cdc.gov/drugresistance/actionplan/html/index.htm*).[1] FDA also published a final rule in February 2003 that requires incorporation of information on antimicrobial resistance and prudent use in the labeling of systemic antibacterial drug products for human use (68 FR 6062, February 6, 2003). FDA has held or participated in a number of meetings on antimicrobial resistance, including an Anti-Infective Drugs Products Advisory Committee in March 2003, an Infectious Diseases Society of America/International Society of Anti-Infective Pharmacology/FDA Workshop on Antimicrobial Drug Development in April 2004, and an FDA Science Board Advisory Committee meeting on the Center for Veterinary Medicine's National Antimicrobial Resistance Monitoring System in April 2007.

In September 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which was signed into law by the President on September 27, 2007 (Public Law 110–85). Section 1112 (Orphan Antibiotic Drugs) of FDAAA requires the Commissioner of Food and Drugs (the Commissioner) to convene a public hearing to discuss which serious and life-threatening infectious diseases, such as diseases caused by gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under section 5(a) of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives. For this reason, FDA is holding this public hearing.

Under the Orphan Drug Act (Public Law 97–414), a drug is an orphan drug if it is intended for use in a rare disease or condition. Sponsors of orphan drugs are eligible for certain research and development incentives. During the period that an orphan drug is in development, the sponsor may be awarded grant funding to defray the cost of qualified clinical testing incurred in connection with the development of the drug for a rare disease or condition. A drug that has been designated as an orphan drug by FDA may receive 7 years of marketing exclusivity for the drug for the designated orphan use upon approval. To receive designation as an orphan drug (as defined in section 526 of the Federal Food, Drug, and Cosmetic Act) (21 U.S.C. 360bb)), a sponsor must meet the requirements in 21 CFR 316.20

[1] (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

and 316.21. These requirements include, but are not limited to, documentation of the following:

- The disease or condition for which the drug is intended affects fewer than 200,000 people in the United States (e.g., tuberculosis, malaria, trypanosomiasis).
- If the drug is a vaccine, diagnostic drug, or preventative drug, the persons to whom the drug will be administered in the United States are fewer than 200,000 per year.
- For a drug intended for diseases or conditions affecting 200,000 or more people, or for a vaccine, diagnostic drug, or preventative drug to be administered to 200,000 or more persons per year in the United States, there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States.

Antimicrobial drugs that have qualified for orphan drug designation in the past include some indicated for the treatment of tuberculosis, malaria, and trypanosomiasis.

II. Purpose and Scope of the Hearing

This hearing is intended to provide the infectious disease community, sponsors, and other interested parties an opportunity to discuss their experience with and concerns about the emerging threat of antimicrobial resistance, possible strategies fostering prudent use to prevent the development of antimicrobial resistance, and the potential for the provisions of the Orphan Drug Act or other incentives to facilitate antimicrobial drug development, including what, if any, conditions might be required to accompany such incentives.

III. Issues for Discussion

FDA invites comments from interested parties on the following questions:

1. Please discuss strategies that should be considered to limit the development of antimicrobial resistance, and studies that could be done to assess the utility, safety and effectiveness of those strategies. Possible examples include limiting the approved conditions of use, limiting the duration of therapy, restricting distribution to encourage appropriate use, using shorter courses of therapy with higher doses of antimicrobials, and using directly observed therapy.

2. Please discuss the possible utility and effectiveness of economic incentives in promoting drug development for antimicrobial resistant organisms.

a. What is the potential role of the Orphan Drug Act in providing incentives to facilitate antimicrobial drug development? Please describe the serious and life-threatening infectious diseases for which the Orphan Drug Act provides viable research and development incentives. Please comment on the potential complexities associated with identifying appropriate orphan populations in the infectious disease context.

b. Are there specific incentives (other than those provided by the Orphan Drug Act) that could facilitate the development of new antimicrobial therapies for serious and life-threatening diseases? Describe those serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antimicrobial-resistant bacteria, which could be considered under an alternative incentive program.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and FDA's Office of Orphan Drugs.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in 21 CFR 15.30(h).

V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 through FDMS only.

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: April 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08–1129 Filed 4–10–08; 12:23 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Privacy Act of 1974, New OIG Privacy Act System of Records: Litigation Files

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of proposed new Privacy Act systems of records.

SUMMARY: The Office of Inspector General (OIG) is proposing a new system of records, entitled Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG (09–90–0077). This proposed notice is in accordance with the Privacy Act

requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition. This new system will replicate the existing system of records, entitled Litigation Files, Administrative Complaints, and Adverse Personnel Actions, HHS/OS/OGC (09–90–0064), to reflect that responsibility for providing legal services to the Inspector General has transferred to OIG's Office of Counsel to the Inspector General (OCIG). The existing Litigation Files system of records (09–90–0064) remains with the Department's Office of General Counsel and will be unchanged. This notice specifically covers that portion of the records that transferred to, or have been since created and maintained by, OCIG. The Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG system of records will be maintained for the purposes of representing OIG and its components in court cases and administrative proceedings, in accordance with the Inspector General Act of 1978 (5 U.S.C. App.).

DATES: *Effective Date:* This system of records will become effective without further notice on June 16, 2008, unless comments received on or before that date result in a contrary determination.

Comment Date: Comments on this new system of records will be considered if we receive them at the addresses provided below no later than 5 p.m. Eastern Standard Time on May 15, 2008.

ADDRESSES: In commenting, please reference file code OIG–796–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission. However, you may submit comments using one of the following three ways (no duplicates, please):

1. *Electronically.* You may submit electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may mail your printed or written submissions to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–796–PN, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* You may deliver, by hand or courier, before the close of the comment period, your printed or written comments to the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 358–3141. *Inspection of Public Comments:* All comments received before the end of the comment period will be posted on *http://www.regulations.gov* for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619–0089.

FOR FURTHER INFORMATION CONTACT: Melissa McCurdy, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION: The Office of Inspector General (OIG) proposes to establish a new Privacy Act system of records, 09–90–0077, Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG. The new system will duplicate an existing Privacy Act system of Records—Litigation Files, Administrative Complaints, and Adverse Personnel Actions HHS/OS/OGC (09–90–0064)—which was last revised and updated in the **Federal Register** on November 9, 1994 (59 FR 55845), by adding a new routine use to permit the disclosure of information from this system to certain individuals working in various offices within the Office of the Secretary, but who do not have the status of agency employees and, in many instances, do not receive pay for their work.

The new system of records—Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG (09–90–0077)—will replicate the 09–90–0064 system of records, but will modify the ''System Name,'' ''System Location,'' ''Categories of Individuals Covered by the System,'' ''Authority for Maintenance of the System,'' ''Routine Uses,'' ''Purposes,'' ''System Safeguards,'' and ''System Manager(s) and Address'' sections. Records in the system have been located and maintained in OIG's headquarters. The modification of the ''System Name,'' ''System Location,'' ''Authority for Maintenance of the System,'' ''Routine Uses,'' ''Purposes,'' ''Storage,'' ''System Safeguards,'' and ''System Manager(s) and Address'' sections are to reflect that responsibility for providing legal services to the Inspector General transferred to the Office of Counsel to the Inspector General (OCIG).

The Inspector General Act of 1978 established OIG ''to conduct and supervise audits and investigations relating to the programs and operations'' of the Department of Health and Human Services (HHS). Within OIG, OCIG (1) provides general legal services to OIG including, among other things, advice and representation on HHS programs and operations, administrative law issues, and criminal procedure; (2) imposes program exclusions and civil money penalties on health care providers and litigates those actions within the Department; (3) represents OIG in the global settlement of cases arising under the False Claims Act; and (4) represents OIG in personnel actions.

Description of the Proposed System of Records

The Litigation Files, Administrative Complaints, and Personnel Actions, HHS/OS/OIG/OCIG system will enable OCIG to access and maintain records for the purpose of representing OIG and its components in court cases and administrative proceedings. The system will house records pertaining to litigation, administrative complaints, and personnel actions in which OIG is, or was, involved.

Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits OIG to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. Any such disclosure of data is known as a routine use. We are proposing to establish the following routine use disclosures of records maintained in the system:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation, information from the system of records may be disclosed to the Department of Justice, to a judicial or administrative tribunal, opposing counsel, and witnesses, in the course of proceedings involving HHS, any HHS employee (where the matter pertains to the employee's official duties), or the United States, or any agency thereof where the litigation is likely to affect

HHS, or HHS is a party or has an interest in the litigation and the use of the information is relevant and necessary to the litigation.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation, or order issued pursuant thereto.

4. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

5. A record from this system of records may be disclosed as a ''routine use'' to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

6. A record from this system of records may be disclosed to a Federal agency in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

7. Information in this system of records may be disclosed to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement records, or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency concerning the hiring or retention of an employee, the issuance of a license, grant, or other benefit.

8. To student volunteers and other individuals performing functions for the Department, but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions.

9. A record may be disclosed to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

Safeguards

OIG has safeguards in place for authorized users and monitors users to ensure against unauthorized use. The system will conform to all applicable Federal laws and regulations and Federal, HHS, and OIG policies and standards as they relate to information security and data privacy.

Effects of the Proposed System of Records on Individual Rights

This system is established in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records notice.

OIG will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of applicants whose data are maintained in the system. OCIG will make disclosures from the proposed system in accordance with the Privacy Act. OCIG does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

This proposed change will not otherwise increase access to these records.

Dated: April 10, 2008.

Daniel R. Levinson,

Inspector General.

09–90–0077

SYSTEM NAME:

Litigation Files, Administrative Complaints, and Personnel Actions, HS/OS/OIG/OCIG.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Counsel to the Inspector General (OCIG), Department of Health and Human Services, Room 5527, Wilbur J. Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The individuals on whom records are maintained in this system are individuals who are involved in civil, criminal, or administrative litigation with the Department or the United States (regarding matters within the jurisdiction of the Department) either as plaintiffs or as defendants, and individuals who either file administrative complaints with the Department or are the subjects of administrative complaints initiated by the Department.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information pertaining to the subject matter of the litigation, administrative complaint, or personnel action. Such records would include complaints, litigation reports, administrative transcripts, various litigation documents, investigative materials, correspondence, briefs, court orders, and judgments.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintaining this system is found in the various statutes, regulations, rules, or orders pertaining to the subject matter of the litigation, administrative complaint, or adverse personnel action, (e.g., Inspector General Act and the Social Security Act).

PURPOSE(S):

To advise and represent the Office of Inspector General and its components in court cases and administrative proceedings.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

b. In the event of litigation, information from the system of records may be disclosed to the Department of Justice, to a judicial or administrative tribunal, opposing counsel, and witnesses, in the course of proceedings involving HHS, any HHS employee (where the matter pertains to the employee's official duties), or the United States, or any agency thereof where the litigation is likely to affect HHS, or HHS is a party or has an interest in the litigation and the use of the information is relevant and necessary to the litigation.

c. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

d. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

e. A record from this system of records may be disclosed as a ''routine use'' to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

f. A record from this system of records may be disclosed to a Federal agency, response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

g. Information in this system of records may be disclosed to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement records, or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency concerning the hiring or retention of an employee, the issuance of a license, grant, or other benefit.

h. To student volunteers and other individuals performing functions for the Department, but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions.

i. A record may be disclosed to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in electronic form and paper files are stored in locked file cabinets.

RETRIEVABILITY:

These records are retrievable by name of the plaintiff or the first plaintiff if there is more than one, or by the name of the first defendant if the plaintiff is the United States. In the case of personnel actions, records are retrievable by name of the individual involved.

SAFEGUARDS:

Office buildings in which these records are maintained are secured by a variety of security systems. The computer terminals used to access the records are secured with passwords, encryptions, and other security devices, comply with all relevant computer security procedures, and are kept in rooms that are locked at the close of the business day, and are generally accessible only to OCIG staff.

RETENTION AND DISPOSAL:

These records are maintained for an indefinite duration.

SYSTEM MANAGER(S) AND ADDRESS:

The agency official responsible for the system policies and practices outlined above is: The Chief Counsel, Office of Counsel to the Inspector General, Department of Health and Human Services, Wilbur J. Cohen Building, Room 5527, 330 Independence Avenue, SW., Washington, DC 20201.

NOTIFICATION PROCEDURES:

Any inquiries regarding these systems of records should be addressed to the System Manager. An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. (These notification and access procedures are in accordance with Department regulations (45 CFR 5b.6).)

RECORDS ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. (These access procedures are in accordance with Department regulations (45 CFR 5b.5 (a)(2).)

CONTESTING RECORD PROCEDURES:

Contact the official at the address System Manager(s) and Address above, and reasonably identify the record and specify the information to be contested and corrective action sought with supporting justification. (These procedures are in accordance with Department regulations (45 CFR 5b.7).)

RECORD SOURCE CATEGORIES:

The information for this system is obtained through a number of sources including the exchange of legal pleadings, documents, formal and informal discovery, program offices and component agencies, private attorneys, State and local governments, their agencies and instrumentalities, and officers of other Federal agencies and the individuals involved.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E8–7987 Filed 4–14–08; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Call for Nominations for the National Cancer Institute Director's Consumer Liaison Group

Notice is hereby given of a change in the Call for Nominations for the National Cancer Institute Director's Consumer Liaison Group which was published in the **Federal Register** on March 18, 2008, 73 FR 14476–14477.

This call for nominations is being amended to revise the due date for candidates interested in being considered for appointment to the Director's Consumer Liaison Group to postmark their nomination package by April 30, 2008 instead of April 15, 2008.

Dated: April 8, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7929 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: May 13–14, 2008.

Closed: May 13, 2008, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 13, 2008, 8:30 a.m. to 12:15 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 13, 2008, 12:15 p.m. to 1:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 13, 2008, 1:15 p.m. to 5:45 p.m.

Agenda: Committee Discussion Place: National Institute on Aging.

Place: Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 13, 2008, 5:45 p.m. to 6:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 14, 2008, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 14, 2008, 8:30 a.m. to 12:15 p.m.

Agenda: Committee Discussion Place: National Institute on Aging.

Place: Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 14, 2008, 12:15 p.m. to 1:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 14, 2008, 1:15 p.m. to 5:30 p.m.

Agenda: Committee Discussion Place: National Institute on Aging.

Place: Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 14, 2008, 5:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Contact Person: Dan L. Longo, MD, Scientific Director, National Institute of Aging, Gerontology Research Center, National Institutes of Health, 5600 Nathan Shock Drive, Baltimore, MD 21224–6825, 410–558–8110, *dl14q@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 7, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7799 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Aging and Immunology.

Date: May 15, 2008.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alicia L. Markowska, PhD, DSC, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Amyloid Oligomers.

Date: May 16, 2008.

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Scientific Review Office, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 7, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7803 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. 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 Allergy and Infectious Diseases Special Emphasis Panel; Developing Imaging Technology.

Date: May 1, 2008.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, 3118 Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Sujata Vijh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–594–0985, *vijhs@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: April 7, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7807 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Ultrasound Therapy.

Date: June 20, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC/Rockville, Executive Meeting Center, 1750 Rockville Pike, The Regency Room, Rockville, MD 20852.

Contact Person: Ruixia Zhou, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, (301) 496–4773, *zhour(c)mail.nih.gov.*

Dated: April 8, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7917 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; LRP.

Date: May 13, 2008.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, 223, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Prabha L. Atreya, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD 20892, (301) 496–8633, *atreyapr@mail.nih.gov.*

Dated: April 8, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7920 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. 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 Environmental Health Sciences Special Emphasis Panel; Expedited Review of Exposure Assessment.

Date: April 30, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, PhD, Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446, *eckerttl@niehs.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. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 8, 2006.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7928 Filed 4–14–08; 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 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 Child Health and Human Development Special Emphasis Panel; Teaching, Brain, & Genetic Basis of Reading Disability.

Date: April 25, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B0 1, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Building, Room 5b01, Bethesda, MD 20892, (301) 435–6911, *hopmannmmail.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. 93.864, 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: April 8, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–7930 Filed 4–14–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 2009 National Survey on Drug Use and Health—(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

In the 2009 NSDUH, one scale measuring impairment from mental health issues will be adopted. The decision to adopt either the Sheehan or the WHO-DAS is currently being evaluated in the 2008 NSDUH by using the SCID-I/NP as a follow-up interview with a subsample of respondents. Based upon a substantive review of questions in the Youth Mental Health Services Utilization module, updates will be made to this section. These updates will also be reflected in the Parenting Experiences module, in order to refine the analysis of overall treatment rates. The remaining modular components of the questionnaire will remain essentially unchanged except for minor modifications to wording.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2009 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

	No. of responses	Responses per respondent	Average burden per response (hr)	Total burden (hrs)
Household Screening	182,250	1	.083	15,127
Interview	67,500	1	1.0	67,500
Clinical Follow-up Interview	500	1	1.0	500
Screening Verification	5,400	1	0.067	362
Interview Verification	10,125	1	0.067	678
	182,250	.....	.....	84,167

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *AND* e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: April 7, 2008.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E8–7977 Filed 4–14–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Advisory Committee for Women's Services; Notice of a Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Advisory Committee for Women's Services on May 6, 2008.

The meeting is open and will include an overview of the history of SAMHSA's women's programs and a discussion on priority issues identified by the Advisory Committee for Women's Services at its September 2007 meeting.

Attendance by the public will be limited to the space available. Public comments are welcome. Please communicate with the Committee's Designated Federal Official, Ms. Carol Watkins (see contact information below) to make arrangements to comment or to request special accommodations for persons with disabilities.

Substantive program information, a summary of the meeting, and a roster of Committee members may be obtained either by accessing the SAMHSA Committee's Web site at *https://www.nac.samhsa.gov/* as soon as possible after the meeting, or by contacting Ms. Watkins. The transcript for the meeting will also be available on the SAMHSA Committee's Web site within three weeks after the meeting.

Committee Name: SAMHSA Advisory Committee for Women's Services.

Date/Time/Type: Tuesday, May 6, 2008, from 9 a.m. to 12 p.m.: Open.

Place: 1 Choke Cherry Road, Seneca Conference Room, Rockville, Maryland 20857.

Contact: Carol Watkins, Designated Federal Official, SAMHSA Advisory Committee for Women's Services, 1 Choke Cherry Road, Room 8–1002, Rockville, Maryland 20857, Telephone: (240) 276–2254; FAX: (240) 276–1024 and E-mail: *carol.watkin2@samhsa.hhs.gov.*

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. E8–7950 Filed 4–14–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2008–0197]

Navigation Safety Advisory Council; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Navigation Safety Advisory Council (NAVSAC) will meet to discuss various issues relating to the safety of navigation. The meeting will be open to the public.

DATES: NAVSAC will meet on Wednesday, May 14, 2008, from 8 a.m. to 5 p.m. and Thursday, May 15, 2008 from 8 a.m. to 5 p.m. The meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before April 28, 2008. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before April 28, 2008.

ADDRESSES: NAVSAC will meet in the Crowne Plaza Hotel Seattle, 1113 6th Avenue, Seattle, WA 98101. Send written material and requests to make oral presentations to Mr. John Bobb, Commandant (CG–54121), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001. This notice is available on our online docket, USCG–2007–0028 at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Sollosi, Executive Director of NAVSAC, or Mr. John Bobb, Assistant to the Executive Director, telephone 202–372–1532, fax 202–372–1929 or e-mail at *john.k.bobb@uscg.mil*.

SUPPLEMENTARY INFORMATION: Notice of the meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–493).

Agenda of Meeting

The agenda for the May 14–15, 2008 NAVSAC meeting is as follows:

(1) COLREGS Rule 34.
(2) NAVAID Mix Template.
(3) AIS Authority.
(4) Arctic Navigation Requirements.
(5) High Speed Craft.

Procedural

The meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the Executive Director no later than April 28, 2008. Written material for distribution at the meeting should reach the Coast Guard no later than April 28, 2008. If you would like a copy of your material distributed to each member of the committee in advance of the meeting, please submit 20 copies to the Executive Director no later than April 28, 2008.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the Executive Director as soon as possible.

Dated: April 4, 2008.

Wayne A. Muilenburg,

Captain, U.S. Coast Guard, Office of Waterways Management.

[FR Doc. E8–7940 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form N–336, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Form N–336, Application Request for Hearing on a Decision in Naturalization Proceedings Under Section 336; OMB Control No. 1615–0050.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 16, 2008.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, NW., Suite 3008, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352, or via e-mail at *rfs.regs@dhs.gov*. When

submitting comments by e-mail add the OMB Control Number 1615–0050 in the subject box.

During this 60-day period USCIS will be evaluating whether to revise the Form N–366. Should USCIS decide to revise the Form N–366 it will advise the public when it publishes the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30-days to comment on any revisions to the Form N–336.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Request for Hearing on a Decision in Naturalization Proceedings under section 336.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–366. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and households. This form provides a method for applicants, whose applications for naturalization are denied, to request a new hearing by an Immigration Officer of the same or higher rank as the denying officer, within 30 days of the original decision.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 7,669 responses at 2 hours and 45 minutes (2.75) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 21,090 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit: *http://www.regulations.gov/search/index.jsp.*

We may also be contacted at: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, NW., Suite 3008, Washington, DC 20529, telephone number 202–272–8377.

Dated: April 10, 2008.

Stephen Tarragon

Acting Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E8–7963 Filed 4–14–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Bennett Testing Service, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Bennett Testing Service, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Bennett Testing Service, Inc., 99 Lafayette Street, Carteret, NJ 07008, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Bennett Testing Service, Inc., as commercial gauger and laboratory became effective on February 23, 2007. The next triennial inspection date will be scheduled for February 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8027 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Camin Cargo Control, Inc., 1800 Dabney Drive, Pasadena, TX 77536, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/*

labs_scientific_svcs/commercial_gaugers/

DATES: The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on December 20, 2007. The next triennial inspection date will be scheduled for December 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8025 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 5237 Halls Mill Road—Buliding F, Mobile, AL 36619, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on July 19, 2007. The next triennial inspection date will be scheduled for July 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8021 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 4350 Oakes Rd. Suite 521 A, Davie, FL 33314, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on September 20, 2007. The next triennial inspection date will be scheduled for September 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8038 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Intertek USA, Inc., 481 A East Shore Parkway, New Haven, CT 06512, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on July 26, 2007. The next triennial inspection date will be scheduled for July 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8045 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 6531 Evergreen Avenue, Jacksonville, FL 32208, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory, became effective on August 20, 2007. The next triennial inspection date will be scheduled for August 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8017 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 3915 Saw Mill Run Blvd., Pittsburg, PA 15227, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on August 08, 2007. The next triennial inspection date will be scheduled for August 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8022 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 2610 S. Federal Highway, Fort Lauderdale, FL 33316, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on September 18, 2007. The next triennial inspection date will be scheduled for September 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and

Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8024 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 780B Primos Avenue, Folcroft, PA 19032, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on July 24, 2007. The next triennial inspection date will be scheduled for July 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8026 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 1026 W. Elizabeth Avenue, Linden, NJ 07036, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on September 19, 2007. The next triennial inspection date will be scheduled for September 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8040 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 1123–A Highway 43, Saraland, AL 36571, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on July 17, 2007. The next triennial inspection date will be scheduled for July 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–7995 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of Intertek USA, Inc., as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of Intertek USA, Inc., as a commercial laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12, Intertek USA, Inc., 1114 Seaco Avenue, Deer Park, TX 77217, has been accredited to test petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12. Anyone wishing to employ this entity to conduct laboratory analyses should request and receive written assurances from the entity that it is accredited by the U.S. Customs and Border Protection to conduct the specific test requested. Alternatively, inquires regarding the specific test this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation of Intertek USA, Inc., as commercial laboratory became effective on December 13, 2007. The next triennial inspection date will be scheduled for December 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8043 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Freeboard International, as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Freeboard International, as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Freeboard International, 2500 Brunswick Ave., Linden, NJ 07036, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquires regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The approval of Freeboard International, as commercial gauger became effective on September 20, 2007. The next triennial inspection date will be scheduled for September 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8057 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Intertek USA, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of lntertek USA, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, lntertek USA, Inc., Urb. Constancia 181 1 Paseo Las Colonias, Ponce, PR 00624, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquires regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The approval of lntertek USA. Inc., as commercial gauger became effective on September 28, 2007. The next triennial inspection date will be scheduled for September 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8054 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of SGS North America, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of SGS North America, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, SGS North America, Inc., 1267 N. Witter St., Pasadena, TX 77536, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquires regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/

DATES: The approval of SGS North America, Inc., as commercial gauger became effective on April 18, 2007. The next triennial inspection date will be scheduled for April 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–8000 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 3904 Corporex Park Drive Suite 145, Tampa, FL 33619, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on August 22, 2007. The next triennial inspection date will be scheduled for August 2010.

FOR FURTHER INFORMATION CONTACT: Randall Breaux, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: April 7, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–7998 Filed 4–14–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2008–N0051; 11120–0008–0221–F2]

Amendment to the Incidental Take Permit for the San Bruno Mountain Habitat Conservation Plan in San Mateo County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and receipt of application.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce that the County of San Mateo and the City of Brisbane, acting on the behalf of the County of San Mateo and Cities of Brisbane, Daly City, and South San Francisco (Applicants or Permittees), have applied for an amendment to an incidental take permit under the Federal Endangered Species Act of 1973, as amended (Act). We are considering the issuance of an amended permit to the Applicants that would add the authorization for take of the federally endangered callippe silverspot butterfly (*Speyeria callippe callippe*) (*callippe*) and the federally threatened bay checkerspot butterfly (*Ephydra editha bayensis*) (*bay checkerspot*) incidental to the Applicant's activities outlined in their proposed amendments to the 1982 San Bruno Mountain Habitat Conservation Plan (HCP) in San Mateo County, California. The HCP amendments would adjust the boundaries of Conserved Habitat within the 228-acre Northeast Ridge (Administrative Parcel 1–07) and provide supplemental HCP funding provisions that would allow additional habitat management and monitoring activities to occur on the approximately 2,828 acres of habitat conserved and managed under the HCP on San Bruno Mountain.

We request comments from the public on the permit application and an Environmental Assessment. The permit application includes the *Biological Study and Analysis of Conserved Habitat for Amendments to the Habitat Conservation Plan for San Bruno Mountain and Incidental Take Permit PRT 2–9818* (Study). The Study describes the proposed changes to the 1982 HCP as it was last amended in 1989, and the measures that the Applicants would undertake to minimize and mitigate take of the covered species.

DATES: We must receive your written comments on or before June 16, 2008.

ADDRESSES: Please address written comments to Eric Tattersall, Acting Chief, Conservation Planning and Recovery Division, Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W–2605, Sacramento, California 95825. You also may send comments by facsimile to (916) 414–6713.

FOR FURTHER INFORMATION CONTACT: Eric Tattersall, Acting Chief, Conservation Planning and Recovery Division, Sacramento Fish and Wildlife Office, at (916) 414–6600.

SUPPLEMENTARY INFORMATION:

Availability of Documents

You may obtain copies of these documents for review by contacting the individual named above [see **FOR FURTHER INFORMATION CONTACT**]. Documents also will be available for public inspection, by appointment, during normal business hours at the Sacramento Fish and Wildlife Office [see **ADDRESSES**].

Background

Section 9 of the Act and Federal regulations prohibit the ''take'' of fish and wildlife species listed as endangered or threatened (16 U.S.C. 1538). Take of federally listed fish or wildlife is defined under the Act to include the following activities: harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532). We may, under limited circumstances, issue permits to authorize incidental take (i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity). Regulations governing incidental take permits for endangered species are found in 50 CFR 17.22 and 50 CFR 17.32.

San Bruno Mountain is located on the northern San Francisco Peninsula, just south of the San Mateo-San Francisco County boundary. The Mountain is surrounded on all sides by the cities of Colma to the west, Daly City to the north, Brisbane to the east, and South San Francisco to the south. The San Bruno Mountain HCP study area consists of 3,537 acres, of which 2,828 acres are presently Conserved Habitat.

The County of San Mateo and City of Brisbane are requesting, on behalf of the HCP permittees, an amendment to an existing incidental take permit for activities covered by proposed amendments to the 1982 HCP, as amended. The proposed HCP amendments would include the following changes. Chapter VII of the HCP would be revised to replace the approved operating program for development of the Northeast Ridge (the 1989 Vesting Tentative Map (VTM)) to allow for the development of Unit II-Neighborhood II (UII–NII) under a proposed 2007 modification (the 2007 VTM). The reconfiguration would reduce the amount of land to be developed and increase the size and value of Conserved Habitat within the Northeast Ridge, as well as reduce impacts to the Species of Concern covered under the HCP.

Section V.B of the HCP would be amended to address supplemental funding of four million dollars to be provided by the developer, Brookfield Northeast Ridge II LLC, concomitant to development of UII–NII within the Northeast Ridge. These funds would establish an HCP Endowment, which would be funded incrementally upon the granting of final map approval for the lots in UII–NII, pursuant to an agreement between Brookfield Northeast Ridge II LLC and the City of Brisbane. The HCP Endowment would be managed by the HCP Trustees and would be available to fund ongoing habitat management and monitoring activities described in the Habitat Management Plan (HMP) that is appended to the Study. Section V.B would also be amended to increase the annual charge per dwelling unit and per 1,000 feet of floor area for commercial and industrial activities within the portion of the HCP area under the City of Brisbane's jurisdiction. All funds from the annual charge would be part of the HCP's Trust Fund and managed by the Trustees.

These amendments and the biological analysis required by the 1982 HCP are detailed in the Study. The Study evaluates the proposed change to the boundary of the Conserved Habitat on the Northeast Ridge parcel described in the HCP and considers the effect of this action, and ongoing management and monitoring activities, on the callippe, the listed species on the existing incidental take permit (the mission blue butterfly (*Icaricia icarioides missionensis*), San Bruno elfin butterfly (*Callophrys mossii bayensis*), bay checkerspot, and San Francisco garter snake (*Thamnophis sirtalis tetrataenia*), and other listed species that currently occur or have been historically documented on the Mountain, including the California red-legged frog (*Rana aurora draytonii*). It also considers the effects of grading that occurred in 2007 for the installation of infrastructure and other drainage and slope stability improvements deemed necessary by the City of Brisbane for public health, safety, and welfare reasons (2007 Infrastructure Grading).

The Service's Environmental Assessment considers the environmental consequences of three alternatives. The Proposed Project Alternative consists of the issuance of an amendment to the incidental take permit and implementation of the Study and HMP. With Alternative 2 (1989 Northeast Ridge Plan), an amendment to the existing incidental take permit would be issued to add take coverage for the callippe silverspot and bay checkerspot for the adopted HCP, which includes the 1989 VTM for Northeast Ridge and continuation of habitat management activities under the existing funding program. With the No Action alternative, there would be no issuance of an amendment to the existing incidental take permit to add take coverage for the callippe silverspot and bay checkerspot. The proposed reconfiguration of the Northeast Ridge would not occur, nor would the supplementary funding for vegetation management on the Mountain be provided. Under the No Action alternative, certain types of habitat management activities for conserved habitats on the Mountain would not have take authorization.

Public Review

We invite the public to review the Plan, Implementing Agreement and Environmental Assessment during a 60-day public comment period (see **DATES**). Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

We provide this notice pursuant to section 10(a) of the Act and the regulations for implementing NEPA, as amended (40 CFR 1506.6). We will evaluate the application, associated documents, and comments submitted thereon to determine whether the application meets the requirements of NEPA regulations and section 10(a) of the Act. If we determine that those requirements are met, we will issue a permit to the Applicant for the incidental take of the covered species. We will make our final permit decision no sooner than 60 days from the date of this notice.

Dated: April 9, 2008.

Ken McDermond,

Deputy Regional Director, Region 8, California and Nevada, Sacramento, California.

[FR Doc. E8–8051 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Marine Fisheries Service; Bay Delta Conservation Plan for the Sacramento-San Joaquin Delta, California

AGENCIES: Bureau of Reclamation, Interior; Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of Intent (NOI) to prepare an environmental impact statement/environmental impact report (EIS/EIR) and notice of public scoping meetings.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended, the Bureau of Reclamation (Reclamation), the Fish and Wildlife Service (FWS), and the National Marine Fisheries Service (NMFS) intend to serve as co-lead agencies in the preparation of a joint EIS/EIR for the Bay Delta Conservation Plan (BDCP). The California Department of Water Resources (DWR) will serve as the lead agency under the California Environmental Quality Act (CEQA). Reclamation will serve as the administrative lead for all actions related to this **Federal Register** Notice.

The BDCP is a conservation plan being prepared to meet the requirements of the Federal Endangered Species Act (FESA), the California Endangered Species Act (CESA), and the State of California's Natural Communities Conservation Planning Act (NCCPA). DWR and State and Federal water contractors intend to apply for FESA and CESA incidental take permits (ITP) for water operations and management activities in the Sacramento-San Joaquin Delta. These incidental take authorizations would allow the incidental take of threatened and endangered species resulting from covered activities and conservation measures that will be identified through the planning process including those associated with water operations of the Federal Central Valley Project (CVP), as operated by Reclamation, the California State Water Project (SWP), as operated by DWR, as well as operations of certain Mirant Delta LLC (Mirant Delta) power plants. Additionally, the BDCP will, if feasible, be used as the basis for FESA compliance by Reclamation, including compliance with Section 7 of FESA in coordination with FWS and NMFS. Ultimately, the BDCP is intended to secure authorizations that would allow projects that restore and protect water supply and reliability, water quality, and ecosystem health to proceed within a stable regulatory framework.

On January 24, 2008, FWS and NMFS issued a NOI to conduct public scoping and prepare an EIR/EIS regarding the BDCP for the Sacramento-San Joaquin Delta, California (73 FR 4178). As the BDCP effort has progressed, Reclamation has determined it has a substantive interest in the development and ultimate implementation of the BDCP. Specifically, Reclamation seeks to improve water supply reliability for its Federal water contractors, while meeting its FESA obligations. Environmental constraints, including measures to protect endangered species in the Sacramento-San Joaquin Delta, impair that water supply reliability. The BDCP will recommend actions and conservation measures for implementation to improve both environmental conditions in the Delta and water supply reliability. Reclamation expects the recommended actions and conservation measures to include activities that are within Reclamation's responsibilities. The NOI is, therefore, being reissued to include Reclamation as a co-lead agency, update the status of the BDCP planning process, correct an error in the January 24, 2008, NOI, and to provide notice of scoping meetings. As the Federal lead agencies continue to refine the purpose and need for the project, additional public notices regarding scoping will be issued and additional scoping meetings will be held.

DATES: Ten public scoping meetings will be held at various times and locations throughout California. See **SUPPLEMENTARY INFORMATION** section for public scoping meeting dates.

Written comments on the scope of the BDCP or issues to be addressed in the EIS/EIR must be received no later than May 30, 2008.

The scoping period on the initial Notice of Intent published jointly by FWS and NMFS on January 24, 2008 (73 FR 4178), is scheduled to close on March 24, 2008. Comments submitted under that NOI need not be resubmitted, as all comments will be consolidated and incorporated under this NOI for review and response by the co-lead agencies (i.e., Reclamation, FWS, and NMFS).

ADDRESSES: Send written comments to Patti Idlof, Bureau of Reclamation, 2800 Cottage Way, MP–150, Sacramento, CA 95825, e-mail to *pidlof@mp.usbr.gov,* or fax to (916) 978–5055.

See **SUPPLEMENTARY INFORMATION** section for public scoping meeting addresses.

FOR FURTHER INFORMATION CONTACT: Patti Idlof, Natural Resource Specialist, Reclamation, at the above address or 916–978–5056; Lori Rinek, FWS, 916–414–6600; or Rosalie del Rosario, NMFS, 916–930–3600.

SUPPLEMENTARY INFORMATION:

Public Scoping Meeting Dates

Public scoping meetings will be held on the following dates and times:

- Monday, April 28, 2008, 10 a.m. to 2 p.m., Sacramento, CA.
- Tuesday, April 29, 2008, 5 p.m. to 9 p.m., Chico, CA.
- Wednesday, April 30, 2008, 6 p.m. to 10 p.m., Clarksburg, CA.
- Monday, May 5, 2008, 6 p.m. to 10 p.m., Stockton, CA.
- Tuesday, May 6, 2008, 6 p.m. to 10 p.m., San Jose, CA.
- Wednesday, May 7, 2008, 6 p.m. to 10 p.m., Los Banos, CA
- Thursday, May 8, 2008, 1 p.m. to 4 p.m., Los Angeles, CA
- Monday, May 12, 2008, 6 p.m. to 10 p.m., San Diego, CA
- Tuesday, May 13, 2008, 6 p.m. to 10 p.m., Fresno, CA
- Wednesday, May 14, 2008, 6 p.m. to 10 p.m., Bakersfield, CA

Public Scoping Meeting Addresses

Public scoping meetings will be held at the following locations:

- Sacramento—California Resources Building Auditorium, 1416 Ninth Street, Sacramento, CA 95816.
- Chico—Chico Masonic Family Center, 1110 West East Avenue, Chico, CA 95926.
- Clarksburg—Clarksburg Middle School, 52870 Netherlands, Clarksburg, CA 95612.
- Stockton—San Joaquin Farm Bureau, 3290 North AdArt Road, Stockton, CA 95215.
- San Jose—Santa Clara Valley Water District, 5700 Almaden Expressway, San Jose, CA 95118.
- Los Banos—City of Los Banos, Public Services Department Main Office Senior Center—Miller & Lux Building, 830 6th Street, Los Banos, CA 93635.
- Los Angeles—Junipero Serra State Office Building, 320 West Fourth, Carmel Room 225, Los Angeles, CA 90013.

• San Diego—Marina Village Conference Center, 1936 Quivira Way, Starboard Room, San Diego, CA 92109.
• Fresno—Four Points-Fresno, 3737 North Blackstone, Fresno, CA 93726.
• Bakersfield—Board of Supervisors Chambers, 1115 Truxtun Avenue, First Floor, Bakersfield, CA 93301.

Modification to January 24, 2008, NOI published by FWS and NMFS

The NOI dated January 24, 2008 (73FR4178) erroneously identified Contra Costa Water District (CCWD) as a Potentially Regulated Entity (PRE). CCWD is a participant in the process, but has not yet and may not become a PRE.

Background Information

The BDCP is being prepared through a collaboration of State, Federal, and local water agencies, and Mirant Delta, an electric power generating facility located in West Pittsburg, California in Contra Costa County, under: (1) Section 10(a)(1)(B) of the FESA of 1973, as amended, and (2) the NCCPA, California Fish and Game Code, Section 2800 et. seq., or Fish and Game Code Section 2081 of CESA. The BDCP is intended to provide (1) Reclamation the ability to obtain a Biological Opinion and incidental take statements (ITS) pursuant to Section 7 of FESA and (2) the basis for the DWR and State and Federal water contractors to apply for ITPs pursuant to Section 10 of FESA and California Fish and Game Code Section 2835 or 2081 for implementation of the BDCP.

DWR and Reclamation, along with the Metropolitan Water District of Southern California (MWD), the Kern County Water Agency (KCWA), the Santa Clara Valley Water District (SCVWD), Alameda County Flood Control and Water Conservation District, Zone 7 Water Agency (Zone 7), the San Luis and Delta-Mendota Water Authority (SLDMWA), the Westlands Water District (WWD), and Mirant Delta (known collectively as the Potentially Regulated Entities or PREs) are currently preparing the BDCP for existing and proposed covered activities within the Statutory Delta. Some of the elements of the BDCP will complement the actions identified in the State of California's Delta Vision process.

It is the goal of the PREs that the BDCP follow the processes that meet:

1. The requirements of Section 10(a)(1)(B) of the FESA for the non-federal PREs and result in the issuance of ITPs from the FWS and NMFS to those PREs;

2. The requirements of an ITP under the California fish and wildlife protection laws, either pursuant to Section 2835 or Section 2081, resulting in take authority under the Fish and Game Code; and

3. The requirements of the Section 7 consultation process under the FESA, resulting in the issuance of Biological Opinions, and ITSs, from the NMFS and FWS on specific activities of certain members of the PREs.

The planning efforts for the BDCP are in the preliminary stages. However, the collective goals of the PREs will help form the purpose and need statement for the project as required by NEPA and the project objective as required by CEQA. Formal preparation of a draft EIS/EIR will commence when the planning efforts progress further in the coming months. The BDCP is being prepared with the cooperation of the FWS, NMFS, California Resources Agency, California Department of Fish and Game (CDFG), the PREs, and various stakeholders, including The Nature Conservancy, Environmental Defense, Defenders of Wildlife, the California Farm Bureau, the Natural Heritage Institute, American Rivers, Contra Costa Water District, and The Bay Institute. These organizations are members of the Steering Committee, which is helping to guide preparation of the BDCP. The regulatory agencies, FWS, NMFS, and CDFG are participating in the Steering Committee to provide technical input and guidance in support of the Steering Committee's efforts to complete the BDCP. Other applicants, co-applicants, or beneficiaries of an ITP, referred to as PREs, may be identified during the planning process.

The participants are undertaking these planning efforts pursuant to: (1) The Planning Agreement that was signed October, 2006, and amended April, 2007, to guide development of the BDCP and (2) the ''Points of Agreement for Continuing into the Planning Process'' dated November 16, 2007 (see Resources Agency Web site, *http://resources.ca.gov/bdcp/* for these agreements). The Points of Agreement document provides a summary of the BDCP planning process to date, along with future direction and procedures. The website provides access to documentation of the planning process, and a schedule of past and future planning activities.

BDCP Description

The BDCP will have several core purposes: Habitat restoration and enhancement to increase the quality and quantity of habitat in the Delta; other conservation actions to help address a number of stressors on covered species; conveyance facilities to enhance operational flexibility and water supply reliability while providing greater opportunities for habitat improvements and fishery conservation; water operations and management actions to achieve conservation and water supply goals; and a comprehensive monitoring, assessment, and adaptive management program guided by independent scientific input. Additional core purposes of the BDCP are to provide for the conservation of covered species within the planning area; to protect and restore certain aquatic, riparian, and associated terrestrial natural communities that support these covered species; and to provide for and restore water quality, water supplies, and ecosystem health within a stable regulatory framework. The EIS/EIR will evaluate the effects of implementing the BDCP, conveyance alternatives, and power line alignments, other nonstructural alternatives, and describe the permits necessary for BDCP implementation.

The BDCP will likely consist of several major elements, including new capital improvements to the water supply conveyance system, a restoration program for important habitats within and adjacent to the Delta in order to improve the ecological productivity and sustainability of the Delta, and monitoring and adaptive management for the restoration program. The plan will also likely include operational improvements for the water supply system in the near-term and for the long-term once any capital improvements have been completed and are operational.

Covered Activities

The BDCP covered activities may include, but are not limited to, existing or new activities related to:

• Existing Delta conveyance elements and operations of the CVP and SWP;
• New Delta conveyance facilities (including power line alignments) and operations of the CVP and SWP generally described in the BDCP November 2007 Points of Agreement;
• Operational activities, including emergency preparedness of the CVP and SWP in the Delta;
• Operational activities in the Delta related to water transfers involving water contractors or to serve environmental programs;
• Maintenance of the CVP, SWP, and other PREs' facilities in the Delta;
• Facility improvements of the CVP and SWP within the Statutory Delta (California Water Code Section 12220);
• Ongoing operation of and recurrent and future projects related to other Delta

water users, as defined by the Planning Agreement;

- Projects designed to improve Delta salinity conditions; and
- Conservation measures included in the BDCP, including, but not limited to, fishery related habitat restoration projects, adaptive management, and monitoring activities in the Delta.

Covered Species

The covered species that are the initial focus of the BDCP include certain aquatic species such as:

- Central Valley steelhead *Oncorhynchus mykiss;*
- Central Valley Chinook salmon *Oncorhynchus tshawytscha* (spring-run and fall/late fall-runs);
- Sacramento River Chinook salmon *Oncorhynchus tshawytscha* (winter-run);
- Delta smelt *Hypomesus transpacificus;*
- Green sturgeon *Acipenser medirostris;*
- White sturgeon *Acipenser transmontanus;*
- Splittail *Pogonichthys macrolepidotus;* and
- Longfin smelt *Spirinchus thaleichthys.*

Other species that will be considered for inclusion in the BDCP include, but may not be limited to:

- Swainson's hawk *Buteo swainsoni;*
- Bank swallow *Riparia riparia;*
- Giant garter snake *Thamnophis gigas;* and
- Valley elderberry longhorn beetle *Desmocerus californicus dimorphus.*

This list identifies the species that will be evaluated for inclusion in the BDCP as proposed covered species; however, the list may change as the planning process progresses. The participants anticipate that species may be added or removed from the list once more is learned about the nature of the covered activities and the impact of covered activities on native species within the planning area.

BDCP Planning Goals

The BDCP will include goals and objectives related to the management of covered activities and the protection of covered species and their habitats. As described in the Planning Agreement, the planning goals include:

1. Provide for the conservation and management of covered species within the planning area;
2. Preserve, restore, and enhance aquatic, riparian, and associated terrestrial natural communities and ecosystems that support covered species within the planning area through conservation partnerships;
3. Allow for projects that restore and protect water supply reliability, water quality, ecosystem, and ecosystem health to proceed within a stable regulatory framework;
4. Provide a means to implement covered activities in a manner that complies with applicable State and federal fish and wildlife protection laws, including the NCCPA or CESA, FESA, and other environmental laws, including CEQA and NEPA;
5. Provide a basis for permits necessary to lawfully take covered species;
6. Provide a comprehensive means to coordinate and standardize mitigation and compensation requirements for covered activities within the planning area;
7. Provide a less costly, more efficient project review process which results in greater conservation values than project-by-project, species-by-species review, and;
8. Provide clear expectations and regulatory assurances regarding covered activities occurring within the planning area.

Project Area

The planning area for the BDCP will consist of the aquatic ecosystems and natural communities and, potentially, the adjacent riparian and floodplain natural communities within the Statutory Delta. The Statutory Delta includes parts of Yolo, Solano, Contra Costa, San Joaquin, and Sacramento counties. However, it may be necessary for the BDCP to include conservation actions outside of the Statutory Delta that advance the goals and objectives of the BDCP within the Delta, including as appropriate, conservation actions in the Suisun Marsh, Suisun Bay, and areas upstream of the Delta. Any conservation actions outside the Statutory Delta would be implemented pursuant to cooperative agreements or similar mechanisms with local agencies, interested non-governmental organizations, landowners, and others. The EIS/EIR project area for which impacts are evaluated may be different than the BDCP geographic scope.

Basis for Preliminary Alternatives

As part of the BDCP process, the Steering Committee evaluated potential options to address water supply reliability, water quality, and ecosystem health in the Delta. Initial options included various combinations of water conveyance facilities and habitat restoration actions. As a result of this evaluation, the Steering Committee developed the Points of Agreement document that provides an overall framework for moving forward with development of the BDCP. Previous evaluations and potential improvements to the water conveyance system and strategies for in-Delta habitat restoration and enhancement outlined in the Points of Agreement document will be used for the basis of alternative development, but will not preclude or limit the range of alternatives to be analyzed under NEPA.

Statutory Authority

Reclamation, as administrative lead for this **Federal Register** action, provides this notice in accordance with NEPA regulations found in 40 CFR 1501.7.

NEPA (42 U.S.C. 4321 *et seq.*) requires that Federal agencies conduct an environmental analysis of their proposed actions to determine if the actions may significantly affect the human environment. Under NEPA and its implementing regulations (40 CFR 1500 *et seq.*; NOAA Administrative Order 216–6), a reasonable range of alternatives to the proposed action are to be developed and considered in an EIS/EIR prepared by the FWS and NMFS. Alternatives considered for analysis in an EIS/EIR may include variations in the scope or types of covered activities; variations in the location, amount, and types of conservation measures and the timing of project activities; variations in permit duration; or a combination of these or other elements. In addition, as required by NEPA, the EIS will identify significant direct, indirect, and cumulative effects, and possible mitigation for those significant effects, on biological resources, land use, air quality, water quality, water resources, socioeconomics, environmental justice, cultural resources, and other environmental issues that could occur with the implementation of the proposed action and alternatives.

Request for Comments

The purpose of this notice is to advise other Federal and State agencies, affected Tribes, and the public of our intention to continue to gather information to support the preparation of an EIS/EIR, to obtain suggestions and information from other agencies and the public on the scope of alternatives and issues to be addressed in the EIS/EIR, and to identify important issues raised by the public related to the development and implementation of the BDCP. Written comments from interested parties are invited to ensure that the full range of alternatives and issues related to the development of the BDCP is identified. Comments during this stage of the scoping process will only be

accepted in written form. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public. A similar notice is being published by DWR in accordance with CEQA requirements. Comments and participation in the scoping process are encouraged.

Special Assistance for Public Scoping Meetings

If special assistance is required at the public meetings, please contact Ms. Patti Idlof at 916–978–5056, TDD 916–978–5608, or via e-mail at *pidlof@mp.usbr.gov.* Please notify Ms. Idlof as far in advance as possible to enable Reclamation to secure the needed services. If a request cannot be honored, the requestor will be notified. A telephone device for the hearing impaired (TDD) is available at 916–978–5608.

Public Disclosure

Before including your name, address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: April 4, 2008.

Susan M. Fry,

Regional Environmental Officer, Mid-Pacific Region, Bureau of Reclamation.

Dated: April 4, 2008.

Ken McDermond,

Deputy Regional Director, U.S. Fish and Wildlife Service, Region 8, Sacramento, CA.

Dated: April 4, 2008.

Russell M. Strach,

Assistant Regional Administrator, Southwest Region, National Marine Fisheries Service.

[FR Doc. E8–8010 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–R–2008–N0047; 30136–1265–0000–S3]

Final Comprehensive Conservation Plan and Environmental Impact Statement for the Trempealeau National Wildlife Refuge, Wisconsin

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service announces that the Final Comprehensive Conservation Plan (CCP) and Environmental Impact Statement (EIS) is available for Trempealeau National Wildlife Refuge.

The Final CCP/EIS was prepared pursuant to the National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, and the National Environmental Policy Act of 1969. Goals and objectives in the CCP describe how the agency intends to manage the refuge over the next 15 years.

DATES: A Record of Decision will be signed by the Regional Director, U.S. Fish and Wildlife Service, Region 3, Fort Snelling, Minnesota, no sooner than 30 days after publication of this notice by the Environmental Protection Agency, in the **Federal Register**.

ADDRESSES: Copies of the Final CCP/EIS may be viewed at the Trempealeau National Wildlife Refuge Headquarters and public libraries near the refuge. You may access and download a copy via the Planning Web site at *http://www.fws.gov/midwest/planning/trempealeau,* or you may obtain a copy on compact disk by contacting: U.S. Fish and Wildlife Service, Division of Conservation Planning, Bishop Henry Whipple Federal Building, 1 Federal Drive, Fort Snelling, Minnesota 55111 (1–800–247–1247, extension 5429) or Trempealeau National Wildlife Refuge, W28488 Refuge Road, Trempealeau, WI 54661–7246 (608–539–2311). A limited number of hardcopies for distribution will be available at the Refuge Headquarters.

FOR FURTHER INFORMATION CONTACT: Vickie Hirschboeck, (608) 539–2311 extension 12.

SUPPLEMENTARY INFORMATION: The Refuge, established by an Executive Order in 1936 to provide a refuge and breeding ground for migratory birds and other wildlife, encompasses 6,226 acres. The Refuge is part of the Upper Mississippi River National Wildlife and Fish Refuge Complex. An estimated 70,000 visitors enjoy birding, hiking, biking, hunting, fishing, or photography at the Refuge. Over 2,000 young people learn about their environment each year through education programs. A dedicated force of volunteers contributes to the quality of the visitor experience, as well as successful habitat management.

The Draft CCP/EIS was released for public review June 12, 2007, for a 60-day comment period ending August 11, 2007. During the comment period the Refuge hosted a public meeting and a workshop attended by a total of 28 people. We received written comments from 18 individuals, two special interest groups, and two governmental agencies during the comment period.

In response to comments by the State of Wisconsin Department of Natural Resources, we made three modifications to species lists, added three strategies, and modified one objective and accompanying strategy in the preferred alternative. We also amended our discussion of climate change impacts. We consider all modifications minor.

When the Record of Decision is available, we will publish a notice of availability in the **Federal Register**. The Record of Decision will document which alternative in the Final CCP/EIS will become the 15-year CCP for the Refuge.

The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd–668ee et seq.), requires the Service to develop a CCP for each National Wildlife Refuge. The purpose in developing a CCP is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In addition to outlining broad management direction for conserving wildlife and their habitats, the CCP identifies wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update these CCPs at least every 15 years in accordance with the National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, and the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370d).

Dated: February 15, 2008.

Charles M. Wooley,

Acting Regional Director, U.S. Fish and Wildlife Service, Fort Snelling, Minnesota.

[FR Doc. E8–7911 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–952–08–1420–BJ, 14X1109]

Filing of Plats of Survey; Nevada

AGENCY: Bureau of Land Management.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public and interested State and local government officials of the filing of Plats of Survey in Nevada.

EFFECTIVE DATES: Filing is effective at 10 a.m. on the dates indicated below.

FOR FURTHER INFORMATION CONTACT: David D. Morlan, Chief, Branch of Geographic Sciences, Bureau of Land Management (BLM), Nevada State Office, 1340 Financial Blvd., P.O. Box 12000, Reno, NV 89520, 775–861–6541.

SUPPLEMENTARY INFORMATION:

1. The Plats of Survey of the following described lands were officially filed at the Nevada State Office, Reno, Nevada, on January 17, 2008:

The plat, representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of section 13, and a metes-and-bounds survey in section 13, Township 15 North, Range 63 East, Mount Diablo Meridian, Nevada, under Group No. 846, was accepted January 15, 2008.

The plat, representing the dependent resurvey of a portion of the west boundary, the subdivision of section 18, and a metes-and-bounds survey in section 18, Township 15 North, Range 64 East, Mount Diablo Meridian, Nevada, under Group No. 846, was accepted January 15, 2008. The plat, in 4 sheets, representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of certain sections, the metes-and-bounds survey of U.S. Highway Nos. 6, 50 and 93 through portions of sections 26 and 35, and metes-and-bounds surveys in certain sections, Township 16 North, Range 63 East, Mount Diablo Meridian, Nevada, under Group No. 847, was accepted January 15, 2008.

These surveys were executed to meet certain administrative needs of the Bureau of Indian Affairs.

2. The Plat of Survey of the following described lands was officially filed at the Nevada State Office, Reno, Nevada, on February 14, 2008.

The plat, in 2 sheets, representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of section 28, and metes-and-bounds surveys in section 28, Township 20 North, Range 20 East, Mount Diablo Meridian, Nevada, under Group No. 842, was accepted February 12, 2008.

This survey was executed to meet certain administrative needs of the City of Sparks and the Bureau of Land Management.

3. The Supplemental Plats of Survey of the following described lands were officially filed at the Nevada State Office, Reno, Nevada, on February 21, 2008. The supplemental plat, showing the subdivision of former lot 20, sec. 19, Township 22 South, Range 60 East, Mount Diablo Meridian, Nevada, was accepted February 19, 2008.

The supplemental plat, showing the subdivision of former lot 13, sec. 8, Township 19 South, Range 61 East, Mount Diablo Meridian, Nevada, was accepted February 19, 2008. These supplemental plats were prepared to meet certain administrative needs of the Bureau of Land Management.

4. The Plat of Survey of the following described lands was officially filed at the Nevada State Office, Reno, Nevada, on February 28, 2008.

The plat, representing the dependent resurvey of a portion of the subdivisional lines and a portion of the subdivision-of-section lines of section 12, the further subdivision of section 12, and a metes-and-bounds survey in section 12, Township 20 South, Range 59 East, Mount Diablo Meridian, Nevada, under Group No. 838, was accepted February 26, 2008.

This survey was executed to meet certain administrative needs of the Bureau of Land Management.

5. The Plats of Survey and the Supplemental Plat of Survey of the following described lands were officially filed at the Nevada State Office, Reno, Nevada, on March 21, 2008: The plat, in 4 sheets, representing the dependent resurvey of a portion of the Third Standard Parallel North, through a portion of Range 62 East, and a portion of the subdivisional lines, the metes-and-bounds survey of the northerly right-of-way line of Headhouse Road through sections 20, 21, 29, and a portion of section 30 and the metes-and-bounds survey of U.S. Highway No. 6 through sections 9, 16, 17, 19, 20 and a portion of section 30, Township 15 North, Range 62 East, Mount Diablo Meridian, Nevada, under Group No. 844, was accepted March 19, 2008.

The supplemental plat, showing corrections to the lotting in the SE1/4 of section 27, Township 16 North, Range 63 East, Mount Diablo Meridian, Nevada, was accepted March 19, 2008.

The plat, representing the dependent resurvey of a portion of the subdivisional lines, the subdivision of sections 27 and 28, the metes-and-bounds survey of the westerly right-of-way line of U.S. Highway No. 93 through portions of sections 22 and 27, and a metes-and-bounds survey in section 22, Township 20 North, Range 64 East, Mount Diablo Meridian, Nevada, under Group No. 845, was accepted March 19, 2008.

These surveys were executed, and this supplemental plat was prepared, to meet certain administrative needs of the Bureau of Indian Affairs.

6. The Plats of Survey of the following described lands were officially filed at the Nevada State Office, Reno, Nevada, on March 27, 2008:

The plat, representing the dependent resurvey of portions of the east and north boundaries and a portion of the subdivisional lines, and the metes-and-bounds survey of the easterly right-of-way line of U.S. Highway No. 93 through section 1, Township 24 South, Range 60 East, Mount Diablo Meridian, Nevada, under Group No. 860, was accepted March 25, 2008.

The plat, representing the dependent resurvey of a portion of the west boundary, a portion of the north boundary and a portion of the subdivisional lines, and a metes-and-bounds survey in section 6, Township 12 South, Range 47 East, Mount Diablo Meridian, Nevada, under Group No. 848, was accepted March 25, 2008.

These surveys were executed to meet certain administrative needs of the Bureau of Land Management.

7. The above-listed surveys are now the basic record for describing the lands for all authorized purposes. These surveys have been placed in the open files in the BLM Nevada State Office and are available to the public as a matter of information. Copies of the surveys and related field notes may be furnished to the public upon payment of the appropriate fees.

Dated: April 2, 2008.

David D. Morlan,

Chief Cadastral Surveyor, Nevada.

[FR Doc. E8–7915 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–963–1430–ET; F–22389]

Public Land Order No. 7699; Extension of Public Land Order No. 6677, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order extends the withdrawal created by Public Land

Order No. 6677, for an additional 20-year period. This extension is necessary to continue protection of the United States Air Force Beaver Creek Radio Relay Site in Alaska which would otherwise expire on May 22, 2008.

DATES: *Effective Date:* May 23, 2008.

FOR FURTHER INFORMATION CONTACT: Renee Fencl, Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7504; 907–271–5067.

SUPPLEMENTARY INFORMATION: The withdrawal extended by this order will expire May 22, 2028, unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (2000), the Secretary determines that the withdrawal shall be further extended.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

Public Land Order No. 6677, (53 FR 18283 (1988)), which withdrew 2.5 acres of public land from settlement, sale, location, or entry under the general land laws including the United States mining laws (30 U.S.C. Ch. 2) and from leasing under the mineral leasing laws, to protect the United States Air Force Beaver Creek Radio Relay Site, is hereby extended for an additional 20-year period until May 22, 2028.

Dated: March 27, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

[FR Doc. E8–8019 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU 0142168]

Public Land Order No. 7701; Modification of Public Land Order No. 3758; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order establishes a 20-year term for a Public Land Order which withdrew 80 acres of public land from surface entry and mining and reserved it on behalf of the Bureau of Bureau of Reclamation for the Provo River Project. The land is still needed for the purpose for which it was withdrawn. The land will remain withdrawn from surface entry and mining but not from mineral and geothermal leasing or mineral material sales.

DATES: *Effective Date:* April 15, 2008.

FOR FURTHER INFORMATION CONTACT: Rhonda Flynn, BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101–1345, 801–539–4132.

SUPPLEMENTARY INFORMATION: The Bureau of Reclamation has determined that the land is still needed for reclamation purposes. A copy of the Public Land Order containing a legal description of the land involved is available from the Bureau of Land Management, Utah State Office at the address above.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

Public Land Order No. 3758 (30 FR 9542), which withdrew public land from surface entry and mining and reserved it on behalf of the Bureau of Reclamation for the Provo River Project, is hereby modified to expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (2000), the Secretary determines that the withdrawal shall be extended.

Dated: March 25, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

[FR Doc. E8–8018 Filed 4–14–08; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Public Meeting of the Advisory Committee on Apprenticeship (ACA)

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of an open ACA meeting.

SUMMARY: Pursuant to section 10 of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. APP. 1), notice is hereby given of an open meeting of the Advisory Committee on Apprenticeship (ACA).

TIME AND DATE: The meeting will begin at approximately 8:30 a.m. on Wednesday, May 14, 2008, and continue until approximately 4:30 p.m. The meeting will reconvene at approximately 8:30 a.m. on Thursday, May 15, 2008, and adjourn at approximately 4:30 p.m.

PLACE: Sheraton Atlanta Hotel, 165 Courtland Street, NE., Atlanta, Georgia 30303, (404) 659–6500.

The agenda is subject to change due to time constraints and priority items which may come before the Committee between the time of this publication and the scheduled date of the ACA meeting.

FOR FURTHER INFORMATION CONTACT: Mr. John V. Ladd, Administrator, Office of Apprenticeship, Employment and Training Administration (ETA), U.S. Department of Labor, Room N–5311, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 693–2796, (this is not a toll-free number).

MATTERS TO BE CONSIDERED: The agenda will focus on the following topics:

- Employment and Training Administration Updates
- Office of Apprenticeship Updates
- NPRM & Regulatory Update
- Integration & Transformation: Apprenticeship and the Workforce System
- Education and Outreach
- Apprenticeship Opportunities in ''Green'' Industries

STATUS: Members of the public are invited to attend the proceedings. Individuals with disabilities should contact Ms. Kenya Huckaby at (202) 693–3795 no later than Wednesday, May 7, 2008, if special accommodations are needed.

Any member of the public who wishes to file written data or comments pertaining to the agenda may do so by sending the data or comments to Mr. John V. Ladd, Administrator, Office of Apprenticeship, U.S. Department of Labor, Room N–5311, 200 Constitution Avenue, NW., Washington, DC 20210. Such submissions should be sent by Wednesday, May 7, 2008, to be included in the record for the meeting.

Any member of the public who wishes to speak at the meeting should indicate the nature of the intended presentation and the amount of time needed by furnishing a written statement to the Designated Federal Official, Mr. John V. Ladd, by Wednesday, May 7, 2008. The Chairperson will announce at the beginning of the meeting the extent to which time will permit the granting of such requests.

Signed at Washington, DC, this 7th day of April 2008.

Brent R. Orrell,

Acting Assistant Secretary for Employment and Training Administration.

[FR Doc. E8–7905 Filed 4–14–08; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act Native American Employment and Training Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and Section 166(h)(4) of the Workforce Investment Act (WIA) [29 U.S.C. 2911(h)(4)], notice is hereby given of the next meeting of the Native American Employment and Training Council, as constituted under WIA.

TIME AND DATE: The meeting will begin at 1:45 p.m., Central Daylight Time (CDT) on Tuesday, May 20, 2008, and continue until 3:15 p.m. that day. The meeting will reconvene at 10:30 a.m. (CDT) on Wednesday, May 21, 2008, and continue until 5 p.m. that day. The meeting will reconvene at 10:30 a.m. (CDT) on Thursday, May 22, 2008, and adjourn at 4:30 p.m. that day. The period from 2:30 p.m. to 4:30 p.m. on May 22, 2008, will be reserved for participation and presentations by members of the public.

LOCATION: All sessions will be held at the Ho-Chunk Convention Center, South 3214 Highway 12, Lower Dells Salon A and B, Wisconsin Dells, Wisconsin 53913.

STATUS: The meeting will be open to the public. Members of the public not present may submit a written statement on or before May 14, 2008, to be included in the record of the meeting. Statements are to be submitted to Mrs. Evangeline M. Campbell, Designated Federal Official, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–4209, Washington, DC 20210. Persons who need special accommodations should contact Mr. Craig Lewis at (202) 693–3384 at least two business days before the meeting.

MATTERS TO BE CONSIDERED: The formal agenda will focus on the following topics: (1) U.S. Department of Labor, Employment and Training Administration Update; (2) The Native American Talent and Economic Development initiative; (3) Indian and Native American Program Update; (4) Program Year 2006 Performance; (5) Fiscal Year 2009 Funding; (6) Designations and Two-Year Strategic Planning Guidance; (7) Council Nominations Update; (8) Public Law 102–477 Update; (9) Workgroup Reports; and (10) Council Recommendations.

FOR FURTHER INFORMATION CONTACT: Ms. Campbell, at telephone number (202) 693–3737 (this is not a toll-free number).

Signed at Washington, DC, this 9th day of April, 2008.

Brent R. Orrell,

Acting Assistant Secretary, Employment and Training Administration.

[FR Doc. E8–7906 Filed 4–14–08; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act; Notice of Agency Meeting

TIME AND DATE: 10 a.m., Thursday, April 17, 2008.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Quarterly Insurance Fund Report.
2. Notice of Proposed Rulemaking: Parts 701 and 705 of NCUA's Rules and Regulations, The Low-Income Definition.
3. Notice of Proposed Rulemaking: Part 740 of NCUA's Rules and Regulations, The Official Advertising Statement.
4. Proposed Rule: Part 792 of NCUA's Rules and Regulations, Revisions for the Freedom of Information Act and Privacy Act Regulations.
5. Proposed Rule: Parts 712 and 741 of NCUA's Rules and Regulations, Credit Union Service Organizations.

RECESS: 11:15 a.m.

TIME AND DATE: 11:30 a.m., Thursday, April 17, 2008.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. One (1) Insurance Appeal. Closed pursuant to Exemption (6).
2. Request for Review under Sections 747.306 and 747.308 of NCUA's Rules and Regulations. Closed pursuant to Exemptions (6) and (8).
3. One (1) Merger Application under Section 205 of the Federal Credit Union Act. Closed pursuant to Exemption (8).
4. One (1) Administrative Action under Section 208 of the Federal Credit Union Act. Closed pursuant to Exemptions (8), (9)(A)(ii), and (B).

FOR FURTHER INFORMATION CONTACT: Mary Rupp, Secretary of the Board, Telephone: 703–518–6304.

Mary Rupp,

Secretary of the Board.

[FR Doc. E8–8035 Filed 4–14–08; 8:45 am]

BILLING CODE 7535–01–M

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee #13883; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following Astronomy and Astrophysics Advisory Committee (#13883) meeting:

Date and Time: May 8–9, 2008, 8:30 a.m.—5 p.m.

Place: National Science Foundation, Room 1235, Stafford I Building, 4201 Wilson Blvd., Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Dr. G. Wayne Van Citters, Director, Division of Astronomical Sciences, Suite 1045, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: 703–292–4908.

Purpose of Meeting: To provide advice and recommendations to the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA) and the U.S. Department of Energy (DOE) on issues within the field of astronomy and astrophysics that are of mutual interest and concern to the agencies.

Agenda: To hear presentations of current programming by representatives from NSF, NASA, DOE, and other agencies relevant to astronomy and astrophysics; to discuss current and potential areas of cooperation between the agencies; to formulate recommendations for continued and new areas of cooperation and mechanisms for achieving them.

Dated: April 9, 2008.

Susanne E. Bolton,

Committee Management Officer.

[FR Doc. E8–7907 Filed 4–14–08; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the Subcommittee on Plant License Renewal; Notice of Meeting

The ACRS Subcommittee on Plant License Renewal will hold a meeting on May 7, 2008, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, May 7, 2008—10:30 a.m. until 4 p.m.

The Subcommittee will discuss the Shearon Harris license renewal application and the associated Safety Evaluation Report (SER) with Open Items prepared by the NRR staff. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, Carolina Power & Light Company, 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, Mr. Peter Wen (telephone 301/415–2832) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted. 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 6:45 a.m. and 3:30 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: April 8, 2008.

Cayetano Santos,

Branch Chief, ACRS.

[FR Doc. E8–7989 Filed 4–14–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Federal Register Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Weeks of April 14, 21, 28, May 5, 12, 19, 2008.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of April 14, 2008

There are no meetings scheduled for the Week of April 14, 2008.

Week of April 21, 2008—Tentative

There are no meetings scheduled for the Week of April 21, 2008.

Week of April 28, 2008—Tentative

Monday, April 28, 2008

9:30 a.m.

Briefing on Reactor Materials Issues (Public Meeting). (Contact: Ted Sullivan, 301 415–2796.)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

Tuesday, April 29, 2008

9:30 a.m.

Discussion of Management Issues (Closed—Ex. 2).

1:25 p.m.

Affirmation Session (Public Meeting) (Tentative).

a. AmerGen Energy Company, LLC (License Renewal for Oyster Creek Nuclear Generating Station), Docket No. 50–219–LR, Citizens' Petition for Review of LBP–07–17 and Other Interlocutory Decisions in the Oyster Creek Proceeding (Tentative).

b. Oyster Creek, Indian Point, Pilgrim, and Vermont Yankee License Renewals, Docket Nos. 50–219–LR, 50–247–LR, 50–286–LR, 50–293–LR, 50–271–LR, Petition to Suspend Proceedings (Tentative).

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

1:30 p.m.

Meeting with Advisory Committee on the Medical Uses of Isotopes (Public Meeting). (Contact: Ashley Tull, 918–488–0552.)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

Wednesday, April 30, 2008

9:30 a.m.

Briefing on Materials Licensing and Security (Public Meeting). (Contact: Tomas Herrera, 301–415–7138.)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

1:30 p.m.

Periodic Briefing on New Reactor Issues (Public Meeting). (Contact: Robert Schaaf, 301–415–1312.)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

Week of May 5, 2008—Tentative

There are no meetings scheduled for the Week of May 5, 2008.

Week of May 12, 2008—Tentative

Friday, May 16, 2008

9 a.m.

Briefing on NRC Infrastructure (Public Meeting.) (Contact: Peter Rabideau, 301 415–7323.)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

Week of May 19, 2008—Tentative

There are no meetings scheduled for the Week of May 19, 2008.

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html*.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *REB3@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov*.

Dated: April 10, 2008.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 08–1134 Filed 4–11–08; 11:20 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 28235; 812–13430]

ALPS Advisers, Inc., et al.; Notice of Application

April 9, 2008.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), 22(e), and 24(d) of the Act and rule 22c–1 under the Act, under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act.

SUMMARY OF APPLICATION: Applicants request an order that would permit (a) Series of open-end management investment companies to issue shares (''Fund Shares'') that can be redeemed only in large aggregations (''Creation Unit Aggregations''); (b) secondary market transactions in Fund Shares to occur at negotiated prices; (c) dealers to sell Fund Shares to purchasers in the secondary market unaccompanied by a prospectus when prospectus delivery is not required by the Securities Act of 1933 (''Securities Act''); (d) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of a Creation Unit Aggregation for redemption; (e) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Unit Aggregations; and (f) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Fund Shares.

APPLICANTS: ALPS Advisers, Inc. (the ''Adviser''), ALPS ETF Trust (the ''Trust''), and ALPS Distributors, Inc. (the ''Distributor'').

FILING DATES: The application was filed on October 2, 2007, and amended on February 28, 2008. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in the notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 30, 2008, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090; Applicants, c/o Tané T. Tyler, Esq., ALPS Fund Services, Inc., P.O. Box 328, Denver, CO 80201–0328.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Counsel at (202) 551–6812, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Public Reference Desk, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1520, telephone (202) 551–5850.

Applicants' Representations

1. The Trust is registered as an open-end management investment company and is organized as a Delaware statutory trust. The Trust will offer Fund Shares of the Cohen & Steers Global Realty Majors ETF (the ''Initial Fund''), a series of the Trust, which will track an index of selected U.S. and non-U.S. real estate equity securities. Applicants may establish one or more registered investment companies in the future (''Future Funds,'' collectively with the Initial Fund, ''Funds''), either as separate trusts or as separate series of one or more trusts, which will be advised by the Adviser or an entity controlling, controlled by, or under common control with the Adviser.[1]

2. The Adviser will serve as the investment adviser to the Initial Fund. The Adviser is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). In the future, the Adviser may enter into sub-advisory agreements with other investment advisers to act as sub-advisers (''Sub-Advisers'') with respect to the Funds. Any Sub-Adviser will be registered under the Advisers Act. The Distributor, a broker-dealer (''Broker'') registered under the Securities Exchange Act of 1934 (the ''Exchange Act''), will serve as the principal underwriter and distributor for the Initial Fund. Each of the Adviser and the Distributor is a Colorado corporation and a wholly owned subsidiary of ALPS Holdings, Inc.

3. Each Fund will hold certain securities (''Portfolio Securities'') selected to correspond generally to the price and yield performance, before fees and expenses, of a specified equity securities index (an ''Underlying Index''). Each Underlying Index will be comprised of equity securities issued by (a) domestic issuers and non-domestic issuers meeting the requirements for trading in U.S. markets (''Domestic Index''), or (b) foreign equity securities or a combination of domestic and foreign securities (''Foreign Index''). No entity that creates, compiles, sponsors or maintains an Underlying Index (an ''Index Provider'') is or will be an affiliated person, as defined in section 2(a)(3) of the Act, or an affiliated person of an affiliated person, of the Trust, the Adviser, the Distributor, promoter or any Sub-Adviser to a Fund.

4. The investment objective of each Fund will be to provide investment results that correspond generally to the price and yield performance, before fees and expenses, of its Underlying Index. Intra-day values of the Underlying Index will be disseminated every 15 seconds throughout the trading day. A Fund will utilize either a ''replication'' or ''representative sampling'' strategy.[2] A Fund using a replication strategy will invest in substantially all of the Component Securities in its Underlying Index in approximately the same weightings as in the Underlying Index. In certain circumstances, such as when there are practical difficulties or substantial costs involved in holding every security in an Underlying Index or when a Component Security is illiquid, a Fund may use a representative sampling strategy pursuant to which it will invest in some, but not all of the

[1] All existing entities that intend to rely on the requested order have been named as applicants. Any other existing or future entity that subsequently relies on the order will comply with the terms and conditions of the application.

[2] Applicants represent that a Fund will normally invest at least 80% of its total assets in the component securities that comprise its Underlying Index (''Component Securities'') or, in the case of Funds that track a Foreign Index (''Foreign Funds''), Component Securities and depositary receipts representing such securities. Each Fund also may invest up to 20% of its assets in certain futures, options and swap contracts, cash and cash equivalents, as well as in stocks not included in its Underlying Index, but which the Adviser believes will help the Fund track its Underlying Index.

relevant Component Securities.[3] Applicants anticipate that a Fund that utilizes a representative sampling strategy will not track the performance of its Underlying Index with the same degree of accuracy as an investment vehicle that invests in every Component Security of the Underlying Index in the same weighting as the Underlying Index. Applicants expect that each Fund will have a tracking error relative to the performance of its Underlying Index of less than 5 percent.

5. Fund Shares will be sold in Creation Unit Aggregations of 25,000 to 200,000 Fund Shares.[4] All orders to purchase Creation Unit Aggregations must be placed with the Distributor by or through a party that has entered into an agreement with the Distributor (''Authorized Participant''). An Authorized Participant must be either: (a) a broker-dealer or other participant in the continuous net settlement system of the National Securities Clearing Corporation (''NSCC''), a clearing agency registered with the Commission, or (b) a participant in the Depository Trust Company (''DTC'', and such participant, ''DTC Participant''). Fund Shares generally will be sold in Creation Unit Aggregations in exchange for an in-kind deposit by the purchaser of a portfolio of securities designated by the Adviser or the Sub-Adviser to correspond generally to the price and yield performance of the relevant Underlying Index (the ''Deposit Securities''), together with the deposit of a specified cash payment (''Balancing Amount''). The Balancing Amount is generally an amount equal to the difference between (a) the net asset value (''NAV'') (per Creation Unit Aggregation) of the Fund and (b) the total aggregate market value (per Creation Unit Aggregation) of the Deposit Securities.[5] Applicants state that in some circumstances it may not be practicable or convenient for a Fund to operate exclusively on an ''in-kind'' basis. The Trust reserves the right to permit, under certain circumstances, a purchaser of Creation Unit Aggregations to substitute cash in lieu of depositing some or all of the requisite Deposit Securities.

6. An investor purchasing a Creation Unit Aggregation from a Fund will be charged a fee (''Transaction Fee'') to prevent the dilution of the interests of the remaining shareholders resulting from costs in connection with the purchase of Creation Unit Aggregations.[6] The exact amounts of Transaction Fees relevant to each Fund (including the maximum Transaction Fee) will be fully disclosed in the prospectus of such Fund (''Prospectus''), and the method for calculating the Transaction Fees will be disclosed in each Prospectus or statement of additional information (''SAI''). All orders to purchase Creation Unit Aggregations will be placed with the Distributor by or through an Authorized Participant, and it will be the Distributor's responsibility to transmit such orders to the Funds. The Distributor also will be responsible for delivering a Prospectus to those persons purchasing Creation Unit Aggregations, and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it. In addition, the Distributor will maintain a record of the instructions given to the applicable Fund to implement the delivery of Fund Shares.

7. Purchasers of Fund Shares in Creation Unit Aggregations may hold such Fund Shares or may sell such Fund Shares into the secondary market. Fund Shares will be listed and traded on the AMEX; Fund Shares of Future Funds will be listed and traded on an Exchange. It is expected that one or more member firms of a listing Exchange will be designated to act as a specialist and maintain a market for Fund Shares trading on the Exchange (a ''Specialist''), or if NASDAQ is the listing Exchange, one or more member firms of NASDAQ will act as a market maker (''Market Maker'') and maintain a market for Fund Shares.[7] Prices of Fund Shares trading on an Exchange will be based on the current bid/offer market. Fund Shares sold in the secondary market will be subject to customary brokerage commissions and charges.

8. Applicants expect that purchasers of Creation Unit Aggregations will include institutional investors and arbitrageurs (which could include institutional investors). A Specialist, or Market Maker, in providing a fair and orderly secondary market for the Fund Shares, also may purchase Creation Unit Aggregations for use in its market-making activities. Applicants expect that secondary market purchasers of Fund Shares will include both institutional investors and retail investors.[8] Applicants expect that the price at which Fund Shares trade will be disciplined by arbitrage opportunities created by the ability to continually purchase or redeem Creation Unit Aggregations at their NAV, which should ensure that Fund Shares will not trade at a material discount or premium in relation to their NAV.

9. Fund Shares will not be individually redeemable, and owners of Fund Shares may acquire those Fund Shares from the Fund, or tender such Fund Shares for redemption to the Fund, in Creation Unit Aggregations only. To redeem, an investor will have to accumulate enough Fund Shares to constitute a Creation Unit Aggregation. Redemption orders must be placed by or through an Authorized Participant. An investor redeeming a Creation Unit Aggregation generally will receive (a) a portfolio of securities designated to be delivered for Creation Unit Aggregation redemptions on the date that the request for redemption is submitted (''Fund Securities''), which may not be identical to the Deposit Securities required to purchase Creation Unit Aggregations on that date, and (b) a ''Cash Redemption Payment,'' consisting of an amount calculated in the same manner as the Balancing Amount, although the actual amount of the Cash Redemption

[3] Under the representative sampling strategy, the Adviser will seek to construct a Fund's portfolio so that its market capitalization, industry weightings, fundamental investment characteristics (such as return variability, earnings valuation and yield) and liquidity measures perform like those of the Underlying Index.

[4] The number of Fund Shares per Creation Unit Aggregation of the Initial Fund will be 50,000. The initial estimated price per Fund Share of the Initial Fund will be $50.

[5] The Trust will sell Creation Unit Aggregations of each Fund on any day that the New York Stock Exchange, the American Stock Exchange, LLC (''AMEX''), a Fund, and the custodian are open for business, including as required by section 22(e) of the Act (a ''Business Day''). Each Business Day, prior to the opening of trading on the Exchange (defined below), the list of names and amount of each security constituting the current Deposit Securities and the Balancing Amount, effective as of the previous Business Day, will be made available. Any national securities exchange as defined in section 2(a)(26) of the Act (each, an ''Exchange'') on which Fund Shares are listed will disseminate, every 15 seconds during its regular trading hours, through the facilities of the Consolidated Tape Association, an amount per Fund Share representing the sum of the estimated Balancing Amount and the current value of the Deposit Securities.

[6] Where a Fund permits a purchaser to substitute cash in lieu of depositing a portion of the requisite Deposit Securities, the purchaser may be assessed a higher Transaction Fee to cover the cost of purchasing such Deposit Securities, including brokerage costs, and part or all of the spread between the expected bid and the offer side of the market relating to such Deposit Securities.

[7] If Fund Shares are listed on NASDAQ, no particular Market Maker will be contractually obligated to make a market in Fund Shares, although NASDAQ's listing requirements stipulate that at least two Market Makers must be registered as Market Makers in Fund Shares to maintain the listing. Registered Market Makers are required to make a continuous, two-sided market at all times or be subject to regulatory sanctions.

[8] Fund Shares will be registered in book-entry form only. DTC or its nominee will be the registered owner of all outstanding Fund Shares. DTC or DTC Participants will maintain records reflecting beneficial owners of Fund Shares.

Payment may differ from the Balancing Amount if the Fund Securities are not identical to the Deposit Securities on that day.[9] An investor may receive the cash equivalent of a Fund Security in certain circumstances, such as if the investor is constrained from effecting transactions in the security by regulation or policy. A redeeming investor will be subject to a Transaction Fee, calculated in the same manner as a Transaction Fee payable in connection with purchases of Creation Unit Aggregations.

10. Neither the Trusts nor any individual Fund will be marketed or otherwise held out as an ''open-end investment company'' or a ''mutual fund.'' Instead, each Fund will be marketed as an ''exchange-traded fund,'' an ''investment company,'' a ''fund,'' or a ''trust.'' All marketing materials that describe the features or method of obtaining, buying or selling Fund Shares, or refer to redeemability, will prominently disclose that Fund Shares are not individually redeemable and that the owners of Fund Shares may purchase or redeem Fund Shares from the Fund in Creation Unit Aggregations only. The same approach will be followed in the SAI, shareholder reports and investor educational materials issued or circulated in connection with the Fund Shares. The Funds will provide copies of their annual and semi-annual shareholder reports to DTC Participants for distribution to beneficial owners of Fund Shares.

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), 22(e), and 24(d) of the Act and rule 22c–1 under the Act, under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provisions of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the owner, upon its presentation to the issuer, is entitled to receive approximately his proportionate share of the issuer's current net assets, or the cash equivalent. Because Fund Shares will not be individually redeemable, applicants request an order that would permit the Trusts to register as open-end management investment companies and issue Fund Shares that are redeemable in Creation Units Aggregations only. Applicants state that investors may purchase Fund Shares in Creation Unit Aggregations and redeem Creation Unit Aggregations from each Fund. Applicants further state that because the market price of Fund Shares will be disciplined by arbitrage opportunities, investors should be able to sell Fund Shares in the secondary market at prices that do not vary substantially from their NAV.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security, which is currently being offered to the public by or through a principal underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Fund Shares will take place at negotiated prices, not at a current offering price described in a Prospectus, and not at a price based on NAV. Thus, purchases and sales of Fund Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Fund Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution of investment company shares by eliminating price competition from dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Fund Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Fund Shares does not involve the Funds as parties and cannot result in dilution of an investment in Fund Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Fund Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the proposed distribution system will be orderly because competitive forces in the marketplace will ensure that the difference between the market price of Fund Shares and their NAV remains narrow.

Section 24(d) of the Act

7. Section 24(d) of the Act provides, in relevant part, that the prospectus delivery exemption provided to dealer transactions by section 4(3) of the Securities Act does not apply to any transaction in a redeemable security issued by an open-end investment company. Applicants seek relief from section 24(d) to permit dealers selling Fund Shares in the secondary market to rely on the prospectus delivery

[9] The Funds will comply with the federal securities laws in accepting Deposit Securities and satisfying redemptions with Fund Securities, including that the Deposit Securities and Fund Securities are sold in transactions that would be exempt from registration under the Securities Act. As a general matter, the Deposit Securities and Fund Securities will correspond pro rata to the securities held by each Fund.

exemption provided by section 4(3) of the Securities Act.[10]

8. Applicants state that Fund Shares are bought and sold in the secondary market in the same manner as closed-end fund shares. Applicants note that transactions in closed-end fund shares are not subject to section 24(d), and thus closed-end fund shares are sold in the secondary market without a prospectus. Applicants contend that Fund Shares likewise merit a reduction in the unnecessary compliance costs and regulatory burdens resulting from the imposition of the prospectus delivery obligations in the secondary market. Because Fund Shares will be listed on an Exchange, prospective investors will have access to information about the product over and above what is normally available about an open-end security. Applicants state that information regarding market price and volume will be continually available on a real time basis throughout the day on brokers' computer screens and other electronic services. The previous day's price and volume information for Fund Shares will be published daily in the financial section of newspapers. In addition, a Web site will be maintained that will include each Prospectus and SAI, the relevant Underlying Index for each Fund, and additional quantitative information that is updated on a daily basis, including the mid-point of the bid-ask spread at the time of the calculation of NAV (''Bid/Ask Price''),[11] the NAV for each Fund, and information about the premiums and discounts at which the Fund Shares have traded.

9. Applicants will arrange for broker-dealers selling Fund Shares in the secondary market to provide purchasers with a product description (''Product Description'') that describes, in plain English, the relevant Fund and the Fund Shares it issues. Applicants state that a Product Description is not intended to substitute for a full Prospectus. Applicants state that the Product Description will be tailored to meet the information needs of investors purchasing Fund Shares in the secondary market.

Section 22(e)

10. Section 22(e) generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. The principal reason for the requested exemption is that settlement of redemptions for the Foreign Funds is contingent not only on the settlement cycle of the United States market, but also on currently practicable delivery cycles in local markets for underlying foreign securities held by the Foreign Funds. Applicants state that local market delivery cycles for transferring certain foreign securities to investors redeeming Creation Unit Aggregations, together with local market holiday schedules, will under certain circumstances require a delivery process in excess of seven calendar days for the Foreign Funds. Applicants request relief under section 6(c) of the Act from section 22(e) to allow the Foreign Funds to pay redemption proceeds up to 14 calendar days (or, with respect to future Foreign Funds, within not more than the number of calendar days known to applicants as being the maximum number of calendar days required for such payment or satisfaction in the principal local foreign market(s) where transactions in Portfolio Securities of each such Fund customarily clear and settle) after the tender of a Creation Unit Aggregation for redemption. At all other times and except as disclosed in the relevant Prospectus and/or SAI, applicants expect that each Foreign Fund will be able to deliver redemption proceeds within seven days.[12] With respect to future Foreign Funds, applicants seek the same relief from section 22(e) only to the extent that circumstances similar to those described in the application exist.

11. Applicants state that section 22(e) was designed to prevent unreasonable, undisclosed and unforeseen delays in the payment of redemption proceeds. Applicants assert that the requested relief will not lead to the problems that section 22(e) was designed to prevent. Applicants state that the SAI will disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of redemption proceeds in seven calendar days, and the maximum number of days needed to deliver the proceeds for the relevant Foreign Fund. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect in-kind purchases and redemptions of Creation Unit Aggregations.

Section 12(d)(1)

12. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring securities of an investment company if such securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter and any other broker-dealer from selling the investment company's shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

13. Applicants request an exemption to permit management investment companies (''Purchasing Management Companies'') and unit investment trusts (''Purchasing Trusts'') registered under the Act that are not sponsored or advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser and are not part of the same ''group of investment companies,'' as defined in section 12(d)(1)(G)(ii) of the Act, as the Trusts (Purchasing Management Companies and Purchasing Trusts collectively, ''Purchasing Funds'') to acquire shares of a Fund beyond the limits of section 12(d)(1)(A). Purchasing Funds exclude registered investment companies that are, or in the future may

[10] Applicants state that they are not seeking relief from the prospectus delivery requirement for non-secondary market transactions, such as transactions in which an investor purchases Fund Shares from the Trust or an underwriter. Applicants further state that each Prospectus will caution broker-dealers and others that some activities on their part, depending on the circumstances, may result in their being deemed statutory underwriters and subject them to the prospectus delivery and liability provisions of the Securities Act. For example, a broker-dealer firm and/or its client may be deemed a statutory underwriter if it purchases Creation Unit Aggregations from a Fund, breaks them down into the constituent Fund Shares, and sells those Fund Shares directly to customers, or if it chooses to couple the creation of a supply of new Fund Shares with an active selling effort involving solicitation of secondary market demand for Fund Shares. Each Prospectus will state that whether a person is an underwriter depends upon all of the facts and circumstances pertaining to that person's activities. Each Prospectus will caution dealers who are not ''underwriters'' but are participating in a distribution (as contrasted to ordinary secondary market trading transactions), and thus dealing with Fund Shares that are part of an ''unsold allotment'' within the meaning of section 4(3)(C) of the Securities Act, that they would be unable to take advantage of the prospectus delivery exemption provided by section 4(3) of the Securities Act.

[11] The Bid/Ask Price per Fund Share of a Fund is determined using the highest bid and the lowest offer on the Exchange on which the Fund Shares are listed.

[12] Rule 15c6–1 under the Exchange Act requires that most securities transactions be settled within three business days of the trade. Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may have under rule 15c6–1.

be, part of the same group of investment companies within the meaning of section 12(d)(1)(G)(ii) of the Act as the Funds. In addition, applicants seek relief to permit the Funds or any Broker that is registered under the Exchange Act to sell Fund Shares to a Purchasing Fund in excess of the limits of section 12(d)(1)(B).

14. Each Purchasing Management Company will be advised by an investment adviser within the meaning of section 2(a)(20)(A) of the Act (the ''Purchasing Fund Adviser'') and may be sub-advised by one or more investment advisers within the meaning of section 2(a)(20)(B) of the Act (each a ''Purchasing Fund Sub-Adviser''). Any investment adviser to a Purchasing Fund will be registered under the Advisers Act. Each Purchasing Trust will be sponsored by a sponsor (''Sponsor'').

15. Applicants submit that the proposed conditions to the relief requested, including the requirement that Purchasing Funds enter into an agreement with a Fund for the purchase of Fund Shares (a ''Purchasing Fund Agreement''), adequately address the concerns underlying the limits in section 12(d)(1)(A) and (B), which include concerns about undue influence, excessive layering of fees and overly complex structures. Applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

16. Applicants believe that neither the Purchasing Funds nor a Purchasing Fund Affiliate would be able to exert undue influence over the Funds.[13] To limit the control that a Purchasing Fund may have over a Fund, applicants propose a condition prohibiting a Purchasing Fund Adviser or a Sponsor, any person controlling, controlled by, or under common control with a Purchasing Fund Adviser or Sponsor, and any investment company and any issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by a Purchasing Fund Adviser or Sponsor, or any person controlling, controlled by, or under common control with a Purchasing Fund Adviser or Sponsor (''Purchasing Fund Advisory Group'') from controlling (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Purchasing Fund Sub-Adviser, any person controlling, controlled by or under common control with the Purchasing Fund Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Purchasing Fund Sub-Adviser or any person controlling, controlled by or under common control with the Purchasing Fund Sub-Adviser (''Purchasing Fund Sub-Advisory Group''). Applicants propose other conditions to limit the potential for undue influence over the Funds, including that no Purchasing Fund or Purchasing Fund Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in any offering of securities during the existence of any underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting''). An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Purchasing Fund Adviser, Purchasing Fund Sub-Adviser, employee or Sponsor of a Purchasing Fund, or a person of which any such officer, director, member of an advisory board, Purchasing Fund Adviser, Purchasing Fund Sub-Adviser, employee, or Sponsor is an affiliated person (except any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

17. Applicants do not believe the proposed arrangement will involve excessive layering of fees. The board of directors or trustees of any Purchasing Management Company, including a majority of the disinterested directors or trustees, will find that the advisory fees charged to the Purchasing Management Company are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract(s) of any Fund in which the Purchasing Management Company may invest. In addition, a Purchasing Fund Adviser or a trustee (''Trustee'') or Sponsor of a Purchasing Trust will waive fees otherwise payable to it by the Purchasing Management Company or Purchasing Trust in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–1 under the Act) received by the Purchasing Fund Adviser or Trustee or Sponsor to the Purchasing Trust or an affiliated person of the Purchasing Fund Adviser, Trustee or Sponsor, from the Funds in connection with the investment by the Purchasing Management Company or Purchasing Trust in the Fund. Applicants state that any sales loads or service fees charged with respect to shares of a Purchasing Fund will not exceed the limits applicable to a fund of funds set forth in Conduct Rule 2830 of the NASD.

18. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that no Fund may acquire securities of any investment company or company relying on sections 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act. Applicants also represent that to ensure that Purchasing Funds comply with the terms and conditions of the requested relief from section 12(d)(1), any Purchasing Fund that intends to invest in a Fund in reliance on the requested order will be required to enter into a Purchasing Fund Agreement between the Fund and the Purchasing Fund. The Purchasing Fund Agreement will require the Purchasing Fund to adhere to the terms and conditions of the requested order. The Purchasing Fund Agreement also will include an acknowledgement from the Purchasing Fund that it may rely on the order only to invest in the Funds and not in any other investment company. The Purchasing Fund Agreement will further require any Purchasing Fund that exceeds the 5% or 10% limitations in section 12(d)(1)(A)(ii) and (iii) to disclose in its prospectus that it may invest in ETFs, and to disclose, in ''plain English,'' in its prospectus the unique characteristics of the Purchasing Funds investing in exchange-traded funds (''ETFs''), including but not limited to the expense structure and any additional expenses of investing in ETFs.

19. Applicants also note that a Fund may choose to reject a direct purchase of Fund Shares in Creation Unit Aggregations by a Purchasing Fund. To the extent that a Purchasing Fund purchases Fund Shares in the secondary market, a Fund would still retain its ability to reject initial purchases of Fund Shares made in reliance on the requested order by declining to enter into the Purchasing Fund Agreement prior to any investment by a Purchasing Fund in excess of the limits of section 12(d)(1)(A).

[13] A ''Purchasing Fund Affiliate'' is a Purchasing Fund Adviser, Purchasing Fund Sub-Adviser, Sponsor, promoter, and principal underwriter of a Purchasing Fund, and any person controlling, controlled by, or under common control with any of those entities. A ''Fund Affiliate'' is an investment adviser, promoter, or principal underwriter of a Fund and any person controlling, controlled by, or under common control with any of these entities.

Section 17(a)(1) and (2) of the Act

20. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such a person, from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' to include any person directly or indirectly owning, controlling or holding with power to vote 5% or more of the outstanding voting securities of the other person, any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled or held with the power to vote by the other person, and any person directly or indirectly controlling, controlled by or under common control with the other person. Section 2(a)(9) of the Act provides that a control relationship will be presumed where one person owns more than 25% of another person's voting securities.

21. Applicants request an exemption from section 17(a) of the Act pursuant to sections 17(b) and 6(c) of the Act to permit persons to effectuate in-kind purchases and redemptions with a Fund when they are affiliated persons, or affiliated persons of affiliated persons, of the Fund solely by virtue of one or more of the following: (a) Holding 5 percent or more, or in excess of 25 percent, of the outstanding Fund Shares of one or more Funds; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5 percent or more, or more than 25 percent, of the shares of one or more other registered investment companies (or series thereof) advised by the Adviser.

22. Applicants assert that no useful purpose would be served by prohibiting these types of affiliated persons from purchasing or redeeming Creation Unit Aggregations through ''in-kind'' transactions. The deposit procedures for both in-kind purchases and in-kind redemptions of Creation Unit Aggregations will be the same for all purchases and redemptions. Deposit Securities and Fund Securities will be valued in the same manner as Portfolio Securities. Therefore, applicants state that in-kind purchases and redemptions will afford no opportunity for these affiliated persons of a Fund, or the affiliated persons of such affiliated persons, to effect a transaction detrimental to other holders of Fund Shares. Applicants also believe that in-kind purchases and redemptions will not result in self-dealing or overreaching of the Funds.

23. Applicants also seek relief from section 17(a) to permit a Fund that is an affiliated person of a Purchasing Fund because the Purchasing Fund holds 5% or more of the Fund Shares of the Fund to sell its Fund Shares to and redeem its Fund Shares from a Purchasing Fund and to engage in the accompanying in-kind transactions with the Purchasing Fund.[14] Applicants note that Creation Unit Aggregations that are purchased or redeemed directly from a Fund will be based on the NAV of the Fund.[15] Applicants believe that any proposed transactions directly between the Funds and Purchasing Funds will be consistent with the policies of each Purchasing Fund. The purchase of Creation Unit Aggregations by a Purchasing Fund directly from a Fund will be accomplished in accordance with the investment restrictions of any such Purchasing Fund and will be consistent with the investment policies set forth in the Purchasing Fund's registration statement. The Purchasing Fund Agreement will require any Purchasing Fund that purchases Creation Unit Aggregations directly from a Fund to represent that the purchase of Creation Unit Aggregations from a Fund by a Purchasing Fund will be accomplished in compliance with the investment restrictions of the Purchasing Fund and will be consistent with the investment policies set forth in the Purchasing Fund's registration statement.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

ETF Relief

1. As long as the Trust operates in reliance on the requested order, Fund Shares will be listed on an Exchange.

2. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Each Prospectus will prominently disclose that Fund Shares are not individually redeemable shares and will disclose that the owners of Fund Shares may acquire those Fund Shares from the Fund and tender those Fund Shares for redemption to the Fund in Creation Unit Aggregations only. Any advertising material that describes the purchase or sale of Creation Unit Aggregations or refers to redeemability will prominently disclose that Fund Shares are not individually redeemable, and that owners of Fund Shares may acquire those Fund Shares from the Fund and tender those Fund Shares for redemption to the Fund in Creation Unit Aggregations only.

3. The Web site maintained for the Funds, which will be publicly accessible at no charge, will contain the following information, on a per Fund Share basis, for each Fund: (a) The prior Business Day's NAV and the Bid/Ask Price, and a calculation of the premium or discount of the Bid/Ask Price at the time of calculation of the NAV against such NAV; and (b) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. In addition, the Product Description for each Fund will state that the Web site for the Fund has information about the premiums and discounts at which Fund Shares have traded.

4. Each Prospectus and annual report also will include: (a) The information listed in condition 3(b), (i) in the case of the Prospectus, for the most recently completed year (and the most recently completed quarter or quarters, as applicable) and (ii) in the case of the annual report, for the immediately preceding five years, as applicable; and (b) the following data, calculated on a per Fund Share basis for one, five and ten year periods (or life of the Fund): (i) The cumulative total return and the average annual total return based on NAV and Bid/Ask Price, and (ii) the cumulative total return of the relevant Underlying Index.

5. Before a Fund may rely on the order, the Commission will have approved, pursuant to rule 19b–4 under the Exchange Act, an Exchange rule requiring Exchange members and member organizations effecting transactions in Fund Shares to deliver a Product Description to purchasers of Fund Shares.

6. Each Prospectus and Product Description will clearly disclose that, for purposes of the Act, Fund Shares are issued by the Fund, which is a registered investment company, and that the acquisition of Fund Shares by investment companies is subject to the restrictions of section 12(d)(1) of the Act, except as permitted by an exemptive order that permits registered

[14] Applicants acknowledge that receipt of compensation by (a) an affiliated person of a Purchasing Fund, or an affiliated person of such person, for the purchase by the Purchasing Fund of Fund Shares or (b) an affiliated person of a Fund, or an affiliated person of such person, for the sale by the Fund of its Fund Shares to a Purchasing Fund may be prohibited by section 17(e)(1) of the Act. The Purchasing Fund Agreement also will include this acknowledgement.

[15] Applicants believe that a Purchasing Fund will purchase Fund Shares in the secondary market and will not purchase or redeem Creation Unit Aggregations directly from a Fund. Nonetheless, a Purchasing Fund that owns 5% or more of a Fund could seek to transact in Creation Unit Aggregations directly with a Fund pursuant to the section 17(a) relief requested.

investment companies to invest in a Fund beyond the limits in section 12(d)(1), subject to certain terms and conditions, including that the registered investment company enter into a Purchasing Fund Agreement with a Fund regarding the terms of the investment.

7. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based exchange-traded funds.

Section 12(d)(1) Relief

8. The members of a Purchasing Fund Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The members of a Purchasing Fund Sub-Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding Fund Shares of a Fund, a Purchasing Fund Advisory Group or a Purchasing Fund Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25% of the outstanding Fund Shares of a Fund, it will vote its Fund Shares in the same proportion as the vote of all other holders of the Fund Shares. This condition does not apply to the Purchasing Fund Sub-Advisory Group with respect to a Fund for which the Purchasing Fund Sub-Adviser or a person controlling, controlled by, or under common control with the Purchasing Fund Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

9. No Purchasing Fund or Purchasing Fund Affiliate will cause any existing or potential investment by the Purchasing Fund in a Fund to influence the terms of any services or transactions between the Purchasing Fund or Purchasing Fund Affiliate and the Fund or a Fund Affiliate.

10. The board of directors or trustees of a Purchasing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to ensure that the Purchasing Fund Adviser and Purchasing Fund Sub-Adviser are conducting the investment program of the Purchasing Management Company without taking into account any consideration received by the Purchasing Management Company or a Purchasing Fund Affiliate from a Fund or a Fund Affiliate in connection with any services or transactions.

11. No Purchasing Fund or Purchasing Fund Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in any Affiliated Underwriting.

12. Before investing in a Fund in excess of the limits in section 12(d)(1)(A), each Purchasing Fund and the Fund will execute a Purchasing Fund Agreement stating, without limitation, that their boards of directors or trustees and their investment advisers or sponsors and trustees, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Fund Shares in excess of the limit in section 12(d)(1)(A)(i), a Purchasing Fund will notify the Fund of the investment. At such time, the Purchasing Fund will also transmit to the Fund a list of the names of each Purchasing Fund Affiliate and Underwriting Affiliate. The Purchasing Fund will notify the Fund of any changes to the list of names as soon as reasonably practicable after a change occurs. The relevant Fund and the Purchasing Fund will maintain and preserve a copy of the order, the agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

13. The Purchasing Fund Adviser, Trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Purchasing Fund in an amount at least equal to any compensation (including fees received under any plan adopted by a Fund under rule 12b–1 under the Act) received from a Fund by the Purchasing Fund Adviser, Trustee or Sponsor, or an affiliated person of the Purchasing Fund Adviser, Trustee or Sponsor, other than any advisory fees paid to the Purchasing Fund Adviser, Trustee or Sponsor, or its affiliated person by a Fund, in connection with the investment by the Purchasing Fund in the Fund. Any Purchasing Fund Sub-Adviser will waive fees otherwise payable to the Purchasing Fund Sub-Adviser, directly or indirectly, by the Purchasing Management Company in an amount at least equal to any compensation received from a Fund by the Purchasing Fund Sub-Adviser, or an affiliated person of the Purchasing Fund Sub-Adviser, other than any advisory fees paid to the Purchasing Fund Sub-Adviser or its affiliated person by the Fund, in connection with the investment by the Purchasing Management Company in a Fund made at the direction of the Purchasing Fund Sub-Adviser. In the event that the Purchasing Fund Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Purchasing Management Company.

14. Any sales charges and/or service fees charged with respect to shares of a Purchasing Fund will not exceed the limits applicable to a fund of funds as set forth in Conduct Rule 2830 of the NASD.

15. Once an investment by a Purchasing Fund in the securities of a Fund exceeds the limit in section 12(d)(1)(A)(i) of the Act, the board of directors/trustees of a Fund (''Board''), including a majority of the disinterested Board members, will determine that any consideration paid by the Fund to a Purchasing Fund or a Purchasing Fund Affiliate in connection with any services or transactions: (a) is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund; (b) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (c) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund and its investment adviser(s), or any person controlling, controlled by, or under common control with such investment adviser(s).

16. The Board, including a majority of the disinterested Board members, will adopt procedures reasonably designed to monitor any purchases of securities by a Fund in an Affiliated Underwriting once the investment by a Purchasing Fund in a Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Purchasing Fund in a Fund. The Board will consider, among other things: (a) Whether the purchases were consistent with the investment objectives and policies of the Fund; (b) how the performance of securities purchased in an Affiliated Underwriting compares to the performances of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (c) whether the amount of securities purchased by the Fund in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if

appropriate, the institution of procedures designed to assure that purchases of securities in Affiliated Underwritings are in the best interests of shareholders of the Fund.

17. Each Fund will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings, once an investment by a Purchasing Fund in shares of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the Board's determinations were made.

18. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Purchasing Management Company, including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund in which the Purchasing Management Company may invest. These findings and their basis will be recorded fully in the minute books of the appropriate Purchasing Management Company.

19. No Fund will acquire securities of any other investment company or companies relying on sections 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–8028 Filed 4–14–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57640; File No. SR–NFA–2008–01]

Self-Regulatory Organizations; National Futures Association; Notice of Filing and Immediate Effectiveness of Proposed Amendments to the Interpretive Notice Regarding Compliance Rule 2–9: FCM and IB Anti-Money Laundering Program

April 9, 2008.

Pursuant to section 19(b)(7) of the Securities Exchange Act of 1934 (''Exchange Act'') [1], and Rule 19b–7 under the Exchange Act,[2] notice is hereby given that on March 17, 2008, National Futures Association (''NFA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change described in Items I, II, and III below, which Items have been substantially prepared by NFA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. NFA also has filed the proposed rule change with the Commodity Futures Trading Commission (''CFTC'').

NFA, on December 5, 2007, submitted proposed rule changes to the CFTC for approval. The CFTC approved the proposed rule changes on January 15, 2008. On March 17, 2008, NFA requested that the CFTC make a determination that review of a technical amendment to the approved rule changes (correcting a **Federal Register** notice citation) is not necessary. On March 28, 2008, the CFTC notified the NFA that the CFTC has determined not to review the technical amendment for approval.[3]

The proposed rule changes approved by the CFTC on January 15, 2008, were previously filed with the SEC in File No. SR–NFA–2007–06. That filing is being withdrawn by NFA and this filing, which includes both the rule changes approved by the CFTC and the technical amendment, is being filed in its place.

I. Self-Regulatory Organization's Description of the Proposed Rule Change

Over the last several months, the Financial Crimes Enforcement Network (''FinCEN'') has taken a number of actions that impact the content of NFA's AML Interpretive Notice. These actions include:

- Adopting a final rule under the Bank Secrecy Act (''BSA'') as amended by Section 312 of the USA Patriot Act to require Futures Commission Merchants (''FCMs'') and Introducing Brokers (''IBs'') [4] to apply enhanced due diligence measures to correspondent accounts maintained for certain foreign banks. This rule will become effective in two parts. Beginning on February 5, 2008, the rule applies to accounts established from that date forward. On May 5, 2008, the rule will apply to all existing accounts established prior to February 5, 2008.[5]
- Issuing guidance clarifying that in a give-up arrangement the clearing FCM, and not the executing FCM, is required to apply its CIP to the customer.[6]
- Issuing guidance clarifying that, upon request, FCMs and IBs are required to provide appropriate law enforcement and regulatory agencies with any supporting documentation related to a Suspicious Activity Report filed with FinCEN.[7]

The amendments to NFA's AML Interpretive Notice incorporate the requirements of FinCEN's final rule under the BSA as amended by Section 312 of the USA Patriot Act and the additional guidance issued by FinCEN.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

NFA has prepared statements concerning the purpose of, and basis for, the proposed rule change, burdens on competition, and comments received from members, participants, and others. The text of these statements may be examined at the places specified in Item IV below. These statements are set forth in sections A, B, and C below.

[1] 15 U.S.C. 78s(b)(7).

[2] 17 CFR 240.19b–7.

[3] *See* letter from Barbara S. Gold, Acxting Deputy Director, CFTC to Thomas W. Sexton, III, Esq., General Counsel, NFA dated March 28, 2008..

[4] An IB that limits its activities to soliciting and accepting orders for the purchase or sale of commodity futures contracts is not required to comply with the due diligence provisions of the correspondent account rule.

[5] 17 CFR 103.175. *See also* Special Due Diligence Programs for Certain Foreign Accounts, 72 FR 44768 (Aug. 9, 2007).

[6] FinCEN Guidance on Application of the Customer Identification Program Rule to Future Commission Merchants Operating as Executing and Clearing Brokers in Give-Up Arrangements, FIN–2007–G001 (Apr. 20, 2007), available at *http://www.fincen.gov/cftc_fincen_guidance.html.*

[7] FinCEN Guidance on Suspicious Activity Report Supporting Documentation, FIN–2007–G003 (June 13, 2007), available at *http://www.fincen.gov/Supporting_Documentation_Guidance.html.*

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 15A(k) of the Exchange Act[8] makes NFA a national securities association for the limited purpose of regulating the activities of NFA members (''Members'') who are registered as brokers or dealers in security futures products under section 15(b)(11) of the Exchange Act.[9] The amendments to the interpretive notice apply to all Members, including those who are registered as security futures brokers or dealers under section 15(b)(11).

The amendments to NFA's AML Interpretive Notice incorporate the requirements that are imposed by FinCEN's final rule under the BSA as amended by section 312 of the USA Patriot Act and the additional guidance issued by FinCEN.

2. Statutory Basis

The rule change is authorized by, and consistent with, section 15A(k) of the Exchange Act. This Section requires NFA to have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest in connection with security futures products. The proposed rule change accomplishes this by requiring that Members comply with applicable AML requirements and providing guidance on how to achieve such compliance.

B. Self-Regulatory Organization's Statement on Burden on Competition

The rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act and the CEA. Any burdens imposed by the rule change are already required under Federal laws or regulations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NFA did not publish the rule change to the membership for comment. NFA did not receive comment letters concerning the rule change.

[8] 15 U.S.C. 78o–3(k).

[9] 15 U.S.C. 78o(b)(11).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

NFA, on December 5, 2007, submitted the proposed Interpretive Notice entitled ''NFA Compliance Rule 2–9: FCM and IB Anti-Money Laundering Program'' to the CFTC for approval. The CFTC approved the rule change on January 15, 2008. On March 17, 2008, NFA submitted a technical amendment to Footnote 22 of the Interpretive Notice entitled ''NFA Compliance Rule 2–9: ''FCM and IB Anti-Money Laundering Program'' (correcting a **Federal Register** notice citation) to the CFTC requesting that the CFTC make a determination that review of the technical amendment is not necessary. The CFTC notified the NFA that it has determined not to review the technical amendment for approval.[10]

Within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refiled in accordance with the provisions of section 19(b)(1) of the Exchange Act.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change conflicts with the Exchange 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–NFA–2008–01 on the subject line.

Paper Comments

- Send nine copies of paper comments to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NFA–2008–01. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 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 NFA. 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–NFA–2008–01 and should be submitted on or before May 6, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–7959 Filed 4–14–08; 8:45 am]

BILLING CODE 8010–01–P

[10] *See* letter from Barbara S. Gold, Acting Deputy Director, CFTC to Thomas W. Sexton, III, Esq., General Counsel, NFA dated March 28, 2008.

[11] 15 U.S.C. 78s(b)(1).

[12] 17 CFR 200.30–3(a)(73).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57633; File No. SR–CBOE–2008–39]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Temporary Membership Status Access Fee

April 8, 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 March 31, 2008, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II and III below, which Items have been prepared by CBOE. The Exchange filed the proposal as one establishing or changing a due,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

fee, or other charge imposed by the Exchange under Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to adjust the monthly access fee for persons granted temporary CBOE membership status (''Temporary Members'') pursuant to Interpretation and Policy .02 under CBOE Rule 3.19 (''Rule 3.19.02''). The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/Legal/*), at the Exchange's Office of the Secretary, 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, CBOE 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. CBOE 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 current access fee for Temporary Members under Rule 3.19.02[5] is $8,468 per month and took effect on March 1, 2008. The Exchange proposes to revise the access fee to be $8,260 per month commencing on April 1, 2008.

The Exchange used the following process to set the proposed access fee: The Exchange polled each of the clearing firms that assists in facilitating at least 10% of the transferable CBOE membership leases and obtained the Clearing Firm Floating Monthly Rate[6] designated by each of these clearing firms for the month of April 2008. The Exchange then set the proposed access fee at an amount equal to the highest of these Clearing Firm Floating Monthly Rates.

The Exchange used the same process to set the proposed access fee that it used to set the current access fee. The only difference is that the Exchange used Clearing Firm Floating Monthly Rate information for the month of April 2008 to set the proposed access fee (instead of Clearing Firm Floating Monthly Rate information for the month of March 2008 as was used to set the current access fee) in order to take into account changes in Clearing Firm Floating Monthly Rates for the month of April 2008.

The Exchange believes that the process used to set the proposed access fee and the proposed access fee itself are appropriate for the same reasons set forth in CBOE rule filing SR–CBOE–2008–12 in support of that process and the original access fee for Temporary Members under Rule 3.19.02.[7]

The proposed access fee will remain in effect until such time either that the Exchange submits a further rule filing pursuant to Section 19(b)(3)(A)(ii) of the Act[8] to modify the proposed access fee or the Temporary Membership status under Rule 3.19.02 is terminated. Accordingly, the Exchange may further adjust the proposed access fee in the future if the Exchange determines that it would be appropriate to do so taking into consideration lease rates for transferable CBOE memberships prevailing at that time.

The procedural provisions of the CBOE Fee Schedule related to the assessment of the proposed access fee are not proposed to be changed and will remain the same as the current procedural provisions regarding the assessment of the current access fee.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(4) of the Act,[10] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among persons using its facilities.

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 either solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change establishes or changes a due, fee, or other charge imposed by the Exchange, it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(2) thereunder.[12] At any time within 60 days of the filing of such 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 the furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2008–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2008–39. This file number should be included on the subject line if e-mail is used. To help the

[3] 15 U.S.C 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Securities Exchange Act Release No. 56458 (September 18, 2007), 72 FR 54309 (September 24, 2007) (SR–CBOE–2007–107) for a description of the Temporary Membership status under Rule 3.19.02.

[6] The term ''Clearing Firm Floating Monthly Rate'' refers to the floating monthly rate that a clearing firm designates, in connection with transferable membership leases that the clearing firm assisted in facilitating, for leases that utilize that floating monthly rate.

[7] *See* Securities Exchange Act Release No. 57293 (February 8, 2008), 73 FR 8729 (February 14, 2008) (SR–CBOE–2008–12), which established the original access fee for Temporary Members under Rule 3.19.02, for detail regarding the rationale in support of the original access fee and the process used to set that fee, which is also applicable to this proposed rule change as well.

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of 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 SR–CBOE–2008–39 and should be submitted on or before May 6, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–7933 Filed 4–14–08; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57636; File No. SR–NYSEArca–2008–09]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of a Proposed Rule Change, and Amendment No. 1 Thereto, Relating to the Listing and Trading of Shares of the AirShares ™ EU Carbon Allowances Fund

April 8, 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 March 14, 2008, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange''), through its wholly owned subsidiary, NYSE Arca Equities, Inc. (''NYSE Arca Equities''), 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. On April 4, 2008, the Exchange filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt new NYSE Arca Equities Rule 8.204 (Commodity Futures Trust Shares) and to list and trade shares (''Shares'') of the AirShares ™ EU Carbon Allowances Fund (''Fund'') pursuant to the proposed rule. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.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 adopt new NYSE Arca Equities Rule 8.204 to permit the listing and trading, or trading pursuant to unlisted trading privileges (''UTP''), of shares issued by a trust that is a commodity pool, as defined in the Commodity Exchange Act (''CEA'') and regulations thereunder, and that is managed by a commodity pool operator (''CPO'') registered with the Commodity Futures Trading Commission (''CFTC''). Such shares would hold long positions in futures contracts on a specified commodity or interests in a commodity pool which, in turn, would hold such long positions. In addition, such shares would be issuable and redeemable daily in specified aggregate amounts at net asset value (''NAV'').[3] The Exchange also proposes to amend NYSE Arca Equities Rule 7.34 (Trading Sessions) to reference the securities described in proposed NYSE Arca Equities Rule 8.204. Additionally, the Exchange proposes to amend its listing fees by incorporating the securities described in proposed NYSE Arca Equities Rule 8.204 in the term ''Derivative Securities Products.''

Further, pursuant to this proposed rule change, the Exchange proposes to list and trade the Shares of the Fund. The Shares, which represent ownership of a fractional undivided beneficial interest in the net assets of the Fund, will conform to the initial and continued listing criteria under proposed NYSE Arca Equities Rule 8.204. The Fund is a commodity pool, as defined in the CEA and the applicable rules of the CFTC, and was formed as a Delaware statutory trust on August 13, 2007.[4] XShares Advisors LLC, a Delaware limited liability company, will serve as sponsor of the Fund (''Sponsor''). The Sponsor was formed on March 15, 2006, is a wholly owned subsidiary of XShares Group LLC, a Delaware limited liability company, and will serve as the CPO of the Fund. The Sponsor will be registered as a CPO with the CFTC and will be a member of the National Futures Association (''NFA'') prior to the commencement of operations of the Fund.

[3] The Commission has approved similar NYSE Arca Equities rules to list and trade products based on or related to commodities. *See* Securities Exchange Act Release Nos. 54025 (June 21, 2006), 71 FR 36856 (June 28, 2006) (SR–NYSEArca–2006–12) (approving new NYSE Arca Equities Rule 8.203 ''Commodity-Indexed Trust Shares'' for trading pursuant to UTP the iShares GSCI Commodity-Indexed Trust); 51067 (January 21, 2005), 70 FR 3952 (January 27, 2005) (SR–PCX–2004–132) (approving new NYSE Arca Equities Rule 8.201 ''Commodity-Based Trust Shares'' for trading pursuant to UTP the iShares COMEX Gold Trust); 56041 (July 11, 2007), 72 FR 39114 (July 17, 2007) (SR–NYSEArca–2007–43) (approving listing of shares of iShares COMEX Gold Trust pursuant to NYSE Arca Equities Rule 8.201); 53875 (May 25, 2006), 71 FR 32164 (June 2, 2006) (SR–NYSEArca–2006–11) (approving new NYSE Arca Equities Rule 8.300 ''Partnership Shares'' for trading pursuant to UTP the United States Oil Fund, LP); and 53736 (April 27, 2006), 71 FR 26582 (May 5, 2006) (SR–PCX–2006–22) (approving new Commentary .02 to NYSE Arca Equities Rule 8.200 ''Investment Shares'' for trading pursuant to UTP the DB Commodity Index Tracking Fund).

[4] The Fund is not an investment company registered under the Investment Company Act of 1940, according to the Registration Statement on Form S–1 for the Fund, which was filed with the Commission on December 14, 2007 (File No. 333–145448) (''Registration Statement''). The information in this proposed rule change is based upon representations in the Registration Statement.

a. Proposed Listing Rules

Proposed NYSE Arca Equities Rule 8.204(c) defines a ''Commodity Futures Trust Share'' as a security that: (1) Is issued by a trust that (a) is a commodity pool, as defined in the CEA and regulations thereunder, managed by a CPO registered with the CFTC, and (b) holds positions in futures contracts that track the performance of a specified commodity, or interests in a commodity pool which, in turn, holds such positions; and (2) is issued and redeemed daily in specified aggregate amounts at NAV. The term ''futures contract'' is a ''contract of sale of a commodity for future delivery'' set forth in Section 2(a) of the CEA. The term ''commodity'' is defined in Section 1(a)(4) of the CEA.

Proposed NYSE Arca Equities Rule 8.204(d) provides that the Exchange may trade, either by listing or pursuant to UTP, Commodity Futures Trust Shares that are based on an underlying commodity futures contract. Each issue of Commodity Futures Trust Shares would be designated as a separate series and would be identified by a unique symbol.

The Commodity Futures Trust Shares will be subject to the criteria for the listing and trading set forth in proposed NYSE Arca Equities Rule 8.204(e). Proposed NYSE Arca Equities Rule 8.204(e)(1) provides that the Exchange will establish a minimum number of Commodity Futures Trust Shares that will be required to be outstanding at the time of commencement of trading. The proposed continued listing criteria in proposed NYSE Arca Equities Rule 8.204(e)(2) provide for the suspension of trading in or removal from listing of the Commodity Futures Trust Shares under any of the following circumstances:

- If, following the initial 12-month period beginning upon the commencement of trading of the Shares: (1) The trust has fewer than 50,000 Shares issued and outstanding; (2) the market value of all Shares is less than $1,000,000; or (3) there are fewer than 50 record and/or beneficial holders of Commodity Futures Trust Shares for 30 consecutive trading days;
- If the value of the underlying futures contract is no longer calculated or available on at least a 15-second delayed basis during the Exchange's Core Trading Session, as defined in NYSE Arca Equities Rule 7.34(a), from a source unaffiliated with the sponsor, the trust, or the trustee;
- If the NAV for the trust is no longer disseminated to all market participants at the same time;
- If the Indicative Trust Value is no longer disseminated on at least a 15-second delayed basis during the Exchange's Core Trading Session, as defined in NYSE Arca Equities Rule 7.34(a); or
- If such other event shall occur or condition exists that, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

In addition, the Exchange will remove the Commodity Futures Trust Shares from listing upon termination of the trust.

Proposed NYSE Arca Equities Rule 8.204(e)(3) provides that the term of a trust is as stated in the trust's prospectus, but that the trust may be terminated earlier as may be specified in the prospectus. Proposed NYSE Arca Equities Rule 8.204(e)(4) sets forth proposed requirements for the trustee of a trust: (1) The trustee of a trust must be a trust company or banking institution having substantial capital and surplus and the experience and facilities for handling corporate trust business; in cases where, for any reason, an individual has been appointed as trustee, a qualified trust company or banking institution must be appointed co-trustee; and (2) no change is to be made in the trustee of a listed issue without prior notice to and approval of the Exchange. Proposed NYSE Arca Equities Rule 8.204(e)(5) provides that voting rights will be as set forth in the applicable trust prospectus.

Proposed NYSE Arca Equities Rule 8.204(f) sets forth certain restrictions on ETP Holders acting as registered Market Makers in Commodity Futures Trust Shares to facilitate surveillance. Proposed NYSE Arca Equities Rules 8.204(f)(2)–(3) require that the ETP Holder acting as a registered Market Maker in the Commodity Futures Trust Shares provide the Exchange with necessary information relating to its trading in the underlying commodity, related futures or options on futures, or any other related derivatives. Proposed NYSE Arca Equities Rule 8.204(f)(4) prohibits the ETP Holder acting as a registered Market Maker in the Commodity Futures Trust Shares from using any material non-public information received from any person associated with an ETP Holder or employee of such person regarding trading by such person or employee in the underlying commodity, related futures or options on futures, or any other related derivative (including the Commodity Futures Trust Shares). In addition, proposed NYSE Arca Equities Rule 8.204(f)(1) prohibits the ETP Holder acting as a registered Market Maker in the Commodity Futures Trust Shares from being affiliated with a market maker in the underlying commodity, related futures or options on futures, or any other related derivative, unless adequate information barriers are in place, as provided in NYSE Arca Equities Rule 7.26.

Proposed NYSE Arca Equities Rule 8.204(g) relates to the Exchange's limitation of liability. Proposed NYSE Arca Equities Rule 8.204(h) specifically provides that the Exchange will file separate proposals under Section 19(b) of the Act [5] before listing and trading separate and distinct Commodity Futures Trust Shares.

Commentary .01 to proposed NYSE Arca Equities Rule 8.204 requires ETP Holders to provide all purchasers of newly issued Commodity Futures Trust Shares with a prospectus. Commentary .02 to proposed NYSE Arca Equities Rule 8.204 provides that trading in the Commodity Futures Trust Shares will occur during the trading hours specified in NYSE Arca Equities Rule 7.34. Commentary .03 to proposed NYSE Arca Equities Rule 8.204 requires that if the Indicative Trust Value or the value of the underlying futures contract is not being disseminated as required, the Exchange may halt trading during the day in which the interruption to the dissemination of the Indicative Trust Value or the value of the underlying futures contract occurs. If the interruption to the dissemination of the Indicative Trust Value or the value of the underlying futures contract persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to a series of Commodity Futures Trust Shares is not disseminated to all market participants at the same time, it will halt trading in such series until such time as the NAV or the Disclosed Portfolio is available to all market participants. Commentary .04 to proposed NYSE Arca Equities Rule 8.204 provides that the Exchange's rules governing the trading of equity securities apply to Commodity Futures Trust Shares. Commentary .05 to proposed NYSE Arca Equities Rule 8.204 provides that the Exchange will implement written surveillance procedures for Commodity Futures Trust Shares.

b. Amendments to NYSE Arca Equities Rule 7.34

The Exchange proposes to amend NYSE Arca Equities Rule 7.34(a)(3) to

[5] 15 U.S.C. 78s(b).

add Commodity Futures Trust Shares to the list of securities for which the Core Trading Session on the Exchange concludes at 4:15 p.m. Eastern Time (''ET''). In addition, the Exchange proposes to amend NYSE Arca Equities Rule 7.34(a)(4) to include Commodity Futures Trust Shares under ''Derivative Securities Products'' with respect to trading halts of certain derivative securities products trading pursuant to UTP on the Exchange.

c. Amendments to Listing Fees

The Exchange proposes to add Commodity Futures Trust Shares to the securities included under the term ''Derivative Securities Products'' in note 3 of the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services.

d. Description of the Fund

The Sponsor has appointed Environmental Capital Management, LLC, an Arizona limited liability company, to serve as the commodity trading advisor (''CTA'') of the Fund. The CTA will be registered with the CFTC prior to commencement of the Fund's operations and will be a member of the NFA in such capacity. The CTA is not an affiliate of the Sponsor or the Fund. The Sponsor has appointed: (1) Brown Brothers Harriman (''Brown Brothers'' or ''Administrator'') as the administrator, custodian, and transfer agent of the Fund; and (2) ALPS Distributors, Inc. (''Distributor'') to assist the Sponsor and the Administrator with certain functions and duties relating to distribution and marketing. Newedge USA, LLC (''Newedge USA'') executes and clears the Fund's futures transactions and provides other brokerage-related services. Newedge Alternative Strategies, Inc. may execute foreign exchange or other over-the-counter transactions with the Fund, as principal. A variety of executing brokers selected by the Sponsor may execute futures transactions on behalf of the Fund. The executing brokers will give up all such transactions to Newedge USA, which will serve as the Fund's clearing broker.

The investment objective of the Fund is to provide investors with investment results that correspond generally, before payment of the Fund's expenses and liabilities, to the performance of a basket of exchange-traded futures contracts for carbon equivalent emissions allowances (''EUAs'') issued under the European Union Emissions Trading Scheme (''EU ETS''). The EU ETS [6] is a ''cap and trade'' emissions trading program instituted by the European Union (''EU''), in furtherance of the joint commitment of its member states under the Kyoto Protocol to achieve certain reductions in their emissions of greenhouse gases from 2008 to 2012.

The net assets of the Fund will consist of long positions in ICE Futures ECX Carbon Financial Instrument Futures Contracts (''ECX CFI Futures Contracts'').[7] The ECX CFI Futures Contracts are standardized contracts developed by the European Climate Exchange (''ECX'') and are listed and admitted to trading on ICE Futures [8] on the London-based electronic platform, owned and operated by IntercontinentalExchange, Inc. (also known as the ICE Platform). ECX CFI Futures Contracts are standardized contractual instruments for futures on deliverable EUAs issued under the EU ETS. Each ECX CFI Futures Contract provides for delivery of 1,000 EUAs on a specified date at a specified price, with each EUA being an entitlement to emit one ton of carbon dioxide equivalent gas.[9]

The ECX CFI Futures Contracts trade on the London-based ICE Platform from 7 a.m. to 5 p.m. Greenwich Mean Time. According to ECX, ICE Futures is the most liquid, pan-European platform for carbon emissions trading, attracting over 80% of the exchange-traded volume in that market.

Initially, the Fund will hold long positions in ECX CFI Futures Contracts. The Fund may also invest in other EUAs, including those that trade on other exchanges.[10] The Exchange will file a proposed change pursuant to Rule 19b–4 under the Act [11] seeking approval to continue trading the Shares if the Fund invests in EUAs that constitute more than 10% of the weight of the Fund and where the principal trading market for such component is not a member or affiliate member of the Intermarket Surveillance Group (''ISG'') or where the Exchange does not have a comprehensive surveillance sharing agreement with such market. If the Kyoto Protocol or the EU ETS is extended beyond 2012, the Sponsor will determine and publicly disclose by no later than September 30, 2012 whether it will extend the operation of the Fund beyond December 2012. The Fund will not be actively managed in that it will not engage in activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the value of its portfolio of EUAs.

More information about the Kyoto Protocol, the EU ETS, the ECX CFI Futures Contracts, the Fund's investment strategy, as well as further descriptions of the Shares, risks, NAV, creation, and redemption is contained in the Registration Statement.[12]

e. Description of the Shares

The Fund will create and redeem Shares from time to time, but only by authorized participants in one or more baskets, with each basket constituting a block of 100,000 Shares. In connection with the Fund, a minimum of 100,000 Shares will be required to be outstanding at the start of trading. The Exchange states that this minimum number of Shares required to be outstanding is generally higher than requirements that have been applied to previously listed series of exchange-traded funds. The Exchange believes that the proposed minimum number of Shares outstanding at the start of trading will be sufficient to provide market liquidity.

f. Dissemination and Availability of Information About the Underlying Futures Contracts and the Shares

The daily settlement prices for the EUAs are publicly available on the ICE Futures Web site at *http://www.icefutures.com*. In addition, various market data vendors and news publications publish futures prices and related data. Quote and last-sale information for the EUAs are widely disseminated through a variety of market data vendors worldwide. ICE Futures also provides delayed futures information on current and past trading sessions and market news free of charge

[6] According to the Registration Statement, while the investment objective of the Fund is to track generally the value of the underlying futures contracts, the Fund's portfolio of fixed income securities, as well as other factors such as the Fund's expenses, and its hedging activities may cause a lack of correlation between the NAV of the Shares and the value of the Fund's portfolio of futures contracts.

[7] The Fund represents that the ECX CFI Futures Contracts meets the definition of ''futures contract'' as set forth in Section 2(a) of the CEA. The Exchange states that carbon equivalent emissions allowances meet the definition of ''commodity'' as defined in Section 1(a)(4) of the CEA.

[8] The Exchange states that ICE Futures, which is a subsidiary of the IntercontinentalExchange, Inc. is a Recognised Investment Exchange in the United Kingdom and is supervised by the Financial Services Authority under the terms of the Financial Services and Markets Act (2000).

[9] The ECX CFI Futures Contract had average daily trading volume of $135,717,089 (USD), or approximately 87,587,602 Euro, representing 3,551 contracts traded daily from January 1, 2008 through March 11, 2008.

[10] The Exchange will file a Form 19b–4 to obtain Commission approval for the continued listing and trading of the Shares should the Fund hold positions in EUAs other than ECX CFI Futures Contracts.

[11] 15 U.S.C. 78a.

[12] *See supra* at note 4.

on its Web site. The specific contract specifications for the EUAs are also available on the ICE Futures Web site.

The Web site for the Fund at *http://www.airsharesfund.com*, which is publicly accessible at no charge, will contain the following information: (1) The prior business day's NAV per Share [13] and the reported closing price; (2) the mid-point of the bid-ask price in relation to the NAV per Share as of the time the NAV is calculated (''Bid-Ask Price''); [14] (3) calculation of the premium or discount of such price against such NAV per Share; (4) data in chart form displaying the frequency distribution of discounts and premiums of the Bid-Ask Price against the NAV per Share, within appropriate ranges for each of the four previous calendar quarters; (5) the prospectus and the most recent periodic reports filed with the Commission or required by the CFTC; [15] and (6) other applicable quantitative information.

The Fund's total portfolio composition, consisting primarily of long positions in ECX CFI Futures Contracts and cash, will be disclosed each business day that the Exchange is open for trading on the Fund's Web site. The Fund has informed the Exchange that Web site disclosure of portfolio holdings will be made daily and will include, as applicable, the name and value of each EUA and amount of cash held in the portfolio of the Fund.

As noted above, the Fund's NAV will be calculated and disseminated daily.[16] The Exchange will disseminate for the Fund on a daily basis by means of Consolidated Tape Association CQ High Speed Lines information with respect to the Indicative Fund Value (as discussed below), recent Fund NAV, Shares outstanding, and the Basket amount. The Exchange will also make available on its Web site daily trading volume, closing prices, and the Fund's NAV per Share. The closing price and settlement prices of the EUAs held by the Fund are also readily available from ICE Futures, automated quotation systems, published or other public sources, or on-line information services.

Information regarding market price and volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information will be published daily in the financial section of newspapers. Quotation and last-sale information for the Shares will be available via the facilities of the Consolidated Tape Association.

All pricing information will be quoted in U.S. dollars, other than the current trading value of the Euro-denominated EUAs, which will be quoted in Euro. The current trading price per Share will be published continuously as trades occur throughout each trading day on the consolidated tape, Reuters, and/or Bloomberg. The most recent trading value of each EUA is published on the Web site of the ECX at *http://www.ecxeurope.com*, under the heading ''Market Data,'' and each vintage futures contract in the Fund's portfolio will be published on the Fund's Web site at *http://www.airsharesfund.com*, or any successor thereto.

To provide updated information relating to the Fund for use by investors, professionals and persons wishing to create or redeem the Shares, the Exchange or a major market data vendor will disseminate through the facilities of the Consolidated Tape Association an updated Indicative Fund Value (''Indicative Fund Value''). [17] The Indicative Fund Value, which is also known as intraday indicative value (IIV) or intraday optimized portfolio value (IOPV), is an estimate, updated on a real-time basis at least every 15 seconds, of the NAV, which is disclosed only once per day. The Indicative Fund Value for the Fund will be disseminated on a per-Share basis at least every 15 seconds during the Exchange's Core Trading Session. The Indicative Fund Value will be calculated based on the previously-disclosed portfolio composition of the Fund, *i.e.*, the futures contracts in the Fund's portfolio, and will be adjusted to reflect the price changes of the relevant EUAs.

The value of a Share may be influenced by the non-concurrent trading hours between the Exchange and the exchanges on which the EUAs trade. While the Shares will trade from 4 a.m. to 8 p.m. ET, the ECX CFI Futures Contracts, for example, trade on the London-based ICE Platform from 7 a.m. to 5 p.m. local time in London, England. When the ICE Platform and the Exchange are both open for trading, the Indicative Fund Value can be expected to closely approximate the NAV per Share. When the ICE Platform is closed and the Exchange is open, trading spreads and the resulting premium or discount on the Shares may widen and, therefore, increase the difference between the public trading price of the Shares and the NAV per Share. The Indicative Fund Value on a per-Share basis disseminated during the Exchange's Core Trading Session should not be viewed as a real-time update of the Fund's NAV, which is calculated only once a day.

g. Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares.[18] Trading in the Shares will be halted if the circuit breaker parameters under NYSE Arca Equities Rule 7.12 are reached. Trading may also be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the underlying EUA futures contracts; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Commentary .03 to proposed NYSE Arca Equities Rule 8.204, which sets forth circumstances under which trading in the Shares may be halted.

h. Trading Rules

Under proposed NYSE Arca Equities Rule 8.204(b), Commodity Futures Trust Shares are included within the Exchange's definition of ''securities.'' The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Commentary .02 to proposed NYSE Arca Equities Rule 8.204 provides that transactions in Commodity Futures Trust Shares will occur during the trading hours specified in Rule 7.34. Therefore, in accordance with NYSE Arca Equities Rule 7.34, the Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m. ET. The Exchange states that it has appropriate rules to facilitate

[13] The most recent end-of-day NAV of the Fund and NAV per Share will be published by the Sponsor as of 4 p.m. ET on Reuters and/or Bloomberg and on the Fund's Web site at *http://www.airsharesfund.com*. The end-of-day NAV per Share will also be published the following morning on the consolidated tape.

[14] The Bid-Ask Price of Shares is determined using the highest bid and lowest offer as of the time of calculation of the NAV per Share.

[15] Monthly account statements conforming to CFTC and NFA requirements are posted on the Fund's Web site at *http://www.airsharesfund.com*. Additional reports may be posted on the Fund's Web site in the discretion of the Sponsor or as required by regulatory authorities.

[16] The Exchange will obtain a representation from the Fund that the Fund's NAV per Share will be calculated daily and made available to all market participants at the same time.

[17] The Indicative Fund Value is referred to as the Indicative Trust Value in proposed new NYSE Arca Equities Rule 8.204(e)(2)(iv).

[18] *See* Commentary .04 to NYSE Arca Equities Rule 7.12.

transactions in the Shares during all trading sessions.

i. Surveillance

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products (which will include Commodity Futures Trust Shares) to monitor trading in the Shares. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The Exchange's current trading surveillance focuses on detecting securities trading outside their normal patterns. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange may obtain information via the ISG from other exchanges who are members or affiliate members of the ISG. In addition, the Exchange has an Information Sharing Agreement in place with ICE Futures for the purpose of providing information in connection with trading in, or related to, futures contracts traded on ICE Futures. In addition, the Exchange will file a proposed change pursuant to Rule 19b–4 under the Act [19] seeking approval to continue trading the Shares if the Fund invests in EUAs (or pricing information is used for a new or existing component) that constitute more than 10% of the weight of the Fund where the principal trading market for such component is not a member or affiliate member of ISG or where the Exchange does not have a comprehensive surveillance sharing agreement with such market. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

j. Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders [20] in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The risks involved in trading the Shares during the Opening and Late Trading Sessions [21] when an updated Indicative Fund Value will not be calculated or publicly disseminated; (2) the procedures for purchases and redemptions of Shares (and that Shares are not individually redeemable); (3) Rule 9.2(a),[22] which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (4) the risk involved in trading the Shares during the Core and Late Trading Sessions when the ECX CFI Futures Contracts are not trading on the ICE Platform; (5) how information regarding the Indicative Fund Value is disseminated; (6) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (7) trading information.

In addition, the Bulletin will reference that: (1) The Fund is subject to various fees and expenses described in the relevant registration statement; (2) that there is no regulated source of last-sale information regarding physical commodities; (3) the Commission has no jurisdiction over the trading of EUAs; and (4) the Financial Services Authority in the United Kingdom has regulatory jurisdiction over the trading of EUAs and related options. The Bulletin will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act and disclose that the NAV for the Shares will be calculated after 4 p.m. ET each trading day.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [23] that a national securities exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that the proposed rules will facilitate the listing and trading of additional types of exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. In addition, the listing and trading criteria set forth in the proposed rules are intended to protect investors and the public interest.

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

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2008–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

[19] 15 U.S.C. 78a.

[20] *See* NYSE Arca Equities Rule 1.1(n) (defining ETP Holder).

[21] The Opening Trading Session is from 4 a.m. to 9:30 a.m. ET and the Late Trading Session is from 4:15 p.m. to 8 p.m. ET. *See* NYSE Arca Equities Rule 7.34.

[22] NYSE Arca Equities Rule 9.2(a) provides that ETP Holders, before recommending a transaction, must have reasonable grounds to believe that the recommendation is suitable for the customer based on any facts disclosed by the customer as to his other security holdings and as to his financial situation and needs. Further, the rule provides, with a limited exception, that prior to the execution of a transaction recommended to a non-institutional customer, the ETP Holder shall make reasonable efforts to obtain information concerning the customer's financial status, tax status, investment objectives, and any other information that the ETP Holder believes would be useful to make a recommendation.

[23] 15 U.S.C. 78f(b)(5).

All submissions should refer to File Number SR–NYSEArca–2008–09. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for 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 Number SR–NYSEArca–2008–09 and should be submitted on or before May 6, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–7934 Filed 4–14–08; 8:45 am]

BILLING CODE 8011–01–P

[24] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 6189]

Bureau of Political-Military Affairs: Directorate of Defense Trade Controls; Notifications to the Congress of Proposed Commercial Export Licenses

SUMMARY: Notice is hereby given that the Department of State has forwarded the attached Notifications of Proposed Export Licenses to the Congress on the dates indicated pursuant to sections 36(c) and 36(d) and in compliance with section 36(f) of the Arms Export Control Act (22 U.S.C. 2776).

DATES: *Effective Date:* As shown on each of the 53 letters.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Maloney, Director, Office of Defense Trade Controls Licensing, Directorate of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (202) 663–2023.

SUPPLEMENTARY INFORMATION: Section 36(f) of the Arms Export Control Act mandates that notifications to the Congress pursuant to sections 36(c) and 36(d) must be published in the **Federal Register** when they are transmitted to Congress or as soon thereafter as practicable.

November 13, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the temporary export of two (2) commercial communications satellites to international waters for launch under the Sea Launch program or to Russia and Kazakhstan for launch. This notification is for the export of the satellites only. Transfer of ownership to a U.S. company will be made once the satellites are in orbit.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 022–07.

November 13, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the temporary export of a commercial communications satellite to international waters for launch. This notification is for the export of the satellite only. Transfer of ownership to a U.S. company will be made once the satellite is in orbit.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 076–07.

November 13, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the temporary export of a commercial communications satellite to international waters for launch under the Sea Launch program. This notification is for the export of the satellite and associated launch support equipment only. Transfer of ownership to a U.S. company will be made once the satellite is in orbit.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 082–07.

November 15, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad in the amount of $3,695,000.

The transaction contained in the attached certification involves the export of technical data, assistance and manufacturing know-how to France for the initial development and subsequent manufacture of Complimentary Metal Oxide Semiconductor (CMOS) Application Specific Integrated Circuits (ASIC). After manufacture, the integrated circuits, in wafer form, will be returned to the United States.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 064–07.

November 16, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) and 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense data, services and articles necessary for Cyclone Aviation Products Ltd. of Israel to manufacture certain Alternate Mission Equipment (AME) for sale to Lockheed Martin, the Government of the United States, and the Governments of Israel, Bahrain, Belgium, Chile, Denmark, Egypt, Greece, Italy, Jordan, the Netherlands, Norway, Oman, Poland, Portugal, the Republic of Korea, Singapore, Taiwan, Thailand, Turkey and the United Arab Emirates for use on the F–16 aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification, which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 010–07.

November 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the United Kingdom to support the maintenance, repair and modification services for the C–130J and C–130K Aircraft and associated equipment, and the participation of military exchange personnel from the government of Canada.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 062–07.

November 30, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Sections 36(c) and 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed amendment to a manufacturing license agreement for the manufacture of significant military equipment abroad and the export of defense articles or defense services abroad in the amount of $50,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, technical data, and defense services to Russia for the RD–180 Liquid Propellant Rocket Engine Program.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 065–07.

December 6, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $50,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to Taiwan, Singapore, Canada, and the United Kingdom for the installation, operation, training, and maintenance of two multi-source remote sensing satellite ground stations for use by the Ministry of National Defense, Republic of China (Taiwan).

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 094–07.

December 7, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Kingdom of Saudi Arabia to support the sale of 16 S–92A helicopters.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 091–07.

December 7, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles or defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Canada related to the acquisition of SNIPER Targeting Pods.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 102–07.

December 7, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of major defense equipment in the amount of $25,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the United Kingdom in support of the sale of one C–17 Globemaster III aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though

unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 123–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense data and services to Italy for the manufacture of upper wing skins for the F–35 Joint Strike Fighter.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 033–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad.

The transaction described in the attached certification involves the transfer of technical data, assistance and manufacturing know-how to Israel for the manufacture of the Advanced Digital Dispensing System (ADDS) II Countermeasure Dispenser System for sale and integration on various military aircraft in Israel, Germany, Singapore and Thailand.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 045–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the manufacture of significant military equipment abroad.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Philippines and South Korea necessary for the assembly of Complimentary Metal Oxide Semiconductor (CMOS) Application Specific Integrated Circuits (ASIC).

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 063–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $50,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to France, Germany, Gibraltar, Luxembourg, the Netherlands, Spain, Sweden, and the United Kingdom for the design, manufacture, and delivery of the New Skies Satellite (NSS)–12 Satellites Program.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 085–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, re-certification of a proposed Agreement for the export of defense services and defense articles in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services in support of the manufacture of components for the AN/APG–66J Fire Control Radar System for end-use by the Japan Air Self Defense Force (JASDF).

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 089–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services in support of the Sistema de Vigilancia de Amazonia (SIVAM) Wide Area Surveillance System for end use by the Government of Brazil.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 090–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Sections 36(c) and 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad and the export of defense services and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to South Korea to support the developmental manufacture of the T–701K helicopter engine in support of the Korean Helicopter Program.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 092–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Israel to support the manufacture of F/A–18 Leading Edge Extensions (LEX) and Aft Nose Landing Gear Doors.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 101–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services in support of the Communication and Information System (CIS) Wideband Programmable Network Radio for end use by the Slovak Republic Ministry of Defense.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 106–07.

December 18, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Canada to support the manufacture of Decoder Assemblies for the Smiths Stores Management System Upgrade (SMUG) Program for the F/A–18 Aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 113–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $50,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to Australia, Canada, France, Italy, and Singapore for the design of the Optus D3 Commercial Communications Satellite Program for Australia.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 074–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of proposed licenses for the export of defense articles in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the temporary export and two commercial communications satellites to French Guiana and ownership transfer of one of the satellites upon launch to Canada.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 078–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $100,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to the United Arab Emirates, Italy, and France for the installation, integration engineering, design, testing, operation, training, and follow-on support of the Rolling Air Frame Missile Guided Missile Launch System on United Arab Emirates Navy ships.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 084–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Mexico to support the manufacture of minor aircraft parts for various military aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military,

economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 103–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Israel to provide continued support for the upgrade of the USAF's T–38 training aircraft's avionics.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 109–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of technical data, defense services and articles in support of the Network Server System for the A400M Aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 112–07.

December 19, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Japan to manufacture Mission Data Recorders, Remote Memory Modules, subassemblies, and mock-ups to support F–15 aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 117–07.

December 20, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of technical data, defense services and defense articles to South Korea to support the manufacture of HMPT500 Series Transmissions for use on Flying Horse, Flying Tiger and Next Infantry Fighting Vehicles.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 066–07.

December 20, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the manufacture of significant military equipment abroad and the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Sweden and Italy related to the application of brushless motors and cable systems for various applications in the SEP Modular Armoured Tactical System Program.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 079–07.

December 20, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) and 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $100,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to Germany for the production and support of various versions of the Paveway weapons system for end use by the German Ministry of Defense.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 099–07.

December 20, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of Up-Armored High Mobility Multipurpose Wheeled Vehicles and spare parts to Iraq to provide support to the Iraqi Ministry of Defense.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though

unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 118–07.

December 21, 2007.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Sections 36(c) and 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the export of defense articles or defense services sold commercially under contract in the amount of $50,000,000 or more and for the manufacture of significant military equipment.

The transaction described in the attached certification involves the transfer of hardware, technical data, assistance and manufacturing know-how to Greece and Israel for the manufacture of High Mobility Multipurpose Wheeled Vehicles (HMMWVs). All manufactured vehicles will be for end-use by the countries of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Macedonia, Romania, Slovenia and Greece.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 009–07.

January 23, 2008.

Hon. Nancy Pelosi, Speaker of the House of Representatives.

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Colombia to support the manufacture of the SP2022 SigPro semi-automatic pistol for end use by the Colombian government.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 093–07.

February 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of technical data, defense services and articles in support of the sale of Sikorsky Model S–70A Helicopters for the United Arab Emirates Armed Forces.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 001–08.

February 26, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of technical data, defense services and articles in support of the Integrated Surveillance System for the A400M Military Transport Aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 014–08.

February 29, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) and (d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $100,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to Japan for the production of the Evolved SeaSparrow Missile (ESSM).

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 011–08.

March 6, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the United Kingdom to support the replication of the Quick Fox software object code for integration into Park Air UHF radio systems. Park Air will sell the modified UHF radio systems to India, Italy, and the United Kingdom.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 015–08.

March 6, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the United Kingdom to support the manufacture of the MX–10205A/GRC Appliqué. The MX–10205A/GRC Appliqué provides Electronic Counter-Counter Measure Have Quick II or Quick Fox capability on UHF radio systems. The technical data related to this Appliqué is designated significant military equipment.

The United States Government is prepared to license the export of these items having

taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 022–08.

March 10, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Australia to provide continued support for the manufacture of F/A–18 structural components.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 115–07.

March 10, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services sold commercially under contract in the amount of $50,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to Mexico for the assembly, test, manufacture, fabrication, and repair of Honeywell Product Lines for various weapons systems and platforms.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 008–08.

March 10, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Mexico to support the manufacture of electrical connectors, backplane assemblies, and cable assemblies for use in military avionics, communications, ordnance, and guidance systems.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 017–08.

March 10, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of an application for a license for the export of defense articles or defense services to be sold under a contract in the amount of $100,000,000 or more.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to the United Kingdom in support of the Directional Infrared Countermeasure System Program.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 019–08.

March 10, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the temporary export of a commercial communications satellite to Russia and Kazakhstan for launch. This notification is for the export of the satellite and associated launch support equipment only. Transfer of ownership to a U.S. company will be made once the satellite is in orbit.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 029–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed agreement for the export of defense articles or defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Japan to provide continued support for the manufacture of fuel control devices for the Japanese Ministry of Defense's F–15J aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 006–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of proposed agreement for the export of defense articles or defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Republic of Korea to provide continued support for maintenance services on the J79 and J85 engines.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 007–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, re-certification of a proposed manufacturing license agreement for the export of defense services and defense articles in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Turkey for the manufacture of the AN/ALQ–178(V)5+ Self Protection Electronic Warfare System (SPEWS II) and the AN/ALQ–178(V)5+M Self Protection Electronic Warfare System with Low Band Jamming Functionality (SPEWS III).

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 026–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the temporary export of two commercial communications satellites to international waters, Russia and Kazakhstan, or France for launch. This notification is for the export of the satellites and fuels only. Transfer of ownership to a U.S. company will be made once the satellites are in orbit.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 028–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to section 36(c) of the Arms Export Control Act, as amended, I am transmitting, herewith, certification of an application for a license for the export of defense articles or defense services to be sold under a contract in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the United Kingdom and France to provide continued support for the installation and integration of the CTS–800–4N gas turbine engine into the Westland SuperLynx Helicopter.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 032–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles that are firearms controlled under Category I of the United States Munitions List sold commercially under a contract in the amount of $1,000,000.

The transaction contained in the attached certification involves the export of firearms to Georgia for use by the Georgian Defense Ministry.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 033–08.

March 14, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, re-certification of a proposed manufacturing license agreement for the export of defense services and defense articles in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Canada for the manufacture and assembly of CF–18 Multi Function Display Indicators for use on F–18 A/B Aircraft.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 037–08.

March 31, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad.

The transaction described in the attached certification involves the transfer of defense articles, including technical data, and defense services to the United Kingdom for the manufacture, assembly, maintenance, modification, repair, overhaul, and sale of radar altimeters and accelerometers.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,
Jeffrey T. Bergner,
Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 035–08.

April 2, 2008.

Hon. Nancy Pelosi, *Speaker of the House of Representatives.*

Dear Madam Speaker: Pursuant to section 36(c) of the Arms Export Control Act, as amended, I am transmitting, herewith, certification of an application for a license for the export of defense articles or defense services to be sold under a contract in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Italy to provide continued support for the sale and operation of C–130J aircraft for the Italian Ministry of Defense.

The United States Government is prepared to license the export of these items having

taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Jeffrey T. Bergner,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 018–08.

Dated: April 4, 2008.

Kevin Maloney,

Director, Office of Defense Trade Controls Licensing, Department of State.

[FR Doc. E8–8065 Filed 4–14–08; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Public Notice 6190]

Policy on Review Time for License Applications

AGENCY: Department of State.

ACTION: Notice.

In National Security Presidential Directive—56, Defense Trade Reform, signed January 22, 2008, the Department of State was directed to complete the review and adjudication of license applications within 60 days of receipt, except in cases where national security exceptions apply. The President further directed that these exceptions be published. In accordance with that directive, the Directorate of Defense Trade Controls has implemented procedures to ensure that this 60 day requirement is affected, except when the following the national security exceptions are applicable:

(1) When a Congressional Notification is required: The Arms Export Control Act Section 36(c) and (d) and the International Traffic in Arms Regulations, 22 CFR 123.15, requires a certification be provided to Congress prior to granting any license or other approval for transactions, if it meets the requirements identified for the sale of major defense equipment, manufacture abroad of significant military equipment, defense articles and services, or the re-transfer to other nations. Notification thresholds differ based on the dollar value, countries concerned and defense articles and services.

(2) Required Government Assurances have not been received. These would include, for example, Missile Technology Control Regime Assurances, and Cluster Munitions assurances.

(3) End-use Checks have not been completed. (Commonly referred to as ''Blue Lantern'' checks. End-use checks are key to the U.S. Government's prevention of illegal defense exports and technology transfers, and range from simple contacts to verifying the bona fides of a transaction to physical inspection of an export.)

(4) Department of Defense has notified the Directorate of Defense Trade Controls that an overriding national security exception exists.

(5) Requires a Waiver of Restrictions. (For example, a sanctions waiver.)

Dated: April 8, 2008.

Frank J. Ruggiero,

Deputy Assistant Secretary for Defense Trade and Regional Security, Department of State.

[FR Doc. E8–8070 Filed 4–14–08; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Public Notice 6175]

U.S. National Commission for UNESCO Notice of Open Advisory Committee Teleconference Meeting

SUMMARY: The U.S. National Commission for UNESCO will meet via telephone conference on Wednesday, April 23, 2008, from 11 a.m. until 12 p.m. Eastern Time. The purpose of the teleconference meeting is for the Commission to make recommendations related to the UNESCO university twinning and networking program (UNITWIN/UNESCO Chairs Program). The U.S. National Commission for UNESCO was asked to provide recommendations on a proposal received to establish a UNESCO Chair. For more information about the Program see *http://www.state.gov/p/io/unesco/c14222.htm*. This meeting notice may provide less than 15 days calendar notice due to an external UNESCO deadline of April 30th for member states' submissions. The call will also be an opportunity to provide an update on recent and upcoming Commission and UNESCO activities. The Commission will accept brief oral comments during a portion of this conference call. This public comment period will last up to 15 minutes, and comments are limited to two minutes per person. Members of the public who wish to present oral comments or to listen to the conference call must make arrangements with the Executive Secretariat of the National Commission by April 22, 2008. For more information or to arrange to participate in the teleconference meeting, contact Alex Zemek, Deputy Executive Director of the U.S. National Commission for UNESCO, Washington, DC 20037. Telephone: (202) 663–0026; Fax: (202) 663–0035; E-mail: *DCUNESCO@state.gov*.

Dated: April 7, 2008.

Alex Zemek,

U.S. National Commission for UNESCO, Department of State.

[FR Doc. E8–8154 Filed 4–14–08; 8:45 am]

BILLING CODE 4710–19–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2005–23112]

Motorcyclist Advisory Council to the Federal Highway Administration

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of meeting of advisory committee.

SUMMARY: This document announces the fourth meeting of the Motorcyclist Advisory Council to the Federal Highway Administration (MAC–FHWA). The purpose of this meeting is to advise the Secretary of Transportation, through the Administrator of the Federal Highway Administration, on infrastructure issues of concern to motorcyclists, including (1) Barrier design; (2) road design, construction, and maintenance practices; and (3) the architecture and implementation of intelligent transportation system technologies, pursuant to section 1914 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU).

DATES: The fourth meeting of the MAC–FHWA is scheduled for May 6–7, 2008, from 10 a.m. until 5 p.m. on May 6, and from 9 a.m. until 1 p.m. on May 7.

ADDRESSES: The fourth MAC–FHWA meeting will be held at the Sheraton Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Halladay, the Designated Federal Official, Office of Safety, 202–366–2288, (*michael.halladay@dot.gov*), or Dr. Morris Oliver, Office of Safety, 202–366–2288, (*morris.oliver@dot.gov*), Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2005, the President signed into law the Safe, Accountable, Flexible, Efficient Transportation Equity

Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59, 119 Stat. 1144). Section 1914 of SAFETEA–LU mandates the establishment of the Motorcyclist Advisory Council as follows: ''The Secretary, acting through the Administrator of the Federal Highway Administration, in consultation with the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Environment and Public Works of the Senate, shall appoint a Motorcyclist Advisory Council to coordinate with and advise the Administrator on infrastructure issues of concern to motorcyclists, including—

(1) Barrier design;

(2) Road design, construction, and maintenance practices; and

(3) The architecture and implementation of intelligent transportation system technologies.''

In addition, section 1914 specifies the membership of the council: ''The Council shall consist of not more than ten members of the motorcycling community with professional expertise in national motorcyclist safety advocacy, including—

(1) At least—

(A) One member recommended by a national motorcyclist association;

(B) One member recommended by a national motorcycle riders foundation;

(C) One representative of the National Association of State Motorcycle Safety Administrators;

(D) Two members of State motorcyclists' organizations;

(E) One member recommended by a national organization that represents the builders of highway infrastructure;

(F) One member recommended by a national association that represents the traffic safety systems industry; and

(G) One member of a national safety organization; and

(2) At least one, and not more than two, motorcyclists who are traffic system design engineers or State transportation department officials.''

To carry out this requirement, the FHWA published a notice of intent to form an advisory committee in the **Federal Register** on December 23, 2005 (70 FR 76353). This notice, consistent with the requirements of the Federal Advisory Committee Act (FACA), announced the establishment of the Council and invited comments and nominations for membership. The FHWA announced the ten members selected to the Council in the **Federal Register** on October 5, 2006 (71 FR 58903). An electronic copy of this document and the previous **Federal Register** notices associated with the MAC–FHWA can be downloaded through the Federal eRulemaking Portal at: *http://www.regulations.gov* and the Office of the Federal Register's home page at: *http://www.archives.gov/federal_register*.

The FHWA anticipates that the MAC–FHWA will meet at least once a year, with meetings held in the Washington, DC, metropolitan area and the FHWA will publish notices in the **Federal Register** to announce the times, dates, and locations of these meetings. Meetings of the Council are open to the public and time will be provided in each meeting's schedule for comments by members of the public. Attendance will necessarily be limited by the size of the meeting room. Members of the public may present oral or written comments at the meeting or may present written materials by providing copies to Ms. Fran Bents, Westat, 1650 Research Boulevard, Rockville, MD 20850–3195, (240) 314–7557, 10 days prior to the meeting.

The agenda topics for the meetings will include a discussion of the following issues: (1) Barrier design; (2) road design, construction, and maintenance practices; and (3) the architecture and implementation of intelligent transportation system technologies.

Conclusion

The fourth meeting of the Motorcyclist Advisory Council to the Federal Highway Administration will be held on May 6–7, 2008, at the Sheraton Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202 from 10 a.m. until 5 p.m. on May 6, and from 9 a.m. until 1 p.m. on May 7.

Authority: Section 1914 of Pub. L. 109–59; Pub. L. 92–463, 5 U.S.C., App. II section 1.

Issued on: April 7, 2008.

James D. Ray,

Acting Administrator.

[FR Doc. E8–7941 Filed 4–14–08; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: AXIS Reinsurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 10 to the Treasury Department Circular 570, 2007 Revision, published July 2, 2007, at 72 FR 36192.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued under 31 U.S.C. 9305 to the following company:

AXIS Reinsurance Company (NAIC #20370). Business Address: 11680 Great Oaks Way, Suite 500, Alpharetta, GA 30022. Phone: (678) 746–9400. Underwriting Limitation b/: $55,089,000. SURETY LICENSES c/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, Ml, MN, MS, MO, MI, NE, NV, NH, NJ, NM, NY, ND, OH, OK, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. Incorporated In: New York.

Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 (''Circular''), 2007 Revision, to reflect this addition.

Certificates of Authority expire on June 30th each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (*see* 31 CFR part 223). A list of qualified companies is published annually as of July 1st in the Circular, which outlines details as to the underwriting limitations, areas in which companies are licensed to transact surety business, and other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.*

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: April 7, 2008.

Vivian L. Cooper,

Director, Financial Accounting and Services Division.

[FR Doc. E8–7976 Filed 4–14–08; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Plaza Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 8 to the Treasury Department Circular 570, 2007 Revision, published July 2, 2007, at 72 FR 36192.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued under 31 U.S.C. 9305 to the following company:

Plaza Insurance Company (NAIC # 30945). Business Address: 700 West 47th Street, Suite 350, Kansas City, MO 64112. PHONE: (816) 412–2800. Underwriting Limitation b/: $1,025,000. Surety Licenses c/: AL, AK, AZ, AR, CA, DE, DC, FL, GA, ID, IL, IN, IA, KY, LA, MD, MI, MS, MO, MT, NE, NV, NM, NC, ND, OK, OR, PA, RI, SC, SD, TN, TX, UT, WA, WV, WI, WY. Incorporated In: Missouri.

Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 (''Circular''), 2007 Revision, to reflect this addition.

Certificates of Authority expire on June each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (*see* 31 CFR part 223). A list of qualified companies is published annually as of July 1 in the Circular, which outlines details as to underwriting limitations, areas in which companies are licensed to transact surety business, and other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570*.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: March 13, 2008.

Vivian L. Cooper,

Director, Financial Accounting and Services Division.

[FR Doc. E8–7886 Filed 4–14–08; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–144615–02]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing notice of proposed rulemaking, REG–144615–02, Methods to Determine Taxable Income in Connection with a Cost Sharing Arrangement (sec. 482).

DATES: Written comments should be received on or before June 16, 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 this regulation should be directed to Carolyn N. Brown, (202) 622–6688, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Carolyn.N.Brown@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Methods to Determine Taxable Income in Connection with a Cost Sharing Arrangement.

OMB Number: 1545–1364.

Regulation Project Number: REG–144615–02.

Abstract: The collection of information related to the IRS's assessment of whether a cost sharing arrangement is valid, and whether each participant's share of costs is proportionate to the participant's share of benefits, and whether arm's length compensation has been paid to those participants providing external contributions such that an appropriate return is provided to those participants for putting their funds at risk to a greater extent than the other participants.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 2 hrs, 30 minutes.

Estimated Total Annual Burden Hours: 1,250.

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: April 9, 2008.

Allan M. Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–8075 Filed 4–14–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[PS–62–87]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995,

Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, PS–62–87 (TD 8302), Low-Income Housing Credit for Federally-assisted Buildings (sec. 1.42–2(d)).

DATES: Written comments should be received on or before June 16, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Allan M. Hopkins, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to Carolyn N. Brown, (202) 622–6688, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Carolyn.N.Brown@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Low-Income Housing Credit for Federally-assisted Buildings.

OMB Number: 1545–1005.

Regulation Project Number: PS–62–87.

Abstract: The regulation provides state and local housing credit agencies and owners of qualified low-income buildings with guidance regarding compliance with the waiver requirement of section 42(d)(6) of the Internal Revenue Code. The regulation requires documentary evidence of financial distress leading to a potential claim against a Federal mortgage insurance fund in order to get a written waiver from the IRS for the acquirer of the qualified low-income building to properly claim the low-income housing credit.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 3 hrs.

Estimated Total Annual Burden Hours: 3,000.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 4, 2008.

Allan M. Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–8076 Filed 4–14–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[GL–238–88]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, GL–238–88 (TD 8549), Preparer Penalties-Manual Signature Requirement (§ 1.6695–1(B)).

DATES: Written comments should be received on or before June 16, 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 the regulation be directed to Carolyn N. Brown, (202) 622–6688, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Carolyn.N.Brown@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Preparer Penalties-Manual Signature Requirement (§ 1.6695–1(B)).

OMB Number: 1545–1385.

Regulation Project Numbers: GL–238–88.

Abstract: This regulation provides that persons who prepare U.S. Fiduciary income tax returns for compensation may, under certain conditions, satisfy the manual signature requirements by using a facsimile signature. However, they will be required to submit to the IRS a list of the names and identifying numbers of all fiduciary returns which are being filed with a facsimile signature.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 20,000.

Estimated Time per Respondent: 1 hour, 17 minutes.

Estimated Total Annual Burden Hours: 25,825.

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: April 8, 2008.

Allan M. Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–8077 Filed 4–14–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8233

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 8233, Exemption from Withholding on Compensation for Independent (and Certain Dependent) Personal Services of a Nonresident Alien Individual.

DATES: Written comments should be received on or before June 16, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Allan M. Hopkins, 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 Carolyn N. Brown, at (202) 622–6688, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet, at *Carolyn.N.Brown@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Exemption From Withholding on Compensation for Independent (and Certain Dependent) Personal Services of a Nonresident Alien Individual.

OMB Number: 1545–0795.

Form Number: 8233.

Abstract: Compensation paid to a nonresident alien individual for independent personal services (self-employment) is generally subject to 30% withholding or graduated rates. However, such compensation may be exempt from withholding because of a U.S. tax treaty or the personal exemption amount. Form 8233 is used to request exemption from withholding. Nonresident alien students, teachers, and researchers performing dependent personal services also use Form 8233 to request exemption from withholding.

Current Actions: There are no changes being made to Form 8233 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 480,000.

Estimated Time per Respondent: 2 hrs., 45 min.

Estimated Total Annual Burden Hours: 1,320,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 4, 2008.

Allan M. Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–8079 Filed 4–14–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Advisory Committee to the Internal Revenue Service; Meeting

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: The Information Reporting Program Advisory Committee (IRPAC) will hold an open meeting on Wednesday, April 30, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Caryl Grant, National Public Liaison, CL:NPL:SRM, Rm. 7566, 1111 Constitution Avenue, NW., Washington, DC 20224. *Telephone:* 202–927–3641 (not a toll-free number). *E-mail address: *public_liaison@irs.gov*.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988), an open meeting of the IRPAC will be held on Wednesday, April 30, 2008 from 9 a.m. to 10 a.m. in Room 3313. The agenda will include recommendations for the Office of Professional Responsibility. Last minute agenda changes may preclude advance notice. Due to limited seating and security requirements, please call or e-mail Caryl Grant to confirm your attendance. Ms. Grant can be reached at 202–927–3641 or e-mail at *public_liaison@irs.gov*. Attendees are encouraged to arrive at least 30 minutes before the meeting begins to allow sufficient time for purposes of security clearance. Should you wish the IRPAC to consider a written statement, please call 202–927–3641, or write to: Internal Revenue Service, Office of National Public Liaison, CL:NPL:SRM, Rm. 7566, 1111 Constitution Avenue, NW., Washington, DC 20224 or *e-mail: *public_liaison@irs.gov*.

Dated: April 7, 2008.

Cynthia Vanderpool,

Branch Chief, National Public Liaison.

[FR Doc. E8–8074 Filed 4–14–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Amendment of a Savings Association Charter

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before May 15, 2008. A copy of this ICR, with applicable supporting documentation, can be obtained from RegInfo.gov at *http://www.reginfo.gov/public/do/PRAMain*.

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, *Attention:* Desk Officer for OTS, U.S. Office of Management and Budget, 725–17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 395–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov*. OTS will post comments and the related index on the OTS Internet Site at *www.ots.treas.gov*. In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov* (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Litigation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Amendment of a Savings Association Charter.

OMB Number: 1550–0018.

Form Number: N/A.

Description: The charter of an insured Federal savings association is a formal document created when a savings association establishes its corporate existence. The charter states the scope, purpose and duration for the corporate entity. Also, for a federally chartered savings association, the charter confirms that the board of directors has formally committed the institution to Section 5 of the Home Owners' Loan Act and other applicable statutes and regulations governing federally chartered savings associations.

All federally chartered savings associations are required to file charter amendment applications or notices with OTS. OTS Regional Office staff review the applications and notices to determine whether the charter amendments comply with the regulations and OTS policy.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 26.

Estimated Number of Responses: 26.

Estimated Burden Hours per Response: 6 hours.

Estimated Frequency of Response: Other; As needed.

Estimated Total Burden: 156 hours.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: April 9, 2008.

Deborah Dakin,

Senior Deputy Chief Counsel, Regulations and Legislation Division.

[FR Doc. E8–8016 Filed 4–14–08; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

General Reporting and Recordkeeping by Savings Associations

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before May 15, 2008. A copy of this ICR, with applicable supporting documentation, can be obtained from *RegInfo.gov* at *http://www.reginfo.gov/public/do/PRAMain.*

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, *Attention:* Desk Officer for OTS, U.S. Office of Management and Budget, 725—17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 395–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov.* OTS will post comments and the related index on the OTS Internet Site at *www.ots.treas.gov.* In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov* (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Litigation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: General Reporting and Recordkeeping by Savings Associations.

OMB Number: 1550–0011.

Form Number: N/A.

Description: Savings associations use the reports and records that the regulations require for internal management control purposes and examiners use them to determine whether savings associations are being operated safely, soundly, and in

compliance with regulations. An absence of the reporting and recordkeeping requirements would not allow for prudent internal controls or for examiners to determine the accurate performance and condition of savings associations. Specifically, OTS examiners use the reports and recordkeeping requirements to determine whether the savings associations are being operated safely, soundly, and in compliance with regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 834.

Estimated Number of Responses: 834.

Estimated Burden Hours per Response: Range between 15 minutes to 100 hours, an average of 19 hours.

Estimated Frequency of Response: On occasion.

Estimated Total Burden: 3,648,563.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: April 9, 2008.

Deborah Dakin,

Senior Deputy Chief Counsel, Regulations and Legislation Division.

[FR Doc. E8–8014 Filed 4–14–08; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Mutual to Stock Conversion Application

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before May 15, 2008. A copy of this ICR, with applicable supporting documentation, can be obtained from *RegInfo.gov* at *http://www.reginfo.gov/public/do/PRAMain*.

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, Attention: Desk Officer for OTS, U.S. Office of Management and Budget, 725–17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 395–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov*. OTS will post comments and the related index on the OTS Internet Site at *www.ots.treas.gov*. In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov* (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Litigation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Mutual to Stock Conversion Application.

OMB Number: 1550–0014.

Form Number: OTS Forms 1680, 1681, 1682, and 1683.

Description: The OTS staff makes an in-depth study of all information furnished in the application in order to determine the safety and soundness of the proposed stock conversion. The purpose of the information collection is to provide OTS with the information necessary to determine if the proposed transaction may be approved. If the information required were not collected, OTS would not be able to properly evaluate whether the proposed transaction was acceptable. The information collection allows OTS to evaluate the merits of the proposed conversion plan and application in light of applicable statutory and regulatory criteria.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 14.

Estimated Number of Responses: 14.

Estimated Burden Hours per Response: 510 hours.

Estimated Frequency of Response: Other; Required once when converting to stock form.

Estimated Total Burden: 7,140 hours.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: April 9, 2008.

Deborah Dakin,

Senior Deputy Chief Counsel, Regulations and Legislation Division.

[FR Doc. E8–8015 Filed 4–14–08; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF VETERANS AFFAIRS

VA Adjudication Procedures Manual, M21–1; Rescission of Manual M21–1 Provisions Related to Exposure to Herbicides Based on Receipt of the Vietnam Service Medal

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) rescinds provisions of its Adjudication Procedures Manual, M21–1 (Manual M21–1) that were found by the U.S. Court of Appeals for Veterans Claims (Veterans Court) not to have been properly rescinded.

DATES: This rescission is effective April 15, 2008.

SUPPLEMENTARY INFORMATION: On November 27, 2007, we proposed to rescind certain provisions of our Manual M21–1. 72 FR 66218. The notice was necessitated by the opinion rendered by the Veterans Court in *Haas* v. *Nicholson*, 20 Vet. App. 257 (2006). Although VA's appeal of that decision has been submitted to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), that court has not yet issued a decision in the case. The comment period has ended, and we now rescind the provisions.

We received more than 75 comments, most of which were very similar and can be addressed in three categories: (1) Citation to scientific evidence, in particular a 2002 study performed for Australia's Queensland Health Scientific Services by their National Research Center for Environmental Toxicology, titled, *Examination of the Potential Exposure of Royal Australian Navy Personnel to Polychlorinated Dibenzodioxins and Polychlorinated*

Dibenzofurans Via Drinking Water (the Australian study); (2) personal stories about the commenters' experiences during service and/or their current illnesses; and, (3) arguments presented in connection with the *Haas* litigation. We will address these three categories of comments, and then address a few additional comments that do not fit within these categories.

Comments Based on Scientific Articles

Several commenters suggested that rescission of the Manual M21–1 is inconsistent with scientific articles purportedly showing that herbicide exposure in offshore waters could have occurred by virtue of wind drift or consumption of drinking water distilled from estuarine waters. We make no change based on these comments for the reasons explained below.

Several commenters cited the Australian study as proof that American military personnel on ships off the coast of Vietnam were exposed to herbicides in drinking water. The Australian study assumed that ocean water near estuarine sources could contain dioxin if dioxin had been used over adjacent land. It then noted that Australian Navy boats distilled water, obtained primarily from locations near such estuarine sources, to use as drinking water. Based on these factual predicates, the study found that the distillation process used by those boats did not remove dioxin when dioxin was added to salt water and the distillation process was performed in a laboratory, but, instead, the distillation concentrated the dioxin level in the water. The study was not peer reviewed or published and, to our knowledge, has never been cited in any subsequent reputable study concerning herbicide exposure.

Even assuming that U.S. Navy ships used a distillation process to obtain drinking water from the ocean (VA has been unable to obtain official confirmation of this from the Department of Defense), VA's scientific experts have noted many problems with this study that caution against placing significant reliance on the study. In particular, the authors of the Australian study themselves noted that there was substantial uncertainty in their assumptions regarding the concentration of dioxin that may have been present in estuarine waters during the Vietnam War. Further, although distillation concentrated the dioxin level in the water, the concentrating effect was shown to depend upon the amount of sediment in the water, such that a large sediment level, consistent with estuarine waters, could significantly reduce the concentrating effect. Moreover, even with the concentrating effect found in the Australian study, the levels of exposure estimated in this study are not at all comparable to the exposures experienced by veterans who served on land where herbicides were applied. This is true even if we were to assume that a person drank only such distilled water and did so for an extended tour.

A few commenters cited other studies that discuss generally the nature of air and water pollution, the manner in which certain pesticides can be borne by the wind, and the effect of water-borne pesticides on marine life. None of these studies bears significantly on the specific question whether herbicides used, and as administered, by the U.S. military during the Vietnam Era could have been blown by the wind into the ocean, or into inland waters that then carried the chemical into the ocean, to reach a boat offshore and result in any significant risk of herbicide exposure. Similarly, the studies do not suggest that if those herbicides could have been so transported, they could then be transmitted through a distillation process (assuming that one was used by U.S. ships) into drinking water, and then consumed by military personnel in any measurable quantity. One study merely indicated that Agent Orange is carcinogenic, a fact that VA does not dispute.

Further, even if the studies show that herbicide exposure in offshore waters is possible in some circumstances, they do not provide a basis for maintaining a provision construed by the Veterans Court to impose a broad presumption of herbicide exposure based on receipt of the Vietnam Service Medal (VSM). The purpose of the presumption of herbicide exposure is to eliminate the need for case-by-case showings of exposure where there is a reasonable basis for presuming the fact. The possibility of exposure in certain circumstances of offshore service does not, in our view, establish a basis for presuming exposure in all circumstances involving offshore service or receipt of the VSM.

In our view, the cited studies are of minimal relevance to the instant action for the additional reason that the M21–1 provisions were not intended to establish a substantive rule, but to implement the congressional intent underlying the statutory presumption of herbicide exposure in 38 U.S.C. 1116(f). The commenters do not suggest that Congress relied upon the cited studies in enacting § 1116(f), but appear only to argue that the cited studies would independently support a presumption of herbicide exposure for veterans who served offshore. It is VA's policy not to issue substantive rules through its M21–1 manual or other internal documents, but through notice-and-comment rule making and subsequent codification in the Code of Federal Regulations. Because the Veterans Court's conclusion that the M21–1 provisions established a substantive rule is inconsistent with VA's intent in issuing the M21–1 provision, VA is rescinding the M21–1 provisions. As stated in the notice of proposed rule making, VA will shortly issue a proposed revision to its governing regulation, 38 CFR 3.307(a)(6)(iii), to clarify our interpretation of 38 U.S.C. 1116(f). The issue of whether and to what extent the cited studies bear upon the congressional intent underlying § 1116(f) is most appropriately dealt with in the context of that rulemaking.

Additionally, we note that many VSM recipients did not even serve on ships off the shore of Vietnam. The VSM was awarded to all members of the Armed Forces who served between July 3, 1965, and March 28, 1973, either: (1) in Vietnam and contiguous waters and airspace thereover; or (2) in Thailand, Laos, or Cambodia, or airspace thereover, in direct support of operations in Vietnam. *See* Army Reg. 600–8–22, para. 2–13.). Clearly, the studies cited by commenters would not affect our decision as to veterans who served in Thailand, Laos, or Cambodia, or in airspace far above the jungles of Vietnam. If commenters relying on these studies believe the studies are relevant to the question whether Vietnam service should be extended to the waters off the shore of Vietnam, we direct readers to the revision of 38 CFR 3.307(a)(6)(iii), which we expect will be proposed before May 2008, and which will directly address the requirement of service on land in Vietnam. For the foregoing reasons, the Australian study and the other studies cited by commenters do not cause us to alter our decision to rescind the Manual M21–1 provisions.

Similar to the above category of comments, several commenters argued that there is no scientific basis for VA to take the position that veterans who served on ships were not exposed to herbicides during that service. These comments misunderstand the nature of VA's action. This action would not result in a finding or presumption that veterans who served on ships were not exposed to herbicides; it would merely clarify that such veterans are not automatically presumed to have been exposed and that the issue of exposure must be resolved on a case-by-case basis to the same extent as most other factual

issues involved in claims for VA benefits.

Comments Based on Personal Experience

The second group of comments received related the personal experiences of veterans who suffer from cancer and other ailments that can be caused by exposure to Agent Orange. While we are sympathetic to the needs of these veterans, Congress has been quite clear that VA cannot presume exposure to herbicides simply because a veteran has a disease linked to exposure to herbicides. Again, section 1116(f) states that a veteran with such a disease is presumed exposed only if he ''served in the Republic of Vietnam.'' To the extent that these commenters seek relief in their own individual cases, these comments are beyond the scope of this notice. The issue presented here is whether VA should rescind a Manual M21–1 provision that the Veterans Court misinterpreted as requiring VA to presume exposure for any veteran who received the VSM.

Comments Related to Haas Litigation

The third category of comments received includes comments presenting the same statutory-interpretation arguments that have been presented to the Federal Circuit in the *Haas* litigation. These comments assert that the language of 38 U.S.C. 1116 plainly requires that offshore service be considered service ''in the Republic of Vietnam'' for purposes of that statute. We do not agree. In its *Haas* opinion, the Veterans Court held that neither the language nor the legislative history of § 1116 reflects a clear intent to treat offshore service as service ''in the Republic of Vietnam.'' *Haas,* 20 Vet. App. at 264–68. We therefore make no change based on these comments, but we note that this issue remains pending before the Federal Circuit.

Additionally, some commenters suggested that VA, by this action, was usurping the power of the courts. We do not agree. VA has the legal right to engage in rulemaking and the legal obligation to interpret title 38, United States Code. As the Federal Circuit has held, the fact that a court has interpreted VA's regulations does not bar VA from later revising those regulations. *See National Organization of Veterans' Advocates* v. *Secretary of Veterans Affairs,* 260 F.3d 1365, 1373–74 (Fed. Cir. 2001). This action in no way usurps the court's authority to review our actions in this regard.

Other Comments

In addition to the categories of comments addressed above, we received the following specific comments. First, one commenter asked why the proposed rescission did not address ''any action [VA] may contemplate to sever service connection'' granted based upon the Manual M21–1 provisions. We have no plans to undertake such action. The same commenter asked whether a claimant who had been presumed exposed to herbicides based on the Manual M21–1 provision would now, post-rescission, not be presumed exposed if he filed a claim based on a new disease. VA has never interpreted the Manual M21–1 provision to require a presumption of service connection for every veteran who received the VSM. (In fact, this is precisely why VA denied Mr. Haas' claim.) That interpretation was made by the Veterans Court, not by VA. Therefore, if a veteran had been presumed exposed to herbicides before this rescission, it is because the evidence in his file, viewed as a whole, supported applying the presumption in the particular case.

The same commenter added that if VA believes that other evidence besides the award of the VSM is relevant to a finding of service in Vietnam, then VA should identify such evidence. This comment is beyond the scope of this rescission, which simply removes from the Manual M21–1 a provision that required VA to consider the VSM in connection with a claim for a disability allegedly caused by herbicide exposure. In this regard, the commenter may wish to review and comment on our revision of 38 CFR 3.307(a)(6)(iii).

Another commenter stated that he ''can understand why blue water sailors [i.e., sailors who served off the coast of Vietnam] would be more closely scrutinized, but not automatically deemed ineligible.'' Removal of the Manual M21–1 provisions would not render blue water sailors ineligible for benefits based on herbicide exposure. Such veterans could establish service connection for herbicide-related conditions by submission of evidence establishing exposure to herbicides during service, just as they always could. If a veteran is eligible for that presumption, then, as a result, VA will not further scrutinize that veteran's claim on the issue of exposure. We are rescinding this misinterpreted Manual M21–1 provision precisely because, like the commenter, VA believes that blue water veterans' claims must be subjected to greater scrutiny than claims by veterans who served on land. Blue water veterans who received the VSM can directly establish the fact of their exposure with evidence of contact with herbicides or evidence that they actually served on land.

Several comments related to the exposure of veterans who served in Thailand, Cambodia and/or Laos. Persons who received the VSM could have served in these regions. However, because we have no confirmed evidence of the extent of the possible exposure of such persons to herbicides, and no statutory mandate to consider such persons to have been exposed, we make no change to our decision based on these comments.

Based on the foregoing, VA rescinds the following manual provisions describing service in Vietnam for the purposes of the presumption of exposure to herbicides: M21–1, pt. III, para. 4.08(k)(1)–(2) (November 8, 1991); M21–1, pt. III, para. 4.24(g)(1)–(2), change 23 (October 6, 1993); M21–1, pt. III, para. 4.24(g)(1)–(2), change 41 (July 12, 1995); M21–1, pt. III, para. 4.24(g)(1)–(2), change 76 (June 1, 1999); M21–1, pt. III, para. 4.24(e)(1)–(2), change 88 (February 27, 2002).

Approved: April 8, 2008.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

[FR Doc. E8–7912 Filed 4–14–08; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register
Vol. 73, No. 73
Tuesday, April 15, 2008

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2006–0186]

RIN 0579–AC24

Importation of Uncooked Pork and Pork Products

Correction

In final rule document E8–6800 beginning on page 17881, in the issue of Wednesday, April 2, 2008, make the following correction:

On page 17883 Table 2 is corrected to read as set forth below:

TABLE 2.—U.S. GLOBAL IMPORTS OF FRESH OR FROZEN PORK, 2003–2007

Source	2003		2004		2005		2006		2007 (Jan–Feb)	
	$Million	Metric tons	$Million	Metric tons	$Million	Metric tons	$Million	Metric tons	$Million	Metric tons
Canada	$644.806	349422.6	$760.886	320339.3	$745.496	315136.5	$681.313	288624.2	$103.11	46102.2
Denmark	156.324	45735.7	182.794	46697.8	154.933	34477.9	141.731	35208.8	22.65	5248.1
Ireland ..	9.998	2905.7	128.38	2889.4	12.192	2590.5	8.657	1750.9	1.627	335.2
Finland ..	2115	822.4	6.792	2186.3	4.797	1356.5	5.235	1292.7	0.513	95.3
Netherlands	0	0	8.511	1923.3	9.373	2249.8	10.508	2490.2	0	0
United Kingdom ...	4.281	1488.7	4.184	1020.6	10.787	2186.3	7.305	1410.7	1.608	323.9
Mexico[1]	0.949	391.9	2.498	725.8	4.212	1038.7	5.102	1496.6	1.201	306.6
Sweden	0.098	40.8	2.95	730.3	2.4	557.9	1.807	386	0.068	23.6
Germany[1]	9.353	137.4	0	0	0.319	117.9	0.381	91.2	0	0
Australia	0.038	12.3	0.05	9.1	0.056	24	0	0	0	0
New Zealand ...	0.037	14.5	0	0	0	0	0	0	0	0
Chile	0	0	0	0	0	0	0.723	320.2	0.468	126.1
Iceland ..	0	0	0	0	0	0	0.161	24	0	0
Belgium[1]	0	0	0	0	0	0	0.058	23.1	0	0
China	0	0	0	0	0	0	0.042	18.1	0	0
World total ...	819	400972.1	928.504	373514.5	944.565	359738.7	863.024	342257.1	131.46	52562.8

[1] Mexico contains regions where CSF exists, but also contains regions recognized as CSF-free. Belgium and Germany are part of the APHIS-defined CSF region, a single region of low risk for CSF. Pork, pork products, and swine from this region may be imported into the United States in accordance with the provisions of § 94.24.

[FR Doc. Z8–6800 Filed 4–14–08; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 232, and 239

[RELEASE NOS. 33–8891; 34–57280; 39–2453; IC–28145; FILE NO. S7–12–07]

RIN 3235–AJ87

Electronic Filing and Revision of Form D

Correction

In rule document E8–3545 beginning on page 10592 in the issue of Wednesday, February 27, 2008, make the following correction:

On page 10609, in the third column, in the first full paragraph, in the second to last line, ''Form D'' should read ''Form ID''.

[FR Doc. Z8–3545 Filed 4–14–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–0230; Directorate Identifier 2007–NM–043–AD; Amendment 39–15419; AD 2008–06–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200, A330–300, A340–200, and A340–300 Series Airplanes

Correction

§39.13 [Corrected]

In rule document E8–4671 beginning on page 13103 in the issue of Wednesday, March 12, 2008, make the following correction:

On page 13106, in §39.13, in table 3, the heading

''Table 3.—All Material Incorporated by reference''

should read

''Table 3.—New Material Incorporated by reference''

[FR Doc. Z8–4671 Filed 4–14–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–168745–03]

RIN 1545–BE18

Guidance Regarding Deduction and Capitalization of Expenditures Related to Tangible Property

Correction

In proposed rule document E8–4466 beginning on page 12838 in the issue of Monday, March 10, 2008, make the following corrections:

§1.263(a)–3 [Corrected]

1. On page 12857, in the second column, in § 1.263(a)–3(d)(2)(iii)(B)(1), in the first line, ''(B) *Plant property*—(1)'' should read ''(B) *Plant property*—*(1)*''.

2. On the same page, in the same column, in § 1.263(a)–3(d)(2)(iii)(B)(2), in the first line, ''(2)'' should read ''*(2)*''.

[FR Doc. Z8–4466 Filed 4–14–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–104946–07]

RIN 1545–BG36

Hybrid Retirement Plans

Correction

In proposed rule document E7–25025 beginning on page 73680 in the issue of Friday, December 28, 2007, make the following corrections:

§1.411(b)(5)–1 [Corrected]

1. On page 73694, in the second column, in the second line, in §1.411(b)(5)–1(c)(4)(v)(A)(1), ''(1) *General rule.*'' should read ''*(1) General rule.*''.

2. On page 73699, in §1.411(b)(5)–1(f)(1)(iii)(A)(1), in the first column, in the second line, ''(1)'' should read ''*(1)*''.

[FR Doc. Z7–25025 Filed 4–14–08; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
April 15, 2008

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413, 414, 488, and 494

[CMS–3818–F]

RIN 0938–AG82

Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule finalizes the February 4, 2005 proposed rule entitled ''Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities.'' It establishes new conditions for coverage that dialysis facilities must meet to be certified under the Medicare program. This final rule focuses on the patient and the results of care provided to the patient, establishes performance expectations for facilities, encourages patients to participate in their plan of care and treatment, eliminates many procedural requirements from the previous conditions for coverage, preserves strong process measures when necessary to promote meaningful patient safety, well-being, and continuous quality improvement. This final rule reflects the advances in dialysis technology and standard care practices since the requirements were last revised in their entirety in 1976.

DATES: The provisions of this final rule are effective October 14, 2008. Compliance with § 494.30(a)(1)(i) and § 494.60(e)(1) is not required until February 9, 2009. In addition, the compliance with § 494.180(h) is effective on February 1, 2009. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 14, 2008.

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Acronym List

AAMI Association for the Advancement of Medical Instrumentation
ACLS Advanced Cardiac Life Support
ADA American Dietetic Association
AED Automated external defibrillator
AIA American Institute of Architects
AHA American Heart Association
ALT Alanine Aminotransferase
APA Administrative Procedures Act
ANSI American National Standards Institute
BMI Body mass index
BONENT Board of Nephrology Nursing Examiners Nursing and Technology
BSW Bachelor's degree social worker
CADE Commission on Accreditation for Dietetics Education
CAHPS Consumer Assessment of Health Plans Survey
CCHT Certified Clinical Hemodialysis Technician
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CLIA Clinical Laboratory Improvement Amendments
CMS Centers for Medicare and Medicaid Services
CNSW Council of Nephrology Social Workers
CPG Clinical practice guidelines
CPM Clinical performance measures
CRAFT CROWN Responsiveness and Feedback Tree
CROWNWeb Consolidated Renal Operations in a Web-enabled Network
DFC Dialysis Facility Compare
DHHS Department of Health and Human Services
DOPPS Dialysis Outcomes and Practice Patterns Study
DOQI Disease Outcomes Quality Initiative
DTR Dietetic Technician, Registered
EDI Electronic Data Interchange
EMS Emergency medical system
ESRD End-Stage renal disease
FDA Food and Drug Administration
HBsAg Hepatitis B surface antigen
HIPAA Health Insurance Portability and Accountability Act 1996
HBV Hepatitis B virus
HCV Hepatitis C virus
HICPAC Healthcare Infection Control Practices Advisory Committee
HMO Health Maintenance Organization
ICC International Code Council
ICH In-center hemodialysis
IOM Institute of Medicine
KCP Kidney Care Partners
KDOQI Kidney Disease Outcomes Quality Initiative
K/DOQI Kidney Disease Outcomes Quality Initiative
LAL Amoebocyte lysate
LDO Large dialysis organization
LPN Licensed practical nurse
LVN Licensed vocational nurse
LSC Life Safety Code
MedPAC Medicare Payment Advisory Commission
MNT Medical nutrition therapy
MPD Mission and Priority Document
MSW Master's degree social worker
NCD National Coverage Determination
NF Nursing Facility
NKF National Kidney Foundation
NKF–KDOQI National Kidney Foundation's Kidney Disease Outcomes Quality Initiative
NNCC Nephrology Nursing Certification Commission
NNCO National Nephrology Certification Organization
NQF National Quality Forum
NTTAA National Technology Transfer and Advancement Act of 1995
OIG Office of the Inspector General
PA Physician assistant

PCT Patient care technician
QAPI Quality assessment and performance improvement
QIS Quality Infrastructure Report
RD Registered dietitian
RN Registered nurse
REMIS Renal Management Information System
RO Reverse osmosis
RPA Renal Physicians Association
SGA Subjective global assessment
SHEA Society for Healthcare Epidemiology of America
SNF Skilled nursing facility
SOW Scope of work
STIC Safe and Timely Immunization Coalition
TEP Technical Expert Panel
VISION Vital Information System to Improve Outcomes in Nephrology

I. Background

A. Introduction

End-Stage Renal Disease (ESRD) is a kidney impairment that is irreversible and permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. Our existing ESRD services conditions for coverage were originally adopted in 1976 (41 FR 22502). In our existing requirements for dialysis facilities at 42 CFR part 405, subpart U, we emphasize the policies and procedures that must be in place to support good patient care, and we focus on a facility's capacity to furnish quality care. To determine if a facility meets ESRD conditions for coverage, the State survey agency performs an on-site survey of the facility. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, we then certify the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. We have made several changes to our ESRD requirements since they were first adopted in 1976. However, they have not been comprehensively revised since that time.

On February 4, 2005, we published in the **Federal Register** a proposed rule entitled ''Conditions for Coverage for End-Stage Renal Disease Facilities'' (70 FR 6183). In that rule, we proposed revisions to the requirements that ESRD dialysis facilities must meet in order to be certified under the Medicare program.

Our decision to propose major changes to the existing conditions was based on several considerations. Revising the ESRD requirements is part of our effort to modernize regulations and improve the availability of quality-of-care information; to promote transparency; and to move toward a patient outcome-based system that focuses on quality assessment and performance improvement. We believe that revising the conditions for coverage would encourage improvement in outcomes of care for beneficiaries. We wish to incorporate the most recent medical and scientific guidelines and recommendations for dialysis facilities from the Centers for Disease Control and Prevention (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), and recognize current practice guidelines and professional standards of practice such as the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF–K/DOQI) clinical practice guidelines (CPGs).

B. Legislative History

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. The ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975 **Federal Register** (40 FR 27782), we published a proposed rule that revised sections of the ESRD requirements. On June 3, 1976 the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment. In addition, section 1881(c) of the Act establishes ESRD Network areas and Network organizations to assure that dialysis patients are provided appropriate care.

We know, based on comments, that many in the community support the overall shift in the ESRD conditions for coverage from an emphasis on process-oriented requirements to a more patient-centered, outcome-oriented approach. Further, we believe that virtually all members of the community support a quality assessment and performance improvement requirement and the development of a comprehensive data set that will contain information including the characteristics of ESRD facilities, their patient populations, as well as outcome measures of patient care.

The fundamental principles that guided us during this collaborative effort to develop new conditions were as follows:

- Ensure that patients' rights and physical safety are protected;
- Stress continuous quality assessment and performance improvement, incorporating, to the greatest extent possible, outcome-oriented, data-driven measures;
- Facilitate flexibility in how dialysis facilities meet our performance requirements;
- Eliminate unnecessary administrative policies. Process-oriented standards are only included where we believe they are essential to protect patient health and safety;
- Focus on the continuous, interdisciplinary, integrated care system that a dialysis patient experiences, centered around patient assessment, care planning, service delivery, and quality assessment and performance improvement; and
- Stress patient satisfaction and ongoing patient involvement in the development of the care plan and treatment.
- Finally, in order for the ESRD facility conditions for coverage to move from a process and structure orientation toward a more patient-centered, outcome-oriented approach, individual patient and facility-specific outcome measures must be identified and evaluated, or in the absence of existing measures, they must be developed and validated with community input to ensure they are clinically meaningful and reflect current scientific knowledge.

C. Existing ESRD Regulation

The requirements from section 1881(b), (c), and (f)(7) of the Act are implemented in regulations at 42 CFR part 405, subpart U, ''Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services.''

The existing regulations describe the health and safety requirements that dialysis facilities must meet to furnish care to Medicare beneficiaries. The regulations in part 405, subpart U also include the provision that dialysis facilities be organized into Network areas and describe the role that Networks play in the ESRD program. Networks are defined at § 405.2110 as ''CMS designated ESRD Networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.''

The purpose of the existing conditions for coverage (also known as conditions) is to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis facilities.

The ESRD conditions for coverage (health and safety provisions for dialysis facilities) will be moved from existing 42 CFR part 405, subpart U, to a new 42 CFR part 494, where they will follow regulations establishing standards for other Medicare providers, such as the conditions of participation for hospitals (42 CFR part 482), long-term care facilities (42 CFR part 483), and home health agencies (42 CFR part 484). The termination of Medicare coverage and alternative sanctions conditions at § 405.2180 through § 405.2184 will be recodified at § 488.604 through § 488.610. Since many of the existing ESRD conditions will be revised, consolidated with other conditions, or deleted, we are renumbering and reorganizing the requirements.

D. The Establishment of Central Requirements

Our 2005 proposed rule proposed new conditions for coverage for ESRD facilities that revise or eliminate many of the existing requirements and establish critical central requirements. The central requirements of this rule were grouped into three broad categories: (1) Patient safety; (2) patient care; and (3) administration. Subpart A contained general provisions, for example, statutory authority, definitions, and requirements for compliance with Federal, State and local laws and regulations. Subpart B (Patient Safety), and subpart C (Patient Care) of the proposed conditions for coverage focused on the actual care delivered to the patients, the performance of the dialysis facility, and the impact of the treatment furnished by the dialysis facility on the health status of its patients. Subpart D contained personnel, ESRD Network, medical records and governance requirements.

In subpart B (Patient Safety), we proposed to retain and strengthen some process-oriented patient safety provisions that we believe remain highly predictive of ensuring desired outcomes and preventing harmful outcomes. Accordingly, the proposed patient safety requirements incorporated current CDC infection control procedures, retained and updated our incorporation by reference of the AAMI standards and guidelines for water quality and dialysate, hemodialyzer reuse practices, and incorporated by reference applicable current Life Safety Code (LSC) provisions.

Subpart C (Patient Care) included provisions: (1) Emphasizing a dialysis facility's fundamental responsibility to respect and promote the rights of each patient (patient rights); (2) requiring a facility to perform a comprehensive assessment to determine appropriate treatments and achieve desired health outcomes (Patient Assessment); (3) requiring an interdisciplinary team approach to providing dialysis services to patients; and specifying the process by which the interdisciplinary team would achieve effective patient health outcomes (Patient Plan of Care); (4) requiring a quality assessment and performance improvement program which would charge each dialysis facility with carrying out a program of its own design to continually improve quality outcomes and patient satisfaction; and (5) consolidating various aspects of home dialysis care into a single condition (Care at home).

Subpart D (Administration) covered the operation of the dialysis facility in a patient outcome-oriented environment, including: (1) Minimum personnel qualifications; (2) the role of the medical director; (3) the facility's relationship with its servicing ESRD Network; (4) medical recordkeeping; and (5) minimum operating responsibilities of the facility, including data collection and reporting requirements (Governance).

On August 22, 2006, President Bush signed Executive Order 13410, entitled ''Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs' (71 FR 51089, August 28, 2006). In order to empower Americans to find better health care value and better health care, they should know their health care options in advance. Patients need access to information regarding the quality of doctors, hospitals, dialysis facilities and other providers in their area, as well as the costs of various medical procedures. The August 2006 executive order directs agencies to increase transparency in pricing by sharing pricing information with patients; to increase transparency in quality by sharing information with patients on the quality of services provided by doctors, hospitals, ESRD facilities, and other health care providers; to encourage the adoption of health information technology systems that meet recognized interoperability standards; and to provide patients with options that promote quality and efficiency in health care, by developing and identifying approaches that facilitate high quality and efficient care. Building on efforts of quality alliances that include a broad range of healthcare stakeholders, we will work collaboratively to improve quality and cost information. Patients will be able to access this information from a variety of potential sources, including insurance companies, employers, and Medicare sponsored Web sites. In order to help dialysis patients make more informed health care decisions and to increase transparency, this final rule promotes a patient-centered approach and focuses on disclosing relevant information regarding care to patients.

We believe that transparency will also be improved by the implementation of an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), which is designed to collect clinical performance measures (CPMs) data from dialysis facilities. CPM data are used to monitor the performance of Medicare-certified dialysis facilities on a national and local level. These data are also used to provide information to individuals who have or may develop ESRD and their caregivers to assist them in making health care decisions; to allow the identification of opportunities for quality improvement at a national, regional, or dialysis facility-level; and to calculate case-mix adjustments and the potential future use of value based purchasing.

Dialysis Facility Compare (DFC) is an online tool at *http://www.medicare.gov* available for dialysis patients and their caregivers, which serves to enhance public accountability in healthcare by increasing transparency regarding the quality of dialysis facility care. DFC allows patients and caregivers to find and compare information about the services and quality of care provided at dialysis facilities in any State. Important information and resources regarding chronic kidney disease is also available on the DFC Web site.

II. Summary of the Proposed Provisions and Response to Comments on the February 4, 2005 Proposed Rule

The comment period for the February 4, 2005 proposed rule was 90 days, and closed on May 5, 2005. We received over 3,000 public comments, but many were form letters, so that the total number of discrete comments was approximately 315. Interested parties that commented included the American Association of Kidney Patients, the American Kidney Fund, the American Nephrology Nurses Association, the American Society of Nephrology, the American Healthcare Association, the Association of Dialysis Advocates, the

Association for the Advancement of Medical Instrumentation, the American Society of Pediatric Nephrology, the American Dietetic Association, DaVita, Inc., Dialysis Centers Inc., Fresenius Medical Care North America, Gambro Healthcare, Kidney Care Partners, Life Options Rehabilitation Advisory Council, the National Kidney Foundation, the National Renal Administrator's Association, the National Association of Nephrology Technicians, the Renal Care Group, the Renal Physicians Association, the Renal Support Network, Medical Education Institute, Inc., state survey agencies, ESRD Networks and the Forum of ESRD Networks, healthcare professionals, administrators, academics, dialysis patients, pharmaceutical and dialysis product companies, and hospital-based and non-hospital-based dialysis providers. Many commenters applauded the long overdue modernization of the ESRD conditions for coverage, even though they may have disagreed with a specific requirement or concept. Below we provide a brief summary of each proposed provision, a summary of the public comments we received, and our responses to the comments.

We received several comments on issues outside of the scope of this final rule, which we will not address. Please note, that in this final rule we have revised the title of subpart U from ''Conditions for Coverage for Suppliers of End-Stage Renal Disease'' to read ''Requirements for End-Stage Renal Disease Facilities.'' We are changing this final rule because the ''Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants'', published on March 30, 2007 (72 FR 15198) updated and recodified the kidney transplant center conditions for coverage and the remaining provisions only apply to the ESRD Networks.

A. Part 414—Payment for Part B Medical and Other Health Services; Payment for Home Dialysis Equipment, Supplies, and Support Services (Proposed § 414.330)

We proposed a new § 414.330(a)(2)(iii)(C) that would require the patient's home dialysis medical equipment supplier to report to the facility, every 30 days, all services and items furnished to the beneficiary, so that the information could be documented in the patient's medical record.

Comment: Two commenters supported the proposed requirement for a 30-day reporting timeframe for durable medical equipment suppliers who provide support services to home dialysis patients. Several other commenters suggested that the 30-day timeframe was inappropriate and restrictive and recommended we allow 45 days in the final rule.

Response: We agree with both sets of comments because we believe that all information showing what supplies and services were provided to the patient and when each was provided should be reported to the ESRD facility on a regular basis. However, we agree with the second group of commenters that the 30-day timeframe is restrictive. Therefore, to allow greater flexibility, we have modified the final rule at § 414.330(a)(2)(iii)(C) to allow durable medical equipment suppliers to report to the ESRD facility providing support services at least once every 45 days.

B. Part 488—Survey, Certification, and Enforcement Procedures; Special Procedures for Approving End-Stage Renal Disease Facilities (Proposed § 488.60)

We proposed to retain the procedures for approving ESRD facilities as specified at § 488.60. We received one public comment pertaining to the procedures for approving ESRD facilities. The comment and response are found at the end of this section. We have recodified § 405.2180, § 405.2181, § 405.2182, and § 405.2184 as § 488.604, § 488.606, § 488.608, and § 488.610, respectively. These provisions were relocated without any modifications. Comments pertaining to hemodialyzer reuse sanctions are addressed in the § 494.50, ''Reuse of hemodilayzers and bloodlines'' discussion, later in this preamble.

Comment: One commenter expressed concern regarding the certification process for ESRD facilities. The commenter remarked that facilities applying for initial approval may not have all of the data required by the conditions for coverage in accordance with § 488.60(a).

Response: Although we understand the commenter's concern that a new provider may not have all of the required data available, data are important for use in improving quality outcomes and play an important part in the management and oversight of the ESRD facilities. Therefore, we are retaining the provisions of § 488.60(a) as proposed. In addition, the absence of data would not necessarily result in the denial of certification. If an ESRD facility is unable to supply all of the data required in § 488.60(a), the facility could be cited at a standard deficiency level, thus emphasizing the importance of the data, but not precluding the ESRD facility from receiving approval to operate in the Medicare program.

C. Part 494—Conditions for Coverage for End-Stage Renal Disease Facilities

1. Subpart A (General Provisions)

a. Basis and Scope (Proposed § 494.1)

We proposed a new organizational format for the conditions for coverage, which permitted the elimination of almost all of § 405.2100, Scope of subpart. This section consists largely of a description of the contents of the existing ESRD conditions for coverage. We proposed at § 494.1 to identify the statutory authority for the revised regulations, and to state that provisions of part 494 would serve as the basis for survey activities for determining whether a dialysis facility met the conditions for coverage under the Medicare program. We received no comments on this section.

b. Definitions (Proposed § 494.10)

We proposed to recodify § 405.2102 as § 494.10, with an abbreviated set of definitions. While § 405.2102 defined 32 terms, we proposed to define only 7 terms at § 494.10. We proposed to eliminate several terms that were self-evident and others that would not be utilized in these revised conditions. In addition, we did not believe it would be appropriate to have substantive requirements contained within definitions, so we proposed to move definitions that contained qualification requirements, such as the term ''interdisciplinary team,'' to the appropriate conditions in the final rule.

Comment: A few commenters suggested revisions to the proposed definition for ''dialysis facility.'' One commenter recommended we adopt the phrase ''chronic kidney dialysis facility'' and two other commenters suggested the addition of ''self-care dialysis'' to the current list of services provided by the facility.

Response: Adding the word ''chronic,'' we believe, would add no value to the term ''dialysis facility'' since kidney disease requiring outpatient dialysis is chronic by nature. The proposed definition for ''dialysis facility'' does recognize self-care dialysis. Self-care dialysis is a modality described in section 1881 of the Act. We believe the proposed definition of ''dialysis facility'' is sufficient. Therefore, we adopt this definition as proposed.

Comment: Two commenters suggested adding language to clarify that a facility that taught a patient how to self-cannulate would not need to obtain

certification as a self-dialysis unit exclusively because of such instruction.

Response: We agree with the commenters that any dialysis facility that is Medicare-certified to provide outpatient dialysis services may include instruction in self-cannulation in its dialysis program. We do not require any additional certifications, nor is a separate ''self-dialysis'' certification category available. Dialysis facilities receive Medicare certification to provide in-center dialysis or home dialysis training and support services, or both. We are not adding a regulatory statement regarding the absence of a self-dialysis certification category to this final rule.

Comment: One commenter requested additional clarification regarding what would constitute ''discharge'' (for example, ''30 days after departure from a facility for any reason'').

Response: Our intent was to describe the cessation or end of patient care services for patients who either voluntarily leave the facility or for patients who are discharged for reasons listed at § 494.180(f). To address the commenter's concern, we have added clarifying language at § 494.10 to read, ''Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.''

Comment: We requested comments regarding whether to reference nursing facilities (NFs) and skilled nursing facilities (SNFs) in the definition for ''home dialysis.'' We received many comments regarding the definition of ''home dialysis.'' Some commenters questioned the definition of ''home,'' while others commented that nursing homes and other institutional settings were appropriate for home dialysis. Yet others stated that nursing homes and other institutional settings were inappropriate for home dialysis. One commenter expressed concern regarding permanent versus temporary residence status within a nursing facility. One commenter suggested we adopt a new term, ''institutional home dialysis,'' to describe patients in a nursing home setting. Other commenters suggested a separate definition for dialysis provided in a nursing home setting that would be distinct from ''home dialysis.''

Many commenters noted the nursing home setting is different from the typical dialysis facility setting, and that the needs of the NF/SNF patient population are unique. One commenter proposed the term ''staff assisted nursing home dialysis'' be used. Other topics of concern included training course specifications, recommendations about peritoneal dialysis and hemodialysis modalities, and the burden associated with including NFs and SNFs in the definition.

Some commenters believed that neither short nor long-term stays in NFs/SNFs should be considered a patient's home for purposes of home dialysis, while others took the opposite view. Other commenters responded that only a long-term stay in a NF/SNF should be considered a patient's home for purposes of home dialysis. Major dialysis associations and a major nursing home association urged Centers for Medicare and Medicaid Services (CMS) not to classify NF/SNF as the patient's ''home'' in this final rule, but to convene an expert panel to study this complex issue and then address it in a separate rule at a later date.

Response: We understand the concerns of commenters. Currently a SNF may be considered a patient's home for self-dialysis, as noted in the Medicare Claims Processing Manual, which can be found at *http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf* and as noted in the Program Integrity Manual, Chapter 5 at *http://www.cms.hhs.gov/manuals/downloads/pim83c05.pdf*.

We recognize that the provision of hemodialysis to nursing home patients presents unique challenges, given this frail population. We note that there was no consensus within either the renal community or the medical community at large as to the inclusion of SNFs or NFs in the definition of ''home dialysis.'' A more detailed discussion of this issue can be found later in this preamble under the ''Care at home'' condition (§ 494.100). Given the variety of differing comments, we believe that a regulation regarding NF/SNF dialysis would be premature. Therefore, we will consider addressing this issue at a later date, and the current guidance for dialysis in a nursing home environment will remain in effect at this time.

Comment: Three commenters suggested that the definition for ''interdisciplinary team'' use the same language as that of § 494.80, and that the definitions be cross-referenced throughout the text.

Response: The composition of the interdisciplinary team is a minimum requirement of this final rule. We are not including requirements in the definition section. We are defining the ''interdisciplinary team'' in the ''Patient assessment'' condition opening paragraph at § 494.80. We have also added the requirement to the ''Patient plan of care'' condition at § 494.90, to include the same language describing the composition of the team. The definition for ''interdisciplinary team'' appearing under § 494.10 in the proposed rule has been removed from this final rule.

Comment: We received several comments regarding the definition of ''self-dialysis.'' Two commenters suggested changing the definition from ''dialysis performed with little or no professional assistance'' to ''dialysis performed with limited or no professional assistance * * *.'' Some commenters stated the definition should not reference the training requirement at § 494.100(a) since such requirement would not apply to all self-dialysis, and that many patients would perform some level of self-care in the facility. One commenter recommended that we issue interpretive guidelines to address the issue of patients that would perform self-care dialysis in a facility. Another commenter suggested dropping ''self-dialysis'' terminology from the definition section of this final rule.

Response: ''Self-dialysis'' is addressed in section 1881 of the Act and the Secretary has the discretion to define ''self-dialysis services'' in regulations. We are retaining the proposed language, which contains the term ''little'' because we believe ''limited'' may imply the necessity of a potentially higher degree of professional assistance for self-dialysis patients than envisioned by the statute. Interpretive guidelines will be developed to instruct the surveyors how to review facilities for compliance with the requirement.

Comment: Several commenters requested clarifications of terminology and additional definitions in the final rule such as: New patient; first dialysis; direct supervision; and grievance.

Response: The terms ''first dialysis'' and ''new patient'' are clarified in the section in which the terms are used. For example, ''new patient'' is now clarified in the ''Patient assessment'' condition at § 494.80(b). The term ''direct supervision'' has been deleted from the final rule, as explained in the preamble discussion for ''Personnel qualifications'' at § 494.140(e)(3). ''Grievance'' is discussed in the preamble for ''Patients' rights'' at § 494.70.

Comment: A renal association recommended that we define the term ''standards'' in the final rule since we used that term in the preamble of the proposed rule. The commenter noted that the use of the term ''standards'' is significant and should be explicitly defined to ensure consistency throughout the regulation. The commenter also noted that each of the NKF's clinical practice guidelines

contains a disclaimer stating that guideline is ''not intended to define a standard of care, and should not be construed as one.''

Response: The term ''standards'' appears throughout the regulation, as it is used to identify levels of requirements within each condition for coverage. Historically, our conditions of participation and conditions for coverage are written in hierarchical form of conditions, with standards and elements (or factors) contained within the conditions. For the most part they are written as individual, surveyable requirements. Merriam-Webster's Collegiate Dictionary defines ''standards'' as ''something established by authority, custom, or general consent as a model or example.'' This definition matches how the term ''standards'' is used in this final rule. When using the term ''standards'' as applied to care of patients, we expect that professionals would rely upon principles and practices of care that are, for example, widely used and supported by professional organizations, academic institutions, and recognized standard-setting organizations. We recognize that professionals may vary in their use of particular ''standards.'' We assume the commenter is concerned about the use of the terms ''standards'' as used in the preamble discussion of facility-wide standards to be used for enforcement. Any facility-level standards for Medicare participation developed subsequent to publication of this final rule, will be developed in accordance with the National Technology Transfer and Advancement Act of 1995 (NTTAA) process adopted by the Secretary, as discussed in the ''Governance'' condition at § 494.180.

c. Compliance With Federal, State, and Local Laws and Regulations (Proposed § 494.20)

We proposed a slightly broader version of § 405.2135 in our February 2005 proposed rule. While § 405.2135 specifies applicable laws and regulations pertaining to licensure, fire safety, equipment, and other relevant health and safety requirements with which a facility had to comply, we proposed that, additionally, facilities specifically comply with State and local building codes, and any laws regulating drugs and medical device usage.

Comment: Several commenters suggested deleting the reference to ''drugs'' at proposed § 494.20. Commenters are concerned that this reference to drugs would restrict physicians' use of Medicare Part B covered drugs for ''off label'' use.

Response: We agree with the commenters. The reference to ''drugs'' has been removed from § 494.20 of the regulation text. Medicare contractors may make reasonable and necessary determinations regarding off-label uses of drugs pursuant to instructions published in program manuals.

Additionally, we removed the phrase ''staff licensure and other personnel staff qualifications'' from § 494.20, as this requirement may be found in ''Personnel qualifications'' at § 494.140. We removed the phrase ''fire safety, equipment, building codes'' from § 494.20, as these issues are addressed in the ''Physical environment'' condition at § 494.60. In addition, we removed the phrase ''medical device usage'' from § 494.20, as it is covered under the condition for ''Water and dialysate quality'' at § 494.40, the condition for ''Reuse of hemodialyzers and bloodlines'' at § 494.50, the ''Physical environment'' condition at § 494.60(b), and in the ''Care at home'' condition at § 494.100.

Comment: A commenter stated that water treatment systems are ''medical devices'' and fall under Food and Drug Administration (FDA) regulations. The commenter stated that the proposed rule preamble suggests that water systems would have to meet FDA guidance document requirements even if installed before May 1997. The commenter is concerned that replacement of water systems with ''510(k) cleared'' systems would incur needless expense.

Response: As explained above, we have removed the words ''equipment'' and ''medical device usage'' from § 494.20 and do not single out these categories of law. Facilities are expected to comply with all Federal, State and local laws regarding health and safety. Under current FDA regulations, all water treatment systems installed after May 30, 1997 must meet review requirements under section 510(k) of the Food, Drug, and Cosmetic Act (21 U.S.C. sec. 360(k)) as described in *Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis (http://www.fda.gov/cdrh/ode/hemodial.pdf).* This document is intended to provide guidance in the preparation of a regulatory submission and reflects the current FDA review guidance for water purification components and systems for hemodialysis. Water purification systems installed before May 30, 1997 are not affected by this guidance; however, all systems installed after this date must meet FDA requirements. Regardless of when a water purification system was installed, the system must yield water and dialysate that meets AAMI standards and must be monitored and maintained in accordance with the AAMI RD52 guidelines, which are incorporated by reference in this final rule at § 494.40.

Comment: A number of commenters recommended we include a reference to the Americans with Disabilities Act of 1990 (Disabilities Act) within this condition. The rationale is that patients must be accommodated for mobility, hearing, vision, or other disabilities or language barriers.

Response: A specific reference to the Disabilities Act is not necessary since ESRD facilities must comply with all applicable Federal, State, and local laws, including the Disabilities Act. The Department of Justice, Civil Rights Division, is charged with oversight and enforcement of the Disabilities Act. We would also continue to support the enforcement of the Disabilities Act provisions through the survey process under § 494.20.

2. Subpart B—Patient Safety

a. Infection Control (Proposed § 494.30)

We proposed a separate condition for coverage for infection control requirements, to update the provisions currently found at § 405.2140(b) and § 405.2140(c). We proposed incorporating by reference ''Recommended Infection Control Practices for Hemodialysis Units at A Glance'' precautions found in the CDC publication ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' (DHHS/CDC, pages 20–21), with the exception of the screening recommendations for hepatitis C. We proposed that dialysis facilities implement appropriate procedures for patient isolation; for the handling, storage, and disposal of waste; and the disinfection of surfaces, devices, and equipment. We proposed the appointment of an infection control officer registered nurse (RN) to ensure oversight of the facility's infection control program, maintenance of current infection control information, reporting of infection control issues to the facility chief executive officer (CEO) or administrator and the facility improvement committee, and the development of facility infection control improvement recommendations. We also proposed monitoring and reporting standards that would require the facility to analyze and document the incidence of infection to identify trends, establish baselines, take action to reduce future infection control incidents, and report incidences of communicable diseases as

required by Federal, State, and local regulations.

Comment: We received numerous comments on § 494.30 ''Infection control'' condition. Many commenters agreed with the inclusion of the CDC infection control precautions for hemodialysis settings. Some commenters recommended that we incorporate in the final rule the entire CDC (RR05) document entitled, ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' (published on April 27, 2001), rather than only the ''At A Glance'' section.

A number of commenters referenced particular infection control precautions included in the ''At A Glance'' section and requested clarification or raised issues related to the cost or logistics of implementing the specific precaution in a hemodialysis facility. The precautions referred to in these comments include: use of disposable items, use of cloth-covered blood pressure cuffs, use of leak-proof containers for used hemodialyzers, specifications for medication carts, carrying supplies or medications in the pockets of staff, and isolation room requirements. Some commenters stated that there was no need for every new dialysis unit to have an isolation room. Two commenters supported having separate staff to care for hepatitis B-positive patients, but other commenters stated the cost of separate staff for this would be prohibitive.

Response: We appreciate the support for inclusion of the CDC hemodialysis infection control precautions in this final rule. Based on the comments, it is apparent that clarifications are needed for the ''At A Glance'' guidelines, which are an abbreviated version of the CDC RR05 ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients.'' The majority of comments concerning specific precautions are addressed in the CDC narrative section entitled ''Recommendations'' on pages 18 through 28 of ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients.'' In order to better clarify the requirements of the infection control precautions, we are expanding our RR05 incorporation by reference to include the entire ''Recommendations'' narrative section of the document (pages 18–28) in the final rule, with one exception (hepatitis C screening), as discussed below. The introduction and background sections of the RR05 document (pages 1–17) provide the evidentiary basis for the recommended precautions. The entire CDC RR05 document provides rich background information and rationale for the recommended practices; we encourage facilities to use the entire document as a resource.

The RR05 CDC infection control precautions state that items taken into the dialysis station should be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. Items that cannot be cleaned and disinfected (for example, adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use only on a single patient. Blood pressure cuff covers may be more cost-effective and may be used for blood pressure cuffs that cannot be decontaminated easily between patients. In contrast, rolls of tape cannot be decontaminated and can serve as a source of contamination for both facility personnel and patients. Tape rolls must be dedicated to a single patient, or disposed of after patient use.

Hemodialyzers carried to the reuse area should always be in a leak-proof container. We wish to prevent a blood-contaminated item from potentially contaminating the treatment (and clean) areas as it is carried from a patient's station. A container could be a plastic bag. We believe that the practice of carrying a contaminated hemodialyzer to the reuse room without the use of a leakproof container does not adequately prevent contamination.

Although one commenter stated that banning a medication cart and taping medication to the hemodialysis machine would ''waste'' RN time, the CDC has made clear that patient safety is best protected and risk of cross-contamination reduced when medications are prepared and distributed from a centralized clean area dedicated to that purpose. Another commenter argued that staff should have immediate access to gloves for times when a patient suddenly starts to bleed, and that staff members should be allowed to carry extra gloves in their pockets. The CDC precautions do not allow this practice. Instead, the facility should have gloves strategically placed so that staff has adequate access to them for both routine and emergency use.

Regarding the treatment of hepatitis B-positive patients, many commenters provided alternative isolation room recommendations and requested clarification of the isolation room requirement for new units as well as for existing units. The ''At A Glance'' page states (under ''Management of HBsAg-Positive Patients'') that the dialysis facility should dialyze hepatitis B surface antigen (HBsAg) positive patients in a separate room using separate machines, equipment, instruments, and supplies; and that staff members caring for HBsAg-positive patients should not care for hepatitis B virus (HBV) susceptible patients at the same time (for example, during the same shift or during patient change-over). CDC language from page 27 of the CDC RR05 document states, ''For existing units in which a separate room is not possible, HBsAg-positive patients should be separated from HBV-susceptible patients in an area removed from the mainstream of activity and should undergo dialysis on dedicated machines. If a machine that has been used on an HBsAg-positive patient is needed for an HBV-susceptible patient, internal pathways of the machine can be disinfected using conventional protocols and external surfaces cleaned using soap and water or a detergent germicide.'' Therefore, we are incorporating this section by reference into the ''Infection control'' condition at § 494.30, as it is found in the ''Recommendations'' narrative section of the CDC ''At A Glance'' infection control precautions. However, we are allowing dialysis facilities extra time to come into compliance with the provision requiring a separate isolation room (recommendation found on pages 27 and 28 under the ''HBV-Infected Patient'' section header of RR05), since in some cases the provision would require that a facility retrofit its building, which would necessitate project development, architectural design, contractor bids, building permits, and time to complete the job. Therefore, we are allowing dialysis facilities 300 days after the publication of this final rule in the **Federal Register** to comply with the requirements of this provision. In addition, any HBsAg-positive patient in an existing dialysis facility should be separated from hepatitis B-susceptible patients either by a buffer zone of hepatitis B-immune patients or by a demarcated physical space at least equal to the width of one dialysis station. Separate dedicated supplies and equipment must be used to provide care to the HBsAg-positive patient. Note that ''separate equipment'' includes glucometers. Use of an ''end of row'' hemodialysis station can facilitate the separation of the area from the mainstream of the dialysis facility's activities and decreases the number of adjacent dialysis stations. If this space is needed for both HBsAg-positive as well as HBsAg-negative patients on other shifts, the space may be disinfected using conventional protocols and used for both types of patients at different

times. If a facility does not have any HBsAg-positive patients, this space may be used by non-HBsAg-positive patients on a normal basis. Every facility must have the capacity to separate HBsAg-positive patients in the facility.

In response to comments that not every new unit should be required to have an isolation room due to the low incidence of hepatitis B in hemodialysis patients, we have added a waiver provision at § 494.30(a)(1)(ii) that states, ''When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Such waivers are at the discretion of and subject to such additional qualifications as may be deemed necessary by the Secretary.''

The CDC infection control precautions specifically call for separate staff to care for hepatitis B-positive patients to prevent infection of susceptible dialysis patients. According to the CDC, using separate staff is a very effective method to reduce the spread of HBV. One staff person may care for a HBsAg-positive patient and immune patients at the same time, but may not simultaneously care for hepatitis B-susceptible patients. Section 494.30 requires dialysis facilities to implement this infection control precaution.

Comment: Two commenters pointed out that the RR05 ''At A Glance'' section uses the word ''should'' and seems to allow less than full compliance with the infection control precautions.

Response: We recognize that the RR05 CDC document uses the word ''should'' when describing implementation of the infection control precautions, for example, ''clean areas should be clearly designated for the preparation, handling and storage of medications * * *'' The CDC document is written as guidelines and therefore guideline language is used. For purposes of these Conditions for Coverage, the CDC infection control precautions, which are incorporated by reference, are mandatory and must be adhered to and demonstrated within the dialysis facility. The regulation states, ''the facility must demonstrate that it follows standard infection control precautions' by implementing the CDC hemodialysis infection control practices found in the RR05 document. The guidelines incorporated by reference will be deemed mandatory in the survey process.

Comment: One commenter asked whether a reverse isolation negative pressure room would be required.

Response: The RR05 CDC recommended infection control practices incorporated by reference address the unique needs of a hemodialysis unit and include contact precautions. When airborne pathogens are discovered within the dialysis unit, the CDC infection control recommendations regarding airborne pathogens should be consulted and the proper measures taken to protect patients and staff from exposure. This could mean that the affected patient is transferred to a setting that provides the necessary isolation precautions for the pathogen. The facility may want to have an agreement with a hospital if the facility discerns that this is necessary; however, we are not incorporating this provision into the Medicare ESRD conditions for coverage.

Comment: One commenter asked whether staff cover gowns are required.

Response: Staff scrubs or uniforms are sufficient attire within the dialysis unit, except for times when one might expect to be exposed to a blood spattering. Cover gowns primarily serve to protect a staff member from exposure to blood within the dialysis unit. This is addressed on page 22 of RR05 CDC document.

Comment: We received more than a dozen comments regarding the CDC RR05 recommendation for hepatitis C screening of dialysis patients. Most of the comments supported the CDC recommendation and several suggested that Medicare pay for hepatitis C screenings. Commenters stated that hepatitis C is an important pathogen for dialysis patients, screening would allow for early detection, and would alert the facility to significant breaks in use of infection control precautions. Some commenters did not support hepatitis C screening by the dialysis facility, and one noted that a positive diagnosis would not change treatment or patient care within the dialysis facility.

Response: In the proposed rule, we specified an exemption for hepatitis C screening, since Medicare only covers diagnostic hepatitis C testing when indicated, and does not cover general screening for hepatitis C. A patient with a hepatitis C positive test is treated in the dialysis facility with the same protocols as a patient who is not positive for hepatitis C. However, transmission of hepatitis C serves as a marker to evaluate the adequacy of infection control practices within a dialysis facility. Medicare generally covers preventive care and screenings if stipulated in law, including diagnostic testing. We will continue to omit from our incorporation by reference the CDC RR05 sections that specify hepatitis C screening.

On December 14, 2005, we published a coverage decision memo (CAG–00304N) that allows Medicare coverage of hepatitis panel testing when there is an elevation of liver enzyme levels. The memo title is ''Decision Memo for Addition of ICD–9–CM code 790.4, Nonspecific Elevation of Levels of Transaminase or Lactic Acid Dehydrogenase, as a Covered Indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination'' and may be found at *http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=173.* Elevated liver enzymes, with or without other signs or symptoms of hepatitis, is a covered indication for the hepatitis panel. Most hemodialysis patients with newly acquired Hepatitis C virus (HCV) infection have elevated serum transaminase levels. Elevations in serum transaminase levels often precede anti-HCV seroconversion. Monthly serum ALT (a transaminase) determination is included in the composite payment to renal dialysis facilities. Consequently, if a beneficiary has an elevated ALT, the provider may order a diagnostic hepatitis panel, which includes a hepatitis C antibody test as part of the panel. The hepatitis panel National Coverage Determination (NCD) does not require the physician to order all of its constituent component tests. Thus, a provider may order a hepatitis C antibody test when the beneficiary's serum ALT, ordered and covered for monthly testing in the composite rate, is elevated.

Comment: A few commenters referred to the CDC guidelines regarding injectable medications and disagreed with the established protocol that allows re-entry of single-use medication vials.

Response: The April 27, 2001/50 (RR05); 1–43 CDC infection control guidelines, ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' (*http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm*) state: ''Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once (196,197). Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial.''

We have retained the intent of this policy and the proposed requirement at § 494.30(b)(2), regarding current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication. However, we have modified the wording slightly because we have

removed the proposed infection control officer requirement, as discussed below.

Under the ''Oversight'' standard at § 494.30(b)(2) we are requiring the clinical staff to ''demonstrate compliance with current aseptic technique when dispensing and administering intravenous medications from vials and ampules.''

Comment: Several comments were submitted in response to our solicitation as to whether we should incorporate by reference the Healthcare Infection Control Practices Advisory Committee's (HICPAC) ''Hand Hygiene in Healthcare Settings'' guidelines and the ''Guideline for Preventing Intravascular Device-Related Infections.'' Comments were evenly divided regarding incorporation of the hand hygiene guidelines. Two of the commenters stated there is no consensus between HICPAC hand hygiene guidelines and guidelines developed by Society for Healthcare Epidemiology of America (SHEA) regarding standards of care for preventing nosocomial transmission of staph aureus and enterococcus. While one commenter did not support incorporation of the intravascular device guidelines, there was some support for their inclusion, notably from the American Nephrology Nurses Association.

Response: We would expect that dialysis facilities demonstrate adherence to professional standards of practice for infection control, which include adherence to hand hygiene guidelines. This expectation is included in the stem statement of the infection control condition: ''The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.'' The expectation of acceptable hand hygiene extends to all healthcare providers. We will not specifically incorporate by reference the HICPAC hand hygiene standards, but we do expect compliance to the hand hygiene professional standards of practice.

We do not agree that the guidelines developed by SHEA regarding standards of care for preventing nosocomial transmission of staph aureus and enterococcus conflict with the HICPAC hand hygiene standards. We note that the SHEA guidelines are not specific to dialysis facilities where contact precautions are recommended, but address infection control issues in the hospital setting. The SHEA guidelines reflect the general lack of adherence by health care workers to hand hygiene standards and recommend additional measures, such as surveillance cultures, to prevent and monitor cross-contamination. Facilities have the flexibility to use appropriate resources to assist in the development and implementation of their hand hygiene infection control and prevention program.

Catheter infections continue to be a concern in hemodialysis facilities and lead to hospitalizations. HICPAC states in its ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' RR–10 document (*http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm*) (page 11), that the use of catheters for hemodialysis is the most common factor contributing to bacteremia in dialysis patients and the relative risk for bacteremia in patients with dialysis catheters is sevenfold the risk for patients with primary arteriovenous fistulas. In § 494.30(a)(2) we are incorporating by reference the pertinent hemodialysis catheter use sections (pages 13–14, and 17–18) of RR–10, 2002, ''Guidelines for the Prevention of Intravascular Catheter-Related Infections.'' These guidelines describe appropriate health-care worker education and training, surveillance, hand hygiene (I–III, page 16), aseptic technique (IV, page 16), hemodialysis catheter exit site care (section III–V, page 21), and catheter-site dressing regimens (section VI, C, page 22), and are the nursing standard of practice for catheter care. We expect that incorporation of these guidelines will increase staff awareness of the protections needed for hemodialysis patients with catheters and lead to reduced catheter infections.

Comment: Few commenters responded to our solicitation for comment regarding whether we should incorporate by reference the American Institute of Architects (AIA) Guidelines for Design and Construction of Hospitals and Health Care Facilities, which outline building requirements pertinent to dialysis facilities. Comments were split between supporting and rejecting AIA guidelines, and incorporation by reference if adopting the guidelines.

Response: We have not incorporated the AIA building standards in our final rule. However, facilities must comply with all State and local building codes/requirements.

Comment: Several commenters addressed our proposed infection control officer requirement at § 494.30(b)(2). Some supported having an RN assume the role of the infection control officer. Others believed that a staff member other than an RN should assume the role. Some commenters stated this role was not the best use of RN time, and a few cited cost concerns. Several commenters stated that oversight of infection control should be performed by the medical director or that the medical director should be notified of infection control issues at proposed § 494.30(b)(2)(ii) instead of our proposed notification of the chief executive officer or administrator and the quality improvement committee.

Response: We understand that dialysis facilities may face a shortage of RNs and that in many facilities RNs must be used to perform duties that only an RN can perform. While comments supported infection control to protect patient safety, several alternatives to an RN infection control officer were suggested. In response to comments and in order to increase facility flexibility in assigning staff roles, we have removed the infection control officer requirement from § 494.30(b)(2), and added infection control to the quality assessment and performance improvement (QAPI) condition at § 494.110(a)(2)(ix) as a required topic. This change requires that infection control be addressed within the action-oriented, data-driven QAPI program, which is under the direction of the medical director and requires RN and interdisciplinary team participation.

In response to comments we have also modified the proposed requirement at § 494.30(b)(2)(ii) (now § 494.30(b)(3)), to require that clinical staff report infection control issues to the dialysis facility's medical director and the quality improvement committee instead of the chief executive officer or administrator. The medical director has a critical role in addressing infection control issues in the dialysis facility and § 494.150(c)(2)(i) now requires the medical director to ensure that staff adhere to infection control policies and procedures.

Comment: We received a few comments regarding the role of the patient and patient perceptions of infection control practices in dialysis facilities. One patient stated that patients should be fully informed about infection control so they can protect themselves and be aware of staff infection control violations. Another patient's observation was that facility staff has no training regarding infection control and no one seems to worry about its ramifications.

Response: We agree that the dialysis patient has a role in assisting the staff in preventing the spread of infection. It is appropriate for the patient to be educated regarding infection control. We have added ''infection prevention and personal care'' to the Patient Education standard under § 494.90(d) in

the ''Patient plan of care'' condition. The facility should provide information to dialysis patients on topics including current infection control precautions, the facility's infection control practices, and the role of the patient in preventing the spread of infection. As explained above, we have strengthened infection control by making it a condition for coverage and expect that dialysis staff will comply with the hemodialysis infection control precautions developed by the CDC and required by this rule.

Comment: One commenter asked whether State surveyors could enforce local regulations and laws pertaining to disposal of hazardous wastes.

Response: Surveyors make referrals regarding unlawful disposal of hazardous wastes to the appropriate local authorities. If there is a problem, it can be cited by the surveyor under § 494.20, ''Compliance with Federal, State, and local laws and regulations,'' when local authorities confirm infringement.

Comment: It was suggested that the final rule require more surveillance, include septicemia and infection data elements, include an added CPM or standard for infection control, and require mandatory reporting of such data on the DFC Web site.

Response: As stated above, the facility must address infection control within the action-oriented, data-driven QAPI program. Surveillance and use of infection data will be necessary components of QAPI. We will consider the ''reporting'' as appropriate when developing new CPMs and adding new measures to the DFC Web site. We are not requiring new performance measures that have not been fully developed in this regulation.

b. Water and Dialysate Quality (Proposed § 494.40)

We proposed a separate condition for coverage to update the water purity requirements that were incorporated by reference into part 405, subpart U (§ 405.2140(a)(5)) in 1995. AAMI has since rescinded the document from which the sections were incorporated (ANSI/AAMI RD5:1992, Hemodialysis Systems, second edition) and published updated AAMI guidelines in 2001. We proposed to incorporate sections from the new AAMI document, ''Water Treatment Equipment for Hemodialysis Applications'' (ANSI/AAMI RD62:2001), to update the bacterial and chemical concentrations allowed in water used in hemodialysis. The new AAMI guidelines established action levels for contaminants in addition to merely identifying unsafe contaminant levels. At ''action levels,'' the facility must implement corrective actions to prevent contaminants from reaching unsafe levels. We also proposed water treatment equipment requirements and water testing frequency and sample sites that are consistent with the new AAMI document, ''Dialysate for Hemodialysis'' (ANSI/AAMI RD52:2004). We proposed chlorine and chloramine testing frequency, thresholds, and actions for unacceptable high levels to prevent the occurrence of hemolytic anemia in patients. We proposed corrective action plan and adverse event standards to further protect patient safety. We additionally proposed that facilities use bicarbonate dialysate, which has the potential for high levels of bacterial contamination, within the timeframe specified by the manufacturer.

Comment: We received many comments regarding § 494.40 ''Water quality'' condition. The comments were unanimous in supporting incorporation of AAMI water quality guidelines. Several of the comments recommended that the more recent 2004 ANSI/AAMI RD52 ''Dialysate for hemodialysis'' guidelines, written for water treatment system users, be incorporated by reference, rather than the 2001 ANSI/AAMI RD62 ''Water treatment equipment for hemodialysis applications,'' which are addressed primarily to the manufacturers of equipment. A commenter associated with the AAMI Renal Disease and Detoxification Committee stated that the 2001 ANSI/AAMI RD62 guidelines are slated to be revised in the near future.

Response: We agree with the commenters that ANSI/AAMI RD52:2004 ''Dialysate for hemodialysis'' is the more appropriate set of guidelines to incorporate by reference into these conditions for coverage. In fact, the RD52 guidelines addressing water purity monitoring and equipment parameters are similar to the requirements we proposed at § 494.40(a), § 494.40(b), and parts of § 494.40(c). Therefore, we are incorporating the AAMI guidelines (ANSI/AAMI RD 52:2004) by reference at § 494.40(a). These RD52 guidelines are compatible with the RD62 guidelines that we proposed to incorporate by reference, and are the standard of practice in dialysis facilities. We have removed the redundant sections of proposed § 494.40(a) through § 494.40(c) from the regulation, since the ANSI/AAMI RD52:2004 incorporation by reference addresses this issue. We are also renaming this condition ''Water and dialysate quality'' to more closely reflect the requirements of this condition.

Comment: One commenter recommended that we define ''established pattern'' (as related to collecting cultures for new water systems) (proposed § 494.40(a)(2)(i)(B)), as being on a weekly basis until an established pattern can be demonstrated.

Response: We agree. This issue is addressed in ANSI/AAMI RD52 (section 6.1—page 19; table 4), which, as discussed above, we are incorporating by reference. This section states that cultures should be drawn ''weekly until a pattern of consistent compliance with limits can be demonstrated.'' We have removed proposed § 494.40(a)(2)(i)(B).

Comment: One commenter stated that § 494.40(a)(2)(ii)(C) and (D) are redundant since the ''seasonal variations in source water'' specified as a trigger for chemical analysis at (C) will cause the reverse osmosis (RO) rejection rate to fall below 90 percent, the trigger listed at (D). A second commenter stated that RO is monitored by both rejection rate and dissolved solids or resistivity, and all of these types of monitoring should be indicated as acceptable.

Response: RO monitoring is addressed by ANSI/AAMI RD52 section 5.2.7 (page 10) and section 6.1 (pages 18–19), which we are incorporating by reference. As explained above, we have removed the redundant language from § 494.40(a)(2)(ii)(C) and § 494.40(a)(2)(ii)(D). Facilities also must follow the manufacturers' instructions for feed water treatment and monitoring. In the absence of manufacturer's recommendations, the AAMI guidelines require facilities to monitor product water conductivity, total dissolved solids or resistivity, and calculated rejection at a frequency and using thresholds provided by the manufacturer.

Comments: Many commenters made recommendations or requested clarification regarding carbon tank requirements at proposed § 494.40(c)(1). Many commenters supported a two carbon tank requirement, and some opposed it. A few commenters agreed with the 10-minute empty bed contact time, while one commenter said that the ''adequate'' empty bed contact time standard was too subjective. One commenter recommended that we clarify that the second carbon tank is in series with the first, and that we require the first tank to be replaced if test results are above the specified permissible levels. A few commenters pointed out that high chloramine levels may be mitigated with the use of ascorbic acid.

Response: Section 5.2.1 of the ''Dialysate for hemodialysis'' ANSI/

AAMI RD:52 guidelines specify, ''Whether a device is included in a particular water purification system will be dictated by local conditions.'' Since comments overwhelmingly supported two carbon tanks in series due to patient safety concerns and the fact that carbon tanks also remove organic contaminants from water, we will require at least two carbon tanks or equivalent components at § 494.40(b)(1) of our final rule (proposed § 494.40(c)(1)). Section 5.2.5 of ANSI/AAMI RD52 clarifies that two carbon tanks must be placed in series and that the carbon bed must be replaced in the first tank when depleted. We have added the phrase ''in series'' to our carbon tank requirement at § 494.40(b)(1), as suggested by the commenter. This RD52 section also clarifies that empty bed contact time must be at least 5 minutes in each bed. The empty bed contact time is an indicator of how much water contact with the particles in the carbon bed occurs so that there is adequate binding and removal of impurities.

AAMI does refer to use of ascorbic acid to correct chloramine/chlorine levels in RD62 (section A.4.3.9), though only in reference to portable water treatment systems. In RD52 (section 5.2.5 and appendix section A.5.2.5), AAMI also acknowledges the supplementation of carbon adsorption with other methods of chloramine removal.

In response to comments regarding an alternate means of correcting chloramine/chlorine breakthrough that would permit the continuation of hemodialysis, we have added a provision to the final rule at § 494.40(b)(2)(ii)(A) to allow immediate corrective action, and confirm through testing that the corrective action has been effective. We will not limit the means by which chloramines/chlorine levels are brought back into compliance at § 494.40(b)(2)(ii)(A). This regulation allows for use of other proven methods to remove chloramines including ascorbic acid and new technologies that may be developed. When using alternate methods to remove chloramines/chlorine, the facility must perform the required testing to ensure the successful removal of harmful chloramine/chlorine. After measures have been taken to resolve the immediate problem of chloramine/chlorine breakthrough, the facility must implement actions to maintain long-term compliance with acceptable chloramines/chlorine levels. We have added a provision at § 494.40(b)(2)(ii)(D), which requires facility action to ensure ongoing compliance. This provision reads, ''The facility must * * * Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.''

Comment: Many comments addressed our proposed requirement for chlorine/chloramine testing (proposed § 494.40(c)(2)) before each patient shift or every 4 hours, whichever was shorter. The majority of comments favored chlorine/chloramine testing only before every shift and not every 4 hours. One commenter recommended we change the 4 hours to 6 hours and retain the requirement, while another suggested we delete the phrase ''whichever is shorter.'' A few commenters agreed with the testing frequency of every 4 hours.

Response: According to ANSI/AAMI RD52, section 6.2.5 (page 20), testing should be done at the beginning of the day and again before each shift, and if there are no set shifts, then every 4 hours. We refer to this section, which has been incorporated by reference, at § 494.40(b)(2)(i), and we believe it provides sufficient clarification. We have deleted the proposed requirement at § 494.40(c)(2).

Comment: One commenter stated the regulation should include maximum carbon tank limits on usage time, flow, volume, and that testing for iodine should be required.

Response: The AAMI guidelines call for chlorine/chloramine testing every shift to monitor carbon tank performance. We are not aware of any evidence suggesting that these precautions are insufficient. We believe the commenter is suggesting that a minimum iodine number for the carbon should be required. Section 5.2.5 of the AAMI RD52 document states that ''When granular activated carbon is used as the medium, it shall have a minimum iodine number of 900.''

Comment: A few commenters stated that chlorine/chloramine testing requirements should also allow the testing for total chlorine with a limit of 0.10 mg/L.

Response: This suggestion corresponds with ANSI/AAMI RD52 section 6.1; table 4 (page 8) which allows total chlorine levels of less than 0.1 mg/L. This section is now incorporated by reference. We have modified proposed § 494.40(c)(2)(i), now § 494.40(b)(2)(i) to allow total chlorine testing with acceptable levels of less than 0.1 mg/L as an alternative to testing free chlorine and chloramine levels.

Comment: One commenter stated that chlorine/chloramine requirements at proposed § 494.40(c)(2)(ii) do not account for facilities with a holding tank, and we should allow water in the holding tank to be used if testing shows this water contains total chlorine < 0.1 mg/L.

Response: Water in the holding tanks may be used during failure of carbon tanks only if testing indicates the holding tank water meets AAMI chlorine/chloramines standards of < 0.1 mg/L total chlorine OR < 0.50 mg/L free chlorine AND < 0.1 mg/L chloramines and no additional water is allowed to enter the tank. Revised § 494.40(b)(2)(ii)(B) (proposed (c)(2)(ii)) allows use of purified water in the holding tank when it meets the AAMI standards at § 494.40(b)(2)(i).

Comment: One commenter recommended that endotoxin levels be measured in addition to blood and dialysis cultures when there is an adverse event (proposed at § 494.40(e)(1)), since cultures may be negative even with high endotoxin levels.

Response: We agree with the commenter that measurement of dialysate endotoxin levels should be performed along with dialysate cultures when a suspected adverse event occurs. We note that the AAMI guidelines call for dialysate bacterial cultures to be accompanied by endotoxin level testing. The AAMI guidelines state that endotoxin testing, if performed in the dialysis facility, can give results in about 1 hour, eliminating the long delay between sampling and obtaining a result (ANSI/AAMI RD52:2004, section A.1.4). We have added endotoxin testing to the blood and dialysate culture requirement at § 494.40(d)(1) (proposed § 494.40(e)(1).

Comment: Two commenters requested that we clarify the language of proposed § 494.40(e) ''Adverse events'' (now § 494.40(d)), regarding the active surveillance of patient reactions during and following dialysis. One commenter suggested that the word ''following'' be defined to mean ''after post-dialysis assessment with subsequent discharge by nurse or caregiver.''

Response: We appreciate the comment; however, we believe that the suggested definition is too narrow, since not every adverse advent will be limited to the time period the patient is physically in the dialysis unit. ''Following dialysis'' runs from the moment when the treatment session ends through the time the patient leaves the unit and beyond. In addition, when the patient calls and/or when the patient returns for the next dialysis session, if there are symptoms that are correlated with a water purity adverse event, then cultures and endotoxin testing must be performed.

Comment: Many comments reflected concern regarding the proposed requirement at § 494.40(f) that mixed bicarbonate concentrate be used within the timeframe specified by the manufacturer of the concentrate, and the accompanying preamble statement that fresh bicarbonate must not be mixed with other batches of fresh bicarbonate. Several commenters stated that mixing batches of bicarbonate concentrate may be unavoidable due to mixing processes and the use of holding tanks. Two commenters agreed with limiting use of bicarbonate to the time limit given by the manufacturer, while others stated that it was only necessary to use bicarbonate the same day it was mixed. Some commenters stated that bicarbonate is the most vulnerable part of dialysis solutions.

Response: AAMI addresses procedures for bicarbonate concentrate in ANSI/AAMI RD52, section 7.1 (page 24), stating, ''Storage times for bicarbonate concentrate should be minimized, as well as the mixing of fresh bicarbonate concentrate with unused portions of concentrate from a previous batch.'' Section 5.4.4.3 (page 15), also states, ''Once mixed, bicarbonate concentrate should be used within the time period recommended by the manufacturer of the concentrate. The concentrate shall be shown to routinely produce dialysate meeting the recommendations of 4.3.2.1.'' ANSI/AAMI RD52 stipulates the use of bicarbonate concentrate within the time period recommended by the manufacturer and does not expressly prohibit the mixing of bicarbonate concentrate. If the first batch of bicarbonate concentrate has not yet expired, it could be mixed with a second batch, provided the first batch had not expired in accordance with the manufacturer's time limitations before it was used. We have removed the proposed water and dialysate quality standard at § 494.40(f), regarding unused bicarbonate, since we are instead incorporating ANSI/AAMI RD52 by reference.

Comment: We received many comments regarding whether we should include requirements related to ultrapure dialysate. Although two commenters (including a large patient organization) supported ultrapure dialysate requirements, a number of commenters opposed such requirements, citing a lack of evidence that supported the use of ultrapure dialysate. One commenter stated that in light of new findings showing that ultrapure dialysis could be beneficial to hemodialysis patients, ultrapure dialysate should be strongly encouraged. Another commenter, who was a national expert in the area of dialysis water treatment systems, suggested that we require that all new water systems installed after publication of the final rule be capable of delivering ultrapure dialysate. This would allow facilities to provide ultrapure dialysate in the future should an evidentiary basis be solidified. A few comments suggested that if we require ultrapure dialysate, Medicare should provide corresponding reimbursement.

Response: We appreciate the comments; however, we are not requiring dialysis facilities to provide ultrapure dialysate in this final rule. Current information shows promise of ultrapure dialysate, but we believe that sufficient evidence is lacking. We will revisit this issue in the future when more evidence is available, recognizing that dialysis patients are in favor of a lower permissible level of bacterial contamination in the dialysate. If additional evidence supports the use of ultrapure dialysate, we may undertake the necessary rulemaking to incorporate the requirement at a later date. Facilities choosing to provide ultrapure dialysate must meet section 4.3.2.2 of the ANSI/AAMI RD52 guidelines.

Comment: Some commenters suggested that we avoid codifying dates and values in the regulations, as these may change before the regulation changes.

Response: We believe that the avoidance of values and use of general language for Medicare patient safety requirements may create confusion and allow less than full compliance with these conditions for coverage. There are currently clear thresholds and standards for dialysis water purity, which we have included. Where necessary, we will consider updating specific dates and values via future rulemaking, as appropriate.

Comment: Two commenters pointed out that the AAMI guidelines for bacteria and bacterial toxin sample sites were misquoted in the proposed rule preamble bullets (70 FR 6195) as follows:

- Outlet of the water storage tanks if used
- Concentrate or from the bicarbonate concentrate mixing tank.

Response: The commenters are correct. The bullets above do not accurately reflect the guidelines. However, the language will not appear in this final rule since the issue is covered in ANSI/AAMI RD52; section 7.2.1 (page 25), incorporated by reference at § 494.40(a) in this final rule, which addresses collection sites for water/dialysate samples.

Comment: One commenter stated that the final rule should require a water quality technician who would be independent from the primary caregivers.

Response: Provisions regarding the water treatment system technicians are found at § 494.140(f); water treatment system technicians must complete a training program that has been approved by the medical director and governing body. Section 9 of AAMI RD52 calls for a training program that includes ''quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues.'' Section 9 also states, ''Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer. The training should be specific to the functions performed (that is, mixing, disinfection, maintenance, and repairs). Periodic audits of the operators' compliance with procedures should be performed. The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.'' The dialysis facility has flexibility with staff assignments and the water quality technician may or may not be independent of the primary caregivers. As noted, we are incorporating these provisions by reference.

Comment: One commenter objected to the RO/deionization component requirement at § 494.40(b), which it believed could preclude use of new/improved technologies.

Response: We have removed this language from § 494.40(b). At § 494.40(a), we have incorporated by reference ANSI/AAMI RD52, which states in section 5, ''Equipment'' (page 8):

> Since feed water quality and product water requirements may vary from facility to facility, not all of the components described in the following clauses will be necessary in every purification and distribution system. Components must be included, which would allow product water and dialysate to meet the AAMI standards specified at 4.1.2, 4.2.1, and 4.3.2.1.

Comment: One commenter objected to the requirement to assay cultures within 24 hours since this may not be realistic on weekends. The commenter suggested allowing a 48-hour time period for cultures.

Response: The proposed rule did not prescribe culture assay timelines. However, the ANSI/AAMI RD52 guidelines at section 7.2.3 state that samples that cannot be cultured within 1–2 hours can be refrigerated for up to 24 hours. Samples that are held longer than 24 hours do not accurately measure

the degree of contamination against the established AAMI standards. We have incorporated ANSI/AAMI RD52 standards into this final rule by reference at § 494.40(a).

Comment: One comment stated that facilities should be able to substitute a reuse water sample from the site where the dialyzer connects to the reuse system for a sample taken from the entrance to the reprocessing equipment (described at 70 FR 6195).

Response: AAMI specifies collection of water samples from the outlets supplying the reuse equipment (ANSI/AAMI RD52 section 6.3.3, page 22). We will adhere to this AAMI guideline. We have incorporated ANSI/AAMI RD52 by reference at § 494.40(a) in this final rule.

Comment: One commenter suggested the requirement for a water sample at the outlet of the water storage tank be deleted, since this is only necessary initially and when trouble-shooting.

Response: The commenter refers to proposed rule preamble language (70 FR 6195) describing RD52 sample sites and is correct in observing that samples are taken from the outlet of the water storage only initially and when troubleshooting. This matter is addressed in section 7.2.1 of AAMI RD52, which we are incorporating into this final rule by reference.

Comment: One commenter stated that when referring to water samples from the distribution ''loop'' we should change our wording, as a ''loop'' has no ''beginning'' or ''end''.

Response: We refer the commenter to AAMI RD52 section 6.3.3 (page 22), which states that samples should be taken from the first and last outlets of the water distribution loop and the outlets supplying the reuse equipment and bicarbonate mixing tanks. We have incorporated ANSI/AAMI RD52 by reference at § 494.40(a) into this final rule. We believe that the AAMI language is generally understood.

Comment: We received comments regarding the quality of home hemodialysis water, recommending that there be separate water purity standards for home dialysis systems due to the availability of new technology and the cost burden associated with the proposed water quality requirements.

Response: We acknowledge that the AAMI RD52 water and dialysate purity guidelines were not intended by AAMI for home dialysis or portable systems. However, in the absence of water purity guidelines for home hemodialysis, we believe that the AAMI RD52 water and dialysate purity guidelines offer the best protection for use in preconfigured systems.

Therefore, the dialysis facility must monitor the quality of water and dialysate used by home hemodialysis patients, and conduct an onsite evaluation and testing of the water and dialysate system. The water and dialysate monitoring must be in accordance with the system's manufacturer instructions at § 494.100(c)(1)(v)(A), and the system's FDA approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004 for water and dialysate. In addition, bacteriological and endotoxin testing must be performed at least quarterly, or on a more frequent basis, as needed, to ensure that the water and dialysate are within AAMI standards at § 494.100(c)(1)(v)(B).

In cases where these new preconfigured hemodialysis machines are used in a dialysis facility, the home dialysis requirements do not apply. Therefore, we have added the following language at § 494.40(e) to address in-center use of these machines: ''When using a preconfigured, FDA-approved hemodialysis system designed, tested, and validated to yield AAMI-quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet AAMI RD52:2004 requirements for water and dialysate. However, the facility must perform bacteriological and endotoxin testing on a quarterly or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.''

Comment: One commenter recommended that we require facilities to use only certified labs for analysis of bacteria growth and limulus amoebocyte lysate (LAL) testing.

Response: We are aware that many facilities do their own water and dialysate cultures and endotoxin testing on-site. The AAMI RD52 guidelines address the monitoring of water and dialysate systems for bacteria and endotoxin levels. Section 7.2.3 states that ''Dip samplers may be used for bacterial surveillance. However, they should be used only in conjunction with a quality assurance program designed to ensure their appropriate use.'' Section 7.2.4 addresses in-house testing for endotoxin levels. We have not modified the requirements as the RD52 document provides guidance regarding cultures and endotoxin testing.

c. Reuse of Hemodialyzers and Bloodlines (Proposed § 494.50)

We proposed to update our condition for coverage at § 405.2150, ''Reuse of hemodialyzers and other dialysis supplies'', by replacing it with a new condition for coverage at § 494.50. The ANSI/AAMI ''Reuse of Hemodialyzers'' guidelines (ANSI/AAMI RD47: 1993, second edition), incorporated by reference in 1995, were revised in 2002 and amended in 2003. We proposed incorporation by reference of the third edition of ''Reuse of Hemodialyzers'' (ANSI/AAMI RD47: 2002/A1: 2003). We proposed that only hemodialyzers and bloodlines labeled for reuse could be reprocessed and that reprocessing would have to meet the AAMI guidelines and adhere to the manufacturer's recommendations, unless an alternate method, documented to be safe and effective, was employed. The prohibition on reuse of hemodialyzers for hepatitis B patients was retained in the proposed rule, to protect staff from exposure to the hepatitis B virus. The requirement that the facility use only one germicide for each reprocessed hemodialyzer was retained in the proposed rule, to ensure integrity of the dialyzer membrane; we added a clarification that bleach would not be considered a germicide in this context. We proposed monitoring, evaluation, and reporting requirements to ensure surveillance for adverse patient reactions to reuse, and proposed that the facility suspend reuse when a problem was suspected or discovered. We also proposed that when required by law, adverse outcomes would have to be reported to the FDA and other Federal, State, or local government agencies.

We received more than two dozen comments on the Reuse condition. The comments support inclusion of the updated 2002/2003 AAMI ''Reuse of hemodialyzers'' guidelines.

Comment: Several commenters addressed the first provision of this condition, which states, ''The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.'' Some of the commenters suggested deletion of this statement, while others suggested stronger penalties. One commenter stated this statement merely repeated proposed § 488.604, while another suggested the penalty was too drastic.

Response: The language regarding penalties for failure to meet the reuse

requirements is consistent with section 1881(f)(7) of the Act, which directly addresses dialyzer filter reuse. However, denial of payment for discrete instances of reuse non-compliance, authorized by section 1881(f)(7)(C) of the Act, has not been implemented, due to administrative difficulties associated with identifying which particular treatments would be associated with any specific denial of payment when there is a reuse problem. Currently, when a compliance problem is identified, the surveyor cites the facility and the facility must develop and implement a corrective action plan. If the facility does not make the necessary corrections then the facility is put on a termination track. This process has been effective in protecting patient health and safety when hemodialyzers are reused and will continue under this final rule. Therefore, we have removed the undesignated paragraph ''Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program'' from § 494.50.

We believe dialysis facility termination for reuse deficiencies and non-compliance fulfills the statutory requirement at section 1881(f)(7)(C) of the Act, that CMS deny payment for hemodialyzer reuse non-compliance. Under the current process, when a reuse problem is confirmed by a surveyor, we require immediate corrective action, which protects patient safety. If the reuse problem presented immediate jeopardy to patient safety, we would shut down the reuse program immediately until the facility could demonstrate that the problem had been corrected. CMS also has the authority to withhold payment from a facility when it has determined that there have been specific violations of this provision. If the facility were to continue to compromise patient safety, we would put the facility on a termination track. We believe that termination procedures provide more incentive to return to compliance than the denial of payment alternative sanction.

Comment: One commenter asked how the proposed rule ensures patient consent for dialyzer reuse.

Response: Our requirement for patient consent for dialysis reuse is located at § 494.70(a)(9), which states the patient has the right to be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers. Patients may want to discuss this aspect of their medical treatment with their physician.

Comment: An organization representing kidney disease patients expressed concern regarding the large number of times a hemodialyzer is reused (up to 30 times), and requested that CMS convene a technical expert panel to examine all facets of reuse and make recommendations to improve current practice.

Response: We have added incorporation by reference the AAMI reuse guidelines, ANSI/AAMI RD47:2002 & RD47:2002/A1:2003 ''Reuse of hemodialyzers'' to this final rule at § 494.50(b)(1). The AAMI guidelines, which represent the consensus of technical experts, include dialyzer performance measurements (that is, total cell volume) that must be met in order for a dialyzer to be reused. Currently these parameters do not include a maximum number of allowable reuses. We may consider updates to this final rule through separate rulemaking when AAMI updates its reuse guidelines.

Comment: A few commenters disagreed with some of the AAMI hemodialyzer reuse guidelines. One commenter recommended that we require immediate disinfection of dialyzers and not allow the refrigeration of dialyzers; another commenter suggested that we ban the reuse of bloodlines, since AAMI is withdrawing the bloodline reuse guidelines. A third commenter recommended that dialyzer heat disinfection be prohibited.

Response: We defer to the AAMI guidelines on each of these reuse issues. Section 11 of the AAMI reuse guidelines, ANSI/AAMI RD47:2002 & RD47:2002/A1:2003 ''Reuse of hemodialyzers,'' incorporated into this final rule by reference, describes the approved processes for cleaning and disinfecting dialyzers, including heat disinfection. The guidelines also permit refrigeration of hemodialyzers that cannot be reprocessed within 2 hours, in order to inhibit bacterial growth. The AAMI guidelines allow disinfection procedures that have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with the relevant types of microorganisms. The guidelines also state that the disinfection process shall not adversely affect the integrity of the dialyzer. To date, AAMI has not rescinded the bloodline reuse guidelines and this final rule requires facilities that reuse bloodlines to follow them.

Comment: Two commenters recommended a further clarification of the requirement we proposed at § 494.50(b)(3), which stated that facilities will ''Not expose hemodialyzers to more than one chemical germicide, other than bleach, during the life of the dialyzer.'' One suggestion was to insert a clarifying parenthetical phrase so that this requirement would read, ''Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer.'' This commenter suggested that without adding this phrase the statement would be misleading, as it implied that bleach could be used as a disinfectant, which could damage the dialyzer if used long-term in such a manner.

Response: We agree with the commenter. We have revised § 494.50(b)(3) to clarify that bleach is considered a ''cleaner'' and not a disinfectant in this context.

Comment: We received a few comments regarding § 494.50(c), ''Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.'' Some commenters recommended clarifying the phrase ''cluster of adverse patient reactions'' and two commenters supported a requirement that a blood test be done whenever a febrile reaction occurs, not just when there is a cluster. Another commenter cited a 1987 study published in the Journal of the American Medical Association that established a direct relationship between endotoxin levels and febrile reactions caused by poor reuse reprocessing techniques and recommended that endotoxins be measured in addition to blood and dialysis cultures since cultures may be negative with high endotoxin levels.

Response: ''A cluster of adverse patient reactions'' means a set of undesirable events affecting the health of dialysis patients that could be clinically related to dialyzer reuse practices. In such cases, the physician responsible for the hemodialyzer reprocessing program must act in accordance with the AAMI guidelines found at ANSI/AAMI RD47:2002 & RD47:2002/A1:2003. If a single patient has a suspected adverse reaction, the physician should evaluate the incident and order testing as appropriate in his or her clinical judgment.

The requirements of section 494.50(c) (regarding obtaining blood and dialysate cultures and evaluation of dialyzer reprocessing and water purification systems) would apply if a group of patients (that is, a cluster) was suspected of having adverse reuse reactions. We agree with the commenter that facility personnel should perform dialysate endotoxin level tests along with dialysate cultures when a

suspected adverse event occurs; this is consistent with our requirement in the ''Adverse events'' standard in the ''Water and dialysate quality'' condition at § 494.40. Therefore we have added endotoxin testing requirements at § 494.40(d)(1) and § 494.50(c)(2)(i).

A dialysis facility that uses outside hemodialyzer reprocessing services is responsible for fully protecting patient health and safety and ensuring compliance with these conditions for coverage and AAMI reuse guidelines as well as carrying out appropriate testing and evaluation of reuse processing and water purification systems when a cluster of adverse events occurs.

d. Physical Environment (Proposed § 494.60)

We proposed to update the § 405.2140 ''Physical environment'' requirements, which address facility building safety, equipment maintenance, the patient care environment, emergency preparedness, and fire safety, at new § 494.60. The proposed rule was consistent with part 405, subpart U provisions in requiring that a facility be constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable environment. The proposed rule further addressed patient comfort by requiring that the facility temperature be comfortable for the majority of its patients or that reasonable accommodations be offered. We proposed that the dialysis facility implement processes and procedures to manage medical and nonmedical emergencies (including fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters) that are likely to threaten the health or safety of the patients, the staff, or the public. The proposed rule would require emergency preparedness training for staff and patients, and would specify the emergency equipment that would have to be available in the dialysis facility (including oxygen, airways, suction, defibrillator, artificial resuscitator, and emergency drugs). The proposed fire safety requirements called for facility compliance with applicable provisions of the 2000 edition of the LSC of the National Fire Protection Association. The LSC waiver provisions were included in the proposed rule for those instances when, in the view of CMS, LSC compliance would result in unreasonable hardship and patient health and safety would not be adversely affected; or when a State had fire and safety codes that adequately protected dialysis patients. For a detailed discussion of our proposed physical environment provisions at § 494.60, see the February 4, 2005 proposed rule (70 FR at 6197).

Comment: Under the ''Equipment maintenance'' standard at § 494.60(b), one commenter suggested that equipment be maintained according to a regular maintenance schedule rather than the manufacturer's recommendations. The commenter was concerned that the manufacturer might overstate the amount of maintenance required.

Response: Our intent was to ensure that all dialysis facility equipment was adequately maintained and working properly. We proposed that ''The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) is maintained and operated in accordance with the manufacturer's recommendations.'' It is expected that routine maintenance be performed so that the risk of equipment malfunction is small. The facility will need to use the manufacturer's recommendations as a reference and guide. We have retained § 494.60(b) as proposed.

Comment: While the majority of commenters support our proposed requirement at § 494.60(c)(2) (that the facility maintain a room temperature that would be comfortable for patients, and make reasonable accommodations for the patients who might not be comfortable at the temperature that is comfortable for the majority), several commenters disagreed with this requirement. Some thought the proposal was too prescriptive, ignored the needs of staff (who are required to wear protective clothing), and allowed patients to dictate staff working conditions. Commenters noted that facilities already strive to keep patients comfortable, and stated that patients should be educated as to why body temperature drops during dialysis.

Response: Room temperature is a source of frequent tension in a hemodialysis facility. Generally, the sedentary patients undergoing treatment prefer a warmer room temperature, while staff who are engaged in activity and wearing protective coverings prefer a cooler room temperature. The proposed requirement would have tilted the room temperature in favor of the patients without consideration of the needs of the staff. In response to comments, we have modified the requirement to acknowledge the room temperature needs of staff. The intent of the new requirement is to have facilities arrive at a middle ground so that the room temperature is at least marginally acceptable to both patients and staff. Patients who continue to feel cold could use coverings or blankets. Regardless of the room temperature, patients should not be deprived of the ability to use covers or blankets. The dialysis facility may allow patients to bring their own blanket or may opt to provide a cover. In either case, adequate infection control precautions must be taken considering the risk of blood spatter. Additionally, the access sites and line connections should remain uncovered to allow staff to visually monitor these areas to ensure patient safety. In response to comments, we have revised § 494.60(c)(2)(i) by removing the phrase ''that is comfortable for the majority of its patients'' and inserted the word ''comfortable'' earlier in the sentence. Section § 494.60(c)(2)(i) and § 494.60(c)(2)(ii) now requires a facility to maintain a comfortable temperature within the facility; and make reasonable accommodations for the patients who are not comfortable at this temperature.

Comment: Many commenters recommended that we add privacy requirements to allow facility staff to conduct confidential interviews with patients, and to ensure that facilities utilized physical barriers whenever body exposure necessitated usual privacy. Commenters who supported a confidential area for patient interviews cited the April 14, 2003 Health Insurance Portability and Accountability Act (HIPAA) fact sheet (*http://www.hhs.gov/news/facts/privacy.html*) which outlines patient information privacy protections, including the patient's right to request confidential communications.

Response: HIPAA requirements protecting patient privacy apply to dialysis facilities. Two provisions of the proposed rule would support the patient's right to privacy. Proposed paragraph § 494.70(a)(3) stated that the patient would have the right to privacy and confidentiality in all aspects of treatment. Likewise, proposed § 494.70(a)(4), stated that the patient would have the right to privacy and confidentiality in personal medical records. Our preamble discussion of this requirement in the proposed rule (70 FR 6201) clearly stated our belief that any staff discussion with dialysis patients regarding treatment, the patient care plan, and medical conditions should be held in private and kept confidential, using reasonable precautions. We also pointed out that in situations when there was patient body exposure, the staff would be instructed to provide temporary screens, curtains, or blankets to protect patient privacy. To respond to these comments and to further

strengthen the patient's right to physical privacy, we have added a new provision at § 494.60(c)(3), stating that ''The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.'' This provision also protects those patients who do not wish to intrude on another patient's privacy.

Comment: Several commenters objected to the deletion of the centralized nursing monitoring station requirement in the proposed rule, formerly at § 405.2140(b)(3), as they believe a monitoring station is needed to support adequate surveillance of patients receiving dialysis. One commenter suggested that patient call buttons be required. Another commenter suggested retaining the concept of the nursing station requirement by adding the language, ''Patients should be in view of staff at all times during treatment to ensure patient safety.''

Response: We had proposed deleting the centralized nursing station requirement in order to increase facility flexibility in designing the clinical area. Patients undergoing hemodialysis require surveillance and continuous monitoring. Without vigilant monitoring it is possible for a dialysis needle to become dislodged, which could result in patient death from blood loss in just minutes. The suggested call button would place responsibility on the patient to alert staff to a problem; however, we expect continual monitoring of the patient, which would make a call button unwarranted. We are not restoring the requirement for a ''nursing station'' to allow maximum facility flexibility, but will require staff surveillance of in-center hemodialysis patients during treatment. Therefore, we have added a new provision at § 494.60(c)(4), ''Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).''

Comment: We received several comments regarding ''Emergency preparedness'' at § 494.60(d). Two commenters objected to having specific types of emergencies ''spelled out'' in regulation while another commenter recommended that bioterrorism be added to the list of emergencies for which facilities would be required to be prepared.

Response: In the proposed rule, the list of emergencies at § 494.60(d) for which dialysis facilities must be prepared ''include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.'' This list clarifies for facilities what types of emergencies must be addressed in the emergency plans. Facilities may prepare for many types of emergencies, including bioterrorism, which are identified as a risk after the performance of a facility risk assessment. We are retaining the proposed list of emergencies in this final rule.

Comment: Some commenters concurred with the standard as proposed. Two commenters advocated for a back-up generator requirement. Others requested clarification of proposed requirement for periodic training of staff and patients.

Response: The proposed emergency preparedness standard was designed to allow dialysis facilities maximum flexibility in meeting our requirements, which could include a back-up generator or other means of supplying needed power to the facility.

As for training, our final staff training requirements (§ 494.60(d)(1)) state that the dialysis facility must ''provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually * * *.'' The regulation goes on to specify what topics must be included in the training and the patients' instruction. The frequency of this training must be sufficient so that staff and patients are able to implement emergency procedures at any time. We are adopting § 494.60(d) introductory text and § 494.60(d)(1) introductory text as proposed. We believe this addresses the commenter's concern.

Comment: After the tragic hurricane events of 2005 (Hurricanes Katrina, Rita, and Wilma) we received some additional comments and recommendations from the national ESRD disaster response workgroup related to natural disaster preparedness, as these experiences led to new ''lessons learned.'' One recommendation was to add a requirement that would enable patients to contact their dialysis facility during a disaster, such as requiring each facility to provide an emergency toll-free phone number where patients could obtain critical medical information. A second recommendation was to include evacuation procedures in the disaster plan. A third recommendation was to require not only a plan, but also to require facilities to have a procedure in place to obtain back-up utilities, including agreements with utility companies for water and energy. A fourth suggestion was to require dialysis facilities to contact local disaster management officials at least annually, to ensure that local disaster aid agencies were aware of the dialysis facility's patients' needs in the event of an emergency.

Response: The final emergency preparedness standard includes requirements for the emergency preparedness of staff and patients and addresses instructions that are provided to dialysis patients. We have revised § 494.60(d)(1)(i)(B) to require that staff inform patients of where to go during an emergency, including evacuation instructions for emergencies in which geographic area of the dialysis facility must be evacuated.

We believe it is reasonable for dialysis facilities to provide an alternate phone number if the phone is not being answered, and/or the facility is not functioning during a disaster. We have added this requirement at § 494.60 (d)(1)(i)(C). This additional requirement reads, ''This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions) * * *.''

A disaster plan must include procedures and processes for use in the event of power or water source loss, or a disaster that would make the dialysis facility inoperable. We believe that it is reasonable for a dialysis facility to establish at least annual contact with its local disaster management agency to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency. This pre-emptive contact could facilitate the meeting of dialysis patient needs during a disaster. We have added a new provision, codified at § 494.60(d)(4)(iii), requiring the dialysis facility to, ''Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.''

We did not modify the final rule in response to the disaster response workgroup's recommendation that we require facilities to have a procedure in place to obtain back-up utilities, including agreements with utility companies for water and energy. This final rules requires that dialysis facilities develop an emergency plan that addresses emergency situations that may occur. These emergencies include power failure and water supply problems. The dialysis facility has flexibility in designing an emergency plan for these types of emergencies. The plan may include agreements with utility companies or alternative

interventions. We will not prescribe the methods that must be employed in responding to the various types of emergencies. The emergency plan must provide sufficient guidance to staff in preparing for emergencies and carrying out the plan.

Comment: A few comments were specific to proposed § 494.60(d)(1)(iii), requiring the facility to ensure that nursing staff are properly trained in the use of emergency equipment and emergency drugs. Two commenters objected to such nurse training, because it ''placed an emergency room-type burden on them.'' Other commenters suggested that the relevant emergency drugs be specified, and that suction devices be specifically excluded from the definition of ''emergency equipment.''

Response: We believe it is reasonable for dialysis facility nurses to be trained and prepared to handle emergencies that are likely to occur within the dialysis facility, and to require the facility to have equipment available for treating these emergencies. Suction machines are necessary medical devices used to clear a patient's airway of secretions or vomit. In the absence of these medical devices, it is possible that the patient's airway could not be cleared. Therefore, we are not deleting this requirement. The specific emergency drugs that are to be available should be determined by the medical director and described in the facility's policies and procedures. We are making no changes based on these comments.

Comment: We received many comments regarding the proposed defibrillator requirement at § 494.60(d)(3). The vast majority of commenters support inclusion of a defibrillator requirement, but recommended that an automated external defibrillator (AED) be an acceptable option. Commenters stated that AEDs were preferable because they are easy to use, more affordable, and do not require the extensive Advanced Cardiac Life Support (ACLS) training and certification that a non-automated defibrillator would require. Commenters did not support a defibrillator exception for small rural dialysis facilities, stating that these more remote facilities do not have nearby emergency medical services (EMS) and have a greater need for an in-house AED. A few commenters objected to the defibrillator requirement because they saw this as an unfunded mandate. One commenter said defibrillators should only be required if Medicare funds them, while another dissenting commenter said the need for a defibrillator should be based on the facility's proximity to EMS. The American Heart Association (AHA) commented on this issue and strongly supported a defibrillator requirement and AEDs in dialysis units, and suggested that AED training be combined with cardiopulmonary resuscitation training. The AHA pointed out that defibrillators have been shown to save lives in a variety of settings including office buildings, airplanes, and stadiums, where survival rates without AEDs are otherwise 1 percent. The AHA also noted that cardiac disease accounts for 43 percent of deaths in ESRD patients (United States Renal Data System 2003 Annual Data Report). The AHA recommended no exemptions for small, rural units but suggested a 1-year phase-in period for these types of dialysis facilities.

Response: We received substantial support from commenters for requiring a defibrillator, specifically an AED. In response to comments, we will require a defibrillator or an automated external defibrillator in our ''Emergency equipment'' standard at § 494.60(d)(3). However, we are not allowing a ''1-year phase-in period'' for small, rural units as suggested by one commenter. This is because we believe that a small, rural unit is likely to be further from emergency services and/or ambulance services, and as such, we believe that having a defibrillator or AED on hand would greatly increase the chance of survival for a dialysis patient in the event of a cardiac arrest. We believe that facilities will have sufficient time to purchase a defibrillator or AED and to train staff, since this regulation is effective 180 days after publication in the **Federal Register**.

Comment: We received many comments on proposed § 494.60(e) ''Fire safety.'' Several commenters concurred with the standard as proposed. We received many comments objecting to the proposed LSC provisions that require sprinklers and central monitoring systems in dialysis facilities. The commenters felt that LSC provisions should apply only to new facilities that are built after the effective date of the final rule. Several commenters felt that requiring the installation of sprinkler and a central monitoring system would be costly and burdensome. Some stated this could impose excessive burdens on leased dialysis facilities, building landlords, multi-story buildings and multi-tenant buildings, where sprinkler systems would need to be installed in a general retrofit for the entire structure. Commenters stated that since existing dialysis facilities occupied buildings that met the building codes in effect at the time of construction, they should be grandfathered for the 2000 LSC requirements, as long as State codes were met.

Response: The proposed LSC requirements provide significantly greater protection to dialysis patients than the fire protection provisions of part 405, subpart U at § 405.2140(a) and § 405.2140(c). Commenters objected most strongly to the LSC requirement for a sprinkler system in certain existing buildings. The 2000 LSC only requires buildings with certain structural configurations to have sprinkler systems. Specifically, 2000 LSC requires that only Type II (000) and ordinary constructed Type III (200) buildings, and Type V (000) buildings of two or more stories must be protected throughout by an approved, supervised automatic sprinkler system (2000 LSC section 21.1.6.3). We acknowledged in the proposed rule preamble that for some existing dialysis facilities it could be overly burdensome to comply with certain LSC requirements, and provided the sprinkler requirement as an example (70 FR 6200). We indicated that this could be a situation where a waiver might be warranted. However, the January 10, 2003 final rule, ''Fire Safety Requirements for Certain Health Care Facilities,'' allowed the grandfathering of existing facilities for the sprinkler systems requirement (as long as the facility was not undergoing renovations), without the imposition of a waiver process (68 FR 1375). Likewise, we will only apply the sprinkler provisions called for in the 2000 LSC to new dialysis facilities and existing facilities that are undergoing extensive renovations. Therefore, in new § 494.60(e)(2), we are exempting dialysis facilities in operation on the effective date of this rule and utilizing facilities built before January 1, 2008 from installing sprinkler systems if State law so permits. However, no dialysis facility may open and/or move to a location without a sprinkler system after the effective date of this rule. All other 2000 LSC provisions found in chapters 20 and 21 (New and Existing Ambulatory Health Care Occupancies) will be applied to dialysis facilities, including the provisions regarding automatic notification-equipped fire detection and alarm systems. However, in recognition of the possible extra expense and time required to review current building leases and fire codes, and if necessary, to make changes in the building structure, we are allowing dialysis facilities 300 days after the publication of this final rule in the **Federal Register** to comply with the requirements found at § 494.60(e)(1).

The stipulation at § 494.60(e)(4) regarding the waiver process for other provisions of the LSC has been retained in this final rule. A dialysis facility may apply for a waiver after receiving a notice of deficiency resulting from a survey by the State agency. The State agency will review the request and may seek guidance from the State fire marshal to make recommendations to the appropriate CMS Regional office. Our regional office will review the request and all associated documentation and make a final decision on the waiver.

Comment: Several commenters asked why ESRD facilities would have to meet State and local fire codes along with Federal fire safety standards. Many commenters requested waivers or extensions of the implementation date and stated that if presented with an option, they would prefer to follow State and local fire codes in lieu of the Federal standards.

Response: This final rule provides for a statewide waiver of any provision of the LSC (see § 494.60(e)(3) through § 494.60(e)(4)) that would not adversely affect patient health and safety, if endorsed by State survey authorities and approved by CMS. Any statewide waiver granted would apply to both new and existing facilities in the state. Individual waivers can be requested by both new and existing facilities. In States receiving a CMS-approved LSC waiver, dialysis facilities will only need to meet State fire safety provisions. Additionally, we have removed our proposed language at § 494.60(e)(2), which proposed that Chapter 5 of the 2000 edition of the LSC would not apply to a dialysis facility. Use of Chapter 5 of the LSC allows a dialysis facility a performance-based option for meeting the LSC occupant protection, structural integrity, and systems effectiveness goals and objectives. This change allows the design of a LSC-compliant dialysis facility building using a performance-based template that employs a computer-based methodology. This requirement is consistent with our LSC provisions for other provider-types and increases flexibility for dialysis facilities.

Comment: One commenter suggested that an emergency evacuation chair should be required for dialysis facilities in multi-level buildings.

Response: We appreciate the comment; however, we do not agree that an emergency evacuation chair should be required. We believe that LSC protections at § 494.60(e)(1) will provide an adequate level of safety. Dialysis facilities should develop a disaster preparedness plan as required at § 494.60(d) that includes evacuation procedures. Facilities may choose to have an emergency evacuation chair if necessary.

Comment: Many commenters objected to removing patients from dialysis equipment and evacuating them in order to comply with the fire drill requirement. It was felt that this exercise was unreasonable and medically unsafe. Many commenters preferred annual fire drills instead of quarterly fire drills.

Response: We agree with the commenters regarding removal of patients during fire drills. As we indicated in the preamble of the proposed ESRD conditions for coverage (70 FR 6200), we are not going to require that patients be physically removed during a fire drill. Fire drills may be conducted using simulated patients or empty wheelchairs. According to the LSC 2000, quarterly fire drills are not required. Instead, section 4.7.2 of the LSC—Drill Frequency states, ''Emergency egress and relocation drills, where required by chapters 11 through 42 or the authority having jurisdiction, shall be held with sufficient frequency to familiarize occupants with the drill procedure and to establish conduct of the drill as a matter of routine.''

3. Subpart C—Patient Care

a. Patients' Rights (Proposed § 494.70)

We proposed to update the existing condition for coverage at § 405.2138, ''Patients' rights,'' by replacing it with a new condition for coverage at § 494.70. We proposed that patients or their designated representatives be informed of their rights and responsibilities when beginning treatment in the facility. The essence of the provisions in existing § 405.2138 was retained in the new condition for coverage under § 494.70(a), ''Patients' rights.'' In addition to these provisions, new § 494.70(a)(6) states that patients must be informed about their right to have advance directives. Patients must also be informed of all modality choices, including home hemodialysis. The provision that patients must be informed of facility policies regarding patient care, including, but not limited to, isolation of patients, was proposed at § 494.70(a)(7). We also proposed changes to the existing grievance mechanism requirements at § 405.2138(e). The proposed rule would require facilities to inform patients of internal and external grievance processes, including how to contact the ESRD Network and State survey agency.

Standard (a) also proposed that patients be informed that they could file grievances personally, anonymously, or through a representative, and could do so without reprisal or denial of services. We also proposed a new standard at 494.70(b) to guarantee the patient's right to be informed regarding the facility's discharge, transfer, and discontinuation of services policies. This proposed standard also would have required facilities to provide a written notice to patients 30 days in advance of the facility terminating care, but would provide that in the case of immediate threats to the health and safety of others, an abbreviated discharge procedure could be allowed. We also proposed to require the facility to prominently display a copy of the patients' rights in the facility where patients could easily see and read it. We proposed that this posted information also include up-to-date State agency and ESRD Network telephone complaint numbers.

The Children's Health Act amended the Public Health Service Act by (among other things) adding a new section 591 (Pub. L. 106–310, section 3207; 42 U.S.C. 290ii); this section requires health care facilities to protect and promote the rights of residents to be free from restraint and seclusion imposed for purposes of discipline or convenience. The law applies to any ''public or private general hospital, nursing facility, intermediate care facility, or any other health care facility that receive support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency * * *.'' Section 591(d)(1) of the Public Health Service Act defines restraint as any mechanical or personal restriction that immobilizes or reduces the ability of an individual to move freely or a drug or medication that is used as a restraint to control behavior or restrict freedom of movement. Seclusion is defined as any behavior control technique involving locked isolation, not including a time out.

While we believe that section 591 of the Public Health Service Act applies to Medicare-participating dialysis facilities, this final rule does not address these specific restraint and seclusion provisions because these issues are being considered under a separate rulemaking. Therefore, the patient rights section does not contain any restraint or seclusion requirements at this time.

Comment: We received many public comments regarding the rights of patients. There was overall support for the condition as a whole, as well as many recommendations and suggestions.

Some commenters recommended that we mandate that facilities inform

patients of their rights at the start of care or within 30 days after the start of care. Others suggested that these rights be reviewed with the patient at least annually, or more frequently depending on patient need. One commenter suggested patient rights be reviewed during the first dialysis treatment and reviewed in detail by a social worker within the first month, while another suggested that a summary of patient rights would be sufficient. A number of commenters suggested the addition of language to mandate that facilities inform patients of facility policies, including discharge policies.

Response: Patients are entitled to be informed of their rights at the start of care, meaning within the first 3 treatments in the facility, which, we believe, will allow patients to exercise their rights and make choices regarding their care immediately. We are not prescribing the level of detail for a patient's rights review, nor which facility staff members must perform the review. The facility has flexibility in meeting the intent of this provision, so long as the facility sufficiently informs the patient so that he or she may exercise his or her rights early in dialysis care. The professionals at the dialysis facility should determine the most appropriate time for a more detailed review of patient's rights (including discharge policy information) according to individual patient's needs. Patients must also be informed of dialysis facility discharge policies as required at § 494.70(b)(1), and we expect all information would be provided at one time. We believe requiring a facility to provide patient's rights information within 3 treatments is reasonable, given that dialysis is normally performed 3 times per week for approximately 3 to 4 hours per session.

Comment: We received several comments regarding possible misinterpretations by State surveyors as to what is meant by patients being ''informed'' of facility policies.

Response: The word ''inform'' simply means to communicate knowledge. We have not dictated the mode of communication. Patient rights information may be presented to patients in writing, orally, in audiovisual form, etc. Since the means by which information is communicated to the patient is not specified, facilities and their staff have the necessary flexibility to comply within the intent of the condition. Our interpretive guidelines for surveyors will reflect the intent of the final rule.

Comment: We received several comments regarding discrimination and harassment. Some commenters specifically recommended that we add language that states patients have the right to be free from verbal, physical, sexual abuse, intimidation, and harassment.

Response: The ''Patients' rights'' condition specifies the patient's right to dignity and respect. Moreover, section 494.20 states that facilities and staff must comply with applicable Federal, State, and local laws, and these laws and protections apply to dialysis patients. Illegal acts must not be tolerated in dialysis facilities and should trigger notification of appropriate law enforcement officials. We have not expanded ''Patients' rights'' as suggested by the commenters; we believe sufficient safeguards, laws, and regulations are already in place.

Comment: Two commenters suggested additional language for the protection of patients' rights and dignity. The commenters explained that some patients are disconnected from a dialysis machine only after being made to sign a ''Leaving Against Medical Advice'' waiver of liability, for such activities as using the restroom, taking pain medications, or eating or drinking. The commenters suggested that the ''Patients' rights'' condition include protection for these patients whose rights and dignity are being violated.

Response: At § 494.70(a)(1) patients have the right to receive respect for their personal needs. The intent of this standard is that all facilities must respect patients and their individual characteristics or unique needs. For instance, facilities may want to develop policies for a variety of situations, such as patient restroom use during a dialysis session, to ensure that their patients' rights are protected. We do not expect that patient signatures on liability waivers are necessary or appropriate in most cases. When a patient needs to use the restroom, that time should not be deducted from the dialysis treatment session. Facilities should schedule patients in such a way so that patients are not forced to give up prescribed services for which Medicare provides payment. In addition, CMS considers facilities that fail to schedule patients appropriately and thus, force patients to give up prescribed services, to be a serious matter of program integrity.

Comment: Several commenters suggested that current subpart U regulatory language, requiring a facility to use translators where a significant number of patients exhibit language barriers, remain in the final rule. Two commenters suggested language be added to specify that a facility must make a clear, reasonable effort to provide information in a language the patient can understand and to document such provision in the patient's record. Two commenters suggested that facilities be required to provide information in the appropriate language and in a culturally sensitive manner. Additionally, several commenters suggested that a facility confirm that patients understand the information they receive.

Response: The intent of the proposed rule language was to provide the facility with flexibility in meeting the requirement that it provide information in a way the patient understands. If a facility needs to obtain the use of a translator service to provide information to a patient and respond to questions, then we expect the facility to obtain that service. The suggestion to add language that requires information to be provided in a culturally sensitive manner, as well as in the appropriate language, would be redundant, since this is required as part of § 494.70(a)(2). The information required to be provided under § 494.70 would include all the information patients need to understand their rights and participate in their care if they choose (see § 494.70(a)(5)).

Comment: One commenter suggested that specific language be added to state that a social worker should have the ability to assess a patient's psychological needs in a private environment.

Response: The intention of § 494.70(a)(3) and § 494.70(a)(4) is that all facilities must respect privacy and confidentiality for all patients; therefore social worker-patient interactions that require privacy should be conducted in private.

Comment: A number of commenters stated that patient participation can optimize care. One commenter suggested language to specify that patients and their family members participate in their care and training. Several other commenters suggested we state that patients have some obligation to take part in, and be accountable for their care, and that patients must be fully aware of and engaged in their course of treatment.

Response: The ''Patients' rights'' condition requires that patients or their representatives be informed about patient rights and responsibilities. Section 494.70(a)(5) states that patients have the right to participate in all aspects of care. It may be desirable that patients participate fully in their care; however, neither CMS nor a facility can demand full patient participation. Additionally, we cannot mandate the involvement of patient representatives in the care of patients. We do require that patients have the opportunity to

participate in their care. Patients have the right to accept or decline to participate.

Comment: Two commenters suggested that we add language to specify that a patient has the right to attend care planning meetings and that a patient also has the right to request a care conference that would include his or her care team members. One commenter stated that there was no regulatory language that provides that a patient has the right to be involved in care planning, and that the language only required the patient to be informed of care planning.

Response: Patients have the right to be involved in their care planning as part of the interdisciplinary team, which is defined at § 494.80 and § 494.90. Because patients have the right to be part of the interdisciplinary team, they have the opportunity to participate in all aspects of care, which includes, but is not limited to, care planning. The language in the final rule allows for flexibility in the way a facility demonstrates that a patient has had sufficient opportunity to participate as part of the team. Care plan meetings or conference calls that allow the patient to call in from home would allow the patient to participate. The dialysis facility must encourage patient participation in care planning.

Comment: Some commenters, including patients, suggested language be added to state that a patient has the right to refuse cannulation by specific nurses or patient care technicians (PCTs) if problems cannulating his or her access site have occurred with that staff member. Some patients have experienced situations causing them fear and/or discomfort due to cannulation by specific members of a facility's staff.

Response: Patients have the right to be informed of the right to refuse treatment, as required at § 494.70(a)(5). However, this final regulation includes new minimum qualifications for PCTs, who frequently cannulate patients during in-center hemodialysis sessions. Dialysis facilities will now be required to employ trained and certified patient care technicians. We have added ''proper cannulation techniques'' as part of the technician training program at § 494.140(e)(3)(iii). We would anticipate patients having less difficulty with cannulation due to the more stringent technician training requirements required for certification. Additionally, ''Fistula First'' is a nationwide initiative that promotes the adoption of recommended ''best practices,'' including cannulation methods, in dialysis facilities. Facilities are encouraged to implement these practices, including increased self-cannulation. The initiative encourages self-cannulation with the appropriate course of training, as part of an emphasis on broader patient involvement in care.

Comment: A number of comments reinforced the importance of advance directives. Many comments support the inclusion of providing advance directives information in the ''Patients' rights'' condition. A few comments requested that the proposed advance directives language be strengthened by adding discussion of ''end of life'' options. Another commenter suggested the intent of the regulation text could be clarified further by adding language to require that facilities provide an advance directive planning process. One commenter remarked that patients should not be required to have an advance directive on file. Additionally, a few comments suggested that patients be educated about advance directives rather than just informed.

Response: The large number of supportive comments regarding advance directives is appreciated. We believe that it is important to include this language in the final regulation for several reasons, not the least of which is that while ESRD treatment has prolonged life, the typical patient receiving dialysis treatment is often afflicted with multiple co-morbidities. We are not mandating that facilities discuss ''end of life'' options, requiring units to provide advance directives planning assistance, or requiring patients to complete advance directive documents. We are requiring in the final rule at § 494.70(a)(6) that facilities inform patients of their right to have advance directives and inform patients of the facility's policies regarding advance directives. While the actions suggested by commenters might assist in the planning process, we believe requirements such as these would extend beyond the scope of a facility's expertise and responsibility, as well as beyond the scope and intent of these regulations. Patients requiring assistance in advance directive preparation should look to the facilities' social workers for guidance, as social work professionals are trained to use their clinical judgment to evaluate, provide information and make referrals if necessary.

Comment: Several commenters suggested that we strengthen and clarify the advance directives language by adding specific requirements to the regulation text. One commenter suggested that patients be required to identify a preferred surrogate decision-maker, complete an advance directive and durable power of attorney, as well as indicate the amount of leeway for their chosen surrogates. Another commenter suggested that the social worker be required to inform, encourage, and assist in completion of advance directives.

Response: We appreciate the comments; however, we will not require specific professionals to be responsible for encouraging patients to complete advance directives. The dialysis facility staff must assess individual patient needs, and determine if there is a need for further clarification or discussion. They may suggest referral to a resource, lawyer, or other appropriate professionals if indicated. Some patients may desire to execute very detailed directions and advance directives while other patients may not. We are not specifying patient advance directive execution requirements in this final rule.

Comment: Many commenters suggested that we require a facility to honor an advance directive, including ''do-not-resuscitate'' orders. Two commenters suggested that the rule state that, if a facility could not honor the wishes of an advance directive, the facility would have to notify the patient and transfer patient to a facility that was able to honor those wishes.

Response: The ''Patients' rights'' section of the proposed rule would allow patients the right to be informed of their ability to execute an advance directive. In response to comments, we have added a provision stating that patients have the right to be informed of the facility's policy regarding advance directives. The advance directive language at § 494.70(a)(5) in the proposed rule has been revised and relocated. We have redesignated proposed § 494.70(a)(6) through § 494.70(a)(16) as § 494.70(a)(7) through § 494.70(a)(17) and have added a new § 494.70(a)(6) to require facilities to ensure that a patient is informed about his or her right to execute advance directives and the facility's policy regarding advance directives. We have also added language to the ''Medical records'' condition at § 494.170(b)(2) to require that facilities document in the patient's medical record whether or not an advance directive has been executed by the patient. The facility should address advance directives in their policies and procedures, which must be available to patients as required in the ''Patients' rights'' condition. We expect facilities to make patients aware of their policies regarding honoring properly executed advance directives. If a facility does not honor advance directives, we

expect it to make the patient aware of that policy. In addition, we believe that the facility should develop a protocol for patient transfer, if a facility does not intend to honor advance directives. Some patients will opt to be treated in a facility that will honor their advance directives.

Comment: One commenter suggested there is a need for national guidelines for advance directives specific to dialysis services.

Response: Advance directive guidelines developed by national organizations, such as the Renal Physicians Association (RPA) and the National Kidney Foundation (NKF) already exist. Although we will not require adherence to RPA and NKF advance directive guidelines, we encourage facilities to use these valuable resources.

Comment: Many commenters concurred that information on all modalities should be presented to all patients. One commenter remarked that family members should also be presented with information on all modalities. Another suggested we require facilities to inform patients about all modalities at least annually.

Response: The ''Patients' rights'' condition at § 494.70(a)(7) requires that the patient or his or her representative be informed of patient rights, including information about treatment modalities and settings. Patients must decide what is in their best interest and they should have the flexibility to include family members in their decisions regarding dialysis modalities as they see fit. Patients are periodically reassessed, as required under the condition for patient assessment at § 494.80(d). The patient's suitability for various dialysis modalities and/or transplantation are assessed by the interdisciplinary team, which may include the patient if desired, and reviewed with the patient each year. Consequently, we believe it would be redundant to add the suggested language under the ''Patients' rights'' condition, since the requirement already exists elsewhere.

Comment: One commenter suggested that modality options be broader to allow for new modalities, and that the facility offer an option for ''no treatment.''

Response: Individual patients always have the choice to not seek treatment. As indicated at proposed § 494.70(a)(5), patients have the right to refuse treatment. If an individual is a patient of an ESRD facility, then he or she has likely made the decision to treat his or her illness. However, the patient's medical condition may change in later months or years and there could be a time when the patient decides that dialysis treatment is no longer appropriate. Therefore, in response to this comment, we have modified our requirement so that a patient must be informed of the right to discontinue as well as refuse treatment.

Comment: One commenter suggested that the modality discussion include the offer of transplant information and home dialysis education.

Response: Transplant information and home dialysis education are addressed under the condition ''Patient plan of care.'' The standard for patient education and training at § 494.90(d) mandates that the plan of care include education and training in aspects of the dialysis experience, dialysis management and transplantation, among other things. Since transplant education for patients is captured as a standard level requirement, it would be redundant to include the language in the ''Patients' rights'' section.

Comment: One commenter suggested that all facilities be required to offer home dialysis.

Response: While it may be ideal for every dialysis facility to offer home dialysis, dialysis facilities have the flexibility to choose which modalities to offer. However, patients must be informed of all possible dialysis modalities, and where those modalities are offered. We have revised § 494.70(a)(7) to specify that facilities must provide resource information about those modalities not offered in their specific facilities. In addition, facilities must provide information about alternative scheduling options for working patients within and outside their own facility.

Comment: Many commenters suggested that facilities be required to provide information on where all modalities may be obtained, including home dialysis options. Some recommended that the regulation specify that alternate dialysis locations be located within 120 miles of the facility.

Response: As noted above, patients have the right to receive resource information for modalities not offered in their facilities. The facility may wish to create a resource information packet or provide patients with an existing list from Medicare's DFC Web site. This resource information may include giving the patient a handout, or the DFC Web site information. Doing any of these things would meet the requirement to provide the patient with resource information on where they may obtain alternate care options. Requiring a facility to identify dialysis options within a certain geographical limit would be a burden without benefit, as the suggested 120 mile radius would likely be too far for many patients. Those patients living in rural areas might be more accustomed to traveling longer distances for services than those residing in more urban areas and as such, we expect rural dialysis facilities would consider this and make referrals as appropriate.

Comment: A few commenters suggested that language be added to state that a patient has the right to perform self-care after being trained. Additionally, a number of comments suggested that we add specific language to include self-cannulation and self-care to the list of modalities at § 494.70(a)(7).

Response: Some of the comments received on this issue were vague, but we assume they generally refer to self-cannulation as an example of self-care that may be performed by the patient in the dialysis facility following training. Patients currently are allowed to self-cannulate upon receiving the proper training and demonstrating competency. The patient's right to participate in aspects of his or her care is addressed at § 494.70(a)(5), and as written, is flexible enough to include self-cannulation as well as other forms of in-center self-care and home dialysis.

Comment: Several commenters requested that language be added to require dialysis facilities to inform patients about their right to schedule treatments that can accommodate work and/or school schedules. Others suggested that we add language at proposed § 494.70(a)(7) to specify that patients have a right to have access to a work-friendly dialysis modality or schedule that accommodates work and/or school, and if a schedule cannot be accommodated within that facility, the facility must refer the patients to another facility that can meet the patients' needs. Additionally, another commenter remarked that CMS should not drop the existing requirement that a facility accommodate patients who work.

Response: We believe that facilities should inform patients about different modalities, and where to obtain them. This allows patients to make a choice about what type of dialysis treatment is most convenient for them. Working patients do have the option of home dialysis, which may be more attractive because of the more flexible treatment schedule. Facilities generally are willing to work with patients who have other medical appointments that may affect their dialysis schedule. Facilities with a full patient census may have limited ability to change the dialysis schedule but will try to switch dialysis session

appointments when other patients are agreeable. Dialysis patients who work or attend school should be encouraged to continue doing so and dialysis facilities should recommend the most appropriate modality and setting for dialysis. While we are not requiring a facility to provide every modality or schedule to accommodate patients' unique schedules, we are now requiring that facilities inform the patient where such accommodations may be obtained. We have added new language at § 494.70(a)(7), giving the patient the right to receive resource information about dialysis modalities not offered by that facility, including alternative scheduling options for working patients. Accommodations for working patients may include, for example, home hemodialysis, peritoneal dialysis, or extended facility hours.

Comment: One commenter objected to the proposal that facilities be required to fully inform all patients about isolation, stating that the regulation should ensure that patients have access to policies but not require all policies be provided to all patients.

Response: This requirement is not a new mandate, but has been retained from part 405, subpart U, the ESRD Conditions for Coverage. Open communication between the facility staff and the patient, as well as patient access to information, are both important for enhancing the patient's participation in his or her care; this requirement will remain in the final rule.

Comment: Two commenters recommended that the facility inform the patient about the health and safety risks involved in reusing dialyzers, provide accurate reuse data, provide the patient with treatment options other than reuse, and notify the patient that reuse is a patient choice. Another commenter stated that patients should have the right to decline reuse and receive single use dialyzers in a facility. One commenter questioned whether there should be a reuse consent form, while another asked how patient choice would be protected.

Response: Reuse is a safe practice when performed correctly. Reuse language at proposed § 494.50 was retained from existing regulation and now requires ESRD facilities reusing hemodialyzers to meet the new guidelines and standards adopted by AAMI. Additionally, section 1881(f)(7) of the Act directly addresses dialyzer reuse. Reuse is a care decision that is to be made between the patient and his or her physician. Patients also have the option to seek treatment in a facility that exclusively uses new dialyzers.

Comment: One commenter suggested deletion of the requirement that facilities inform patients of their own medical status. Another suggested that we add broader language in the regulation text, which would allow physicians, nephrologists, nurse practitioners or physician assistants to provide patients with their own medical information.

Response: Providing the patient with his or her medical information is an existing requirement and is found at § 405.2138(a)(3). The commenter provided no rationale for the deletion of this standard language and thus, the language has been retained. We have added the nurse practitioner, clinical nurse specialist and/or physician's assistant treating the patient for ESRD to the list of authorized personnel at § 494.70(a)(10), which now states that patients have the right to be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in his or her medical record, unless the medical record contains a documented contraindication. Individual facilities may determine policies and procedures, in accordance with the State Boards of Practice, regarding the practice of advance practice nurses and PAs in the facility.

Comment: A commenter objected to the requirement that facilities fully inform patients about charges not covered by Medicare. Another commenter suggested that trained and informed staff should explain non-covered charges.

Response: The intent of the existing subpart U language at § 405.2138(a)(2) was carried over into the proposed language at § 494.70(a)(10), now redesignated as § 494.70(a)(11) in this final rule, which requires facilities to tell patients what services are available in the facility, and inform them of charges for services not covered under Medicare. Additionally, if a facility plans to bill a patient for items and/or services which are usually covered by Medicare, but which may not be considered reasonable and necessary for a particular situation (according to section 1862 of the Act), an advanced beneficiary notice must be given pursuant to section 1879 of the Act.

Comment: A few commenters suggested that regulatory language require that patients be given access to social work and psychological services, psychosocial counseling, and nutritional counseling. Some commenters suggested that language be added to the ''Patients' rights'' condition that specifies that patients would have access to, and receive counseling from, a qualified social worker and a dietitian. Some commenters recommended that patients have the right to receive a referral for mental health services, physical or occupational therapy and/or vocational rehabilitation, as needed. Another commenter suggested the addition of language that would stipulate that patients would have the right to receive necessary services, as authorized by their insurance plan.

Response: The ''Patient assessment'' and the ''Patient plan of care'' conditions for coverage (§ 494.80 and § 494.90, respectively), require input by an interdisciplinary team. This team of professionals includes, at minimum, a registered nurse, physician, social worker and dietitian. The team is responsible for properly assessing and treating the patient, which would include identifying additional treatment needs, such as psychosocial counseling, etc. Therefore, we believe that expanding the language at § 494.70(a)(12) to include social work and psychological services, psychosocial counseling and nutritional counseling, as suggested by these public comments, would be redundant under the final rule. Under the final rule, following the comprehensive assessment required at § 494.80, a plan of care for each patient must be implemented, which must include care and services deemed necessary by the interdisciplinary team. The requirements for the provision of services under the ''Plan of care'' condition at § 494.90, do include nutritional and social services, such as psychosocial and nutritional counseling. Furthermore, the ''Patients' rights'' condition at § 494.70(a)(11) requires facilities to inform patients of their right to be informed of services available in the facility and the charges for services not covered under Medicare. At § 494.70(a)(12), patients have the right to receive the necessary services outlined in the patient plan of care. Therefore, we believe the concerns of commenters are adequately addressed at § 494.70, § 494.80 and § 494.90.

Comment: Some commenters suggested adding language to specify that facilities must inform patients of their responsibilities, including punctuality, following dietary/fluid restrictions, following treatment regimens, exhibiting appropriate personal behavior, informing the team of scheduling problems, and issues in filling prescriptions. Other commenters stated that facilities should inform patients that the patients have a responsibility to listen and ask

questions when they do not fully understand their rights or responsibilities. Another commenter stated that CMS should clarify patient responsibilities in the standard for patient rights.

Response: Patient responsibilities are addressed at § 494.70(a)(13). We have retained the existing requirement found at § 405.2138(a)(1), which states that patients must be informed of the rules and expectations of the facility regarding patient conduct and responsibilities. The proposed language has been retained in the final rule. It is essential to recognize that positive patient behavior may be encouraged but cannot be regulated.

Comment: One commenter suggested that we add regulatory language to clarify that there needs to be a balance between providers' duties and patient rights.

Response: Proposed section 494.70(a)(12), now § 494.70(a)(13) of this final rule, requires that the dialysis facility inform patients of their rights, including rules and expectations regarding patient conduct and responsibilities. Moreover, facilities must protect and provide for the exercise of patient rights. Informing patients of their responsibilities promotes and supports patient involvement in their care. We will not attempt to address unique individual situations in this regulation, but we expect that while facility staff informs patients of their rights and responsibilities, we also expect patients to try to adhere to facility rules and guidance from facility staff, which would help patients maintain optimal health while receiving facility services.

Comment: We received many comments in support of more patient-protection requirements regarding facility internal grievance processes. Commenters supported the proposed requirement for facilities to post information on how to file a grievance. Some commenters specifically supported requiring the posting of Network and State Agency phone numbers and/or mailing addresses.

Response: We agree that it would be in the best interest of patients that Network and State Agency mailing addresses and phone numbers be posted. Posting the additional patient rights information will not be a significant burden upon facilities. We have revised § 494.70(c) to include ''mailing addresses.''

Comment: One commenter suggested that CMS establish a separate definition of ''grievance.'' Another remarked that the term ''grievance'' should always be used carefully and with full understanding of its seriousness. One commenter suggested that facilities be required to review the grievance process with patients on a regular basis. One commenter suggested adding language requiring a facility to ''attempt to resolve'' grievances.

Response: We appreciate the comment, as well as the suggestions regarding the grievance procedure. We believe the term ''grievance'' is a commonly understood term and we did not receive substantial public comment indicating this to be a particularly difficult concept to understand within the renal community. We disagree with the commenter and have not added a definition for the term ''grievance'' in the ''Patients' rights'' condition at § 494.70. Whether patients use the term ''complaint'' or ''grievance,'' they have the right to be informed of and use established internal and external grievance procedures. The proposed language was added to inform patients about external mechanisms for filing a grievance and how to contact the ESRD Network and State survey agency; the language strengthens the existing requirements. We believe that it is imperative that all patients be made aware of every grievance option available to them. Mandating regular review of patient rights information with patients, we believe, would be an unnecessary burden since patient rights information must be prominently displayed within the dialysis facility, as required at § 494.70(c), and is thus available for review at any time. We expect that the internal facility grievance procedures would aim to resolve patient grievances. The provision at § 494.180(e) requires facility-level internal grievance processes.

Comment: One commenter sought clarification of the phrase ''appropriateness of discharge.'' Another commenter suggested that the final rule clarify what we meant by stating that we would ''hold the facility responsible'' for ensuring that patients were notified about their rights.

Response: The phrase ''appropriateness of discharge'' did not appear in the proposed rule text; however, clarification may be found in the ''Governance'' condition at § 494.180, which does address the discharge procedure. This section specifies the acceptable circumstances for an involuntary discharge or transfer of a patient, as well as the required actions that must be completed by the interdisciplinary team prior to ceasing treatment within the facility. Regarding our intentions regarding the facility's involuntary discharge responsibilities at § 494.180(f), facilities are required to inform patients of their rights and protect patients' rights; in the event a facility fails to do so, the facility will be cited as being out of compliance during a survey. In addition to the provision at § 494.180(f), patients also have the ''right to be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients'' at § 494.70(b).

Comment: Some commenters recommended the addition of language that would require facilities to provide information on topical analgesics for needle pain.

Response: Facilities have the flexibility to inform patients about topical analgesics. We do not believe this should be a regulatory requirement. We are not adopting this recommendation.

Comment: A commenter remarked on the issue of disruptive and challenging dialysis patients and indicated that there is existing case law regarding this topic, illustrating the inability of the law to assist the abandoned patient who manifests extreme non-compliance. The commenter specifically cited *Payton* v. *Weaver,* 131 Cal. App. 3d 38, 182 Cal. Rptr. 225 (1982), and *Brown* v. *Bower,* No. J86–0759(B) (S.D. Miss., Dec. 21, 1987). Another commenter suggested the addition of language to specify that patients have a right to receive counseling and support from the team in order to resolve behavioral issues and be informed of appropriate/inappropriate behaviors, prior to being discharged from a dialysis facility. There were a large number of comments regarding discharge policies within the dialysis facility. Some comments supported a 30-day notice for involuntary discharge. Several other comments supported the proposed involuntary discharge guidelines regarding an immediate threat. Many commenters suggested the addition of language to specify that patients could not be involuntarily discharged for noncompliant behaviors/non-adherence to medical regimens. A few comments supported the waiver of discharge policies and procedures in the face of an ''immediate threat.''

Response: We appreciate the comments regarding involuntary discharge. While we appreciate the comment regarding *Payton* v. *Weaver* and *Brown* v. *Bower,* the cases cited do not appear to be applicable to this rulemaking. Patients are to be reassessed by the interdisciplinary team, including a Master's degree social worker (MSW) at least monthly when a patient exhibits significant changes in psychosocial

needs (as required at § 494.80(d)(2)(iii)), manifested by, for example, issues such as disruptive behavior, that could result in discharge. In § 494.180(f), we are requiring facilities to have discharge policies and to manage involuntary discharge issues according to facility protocols. Language at § 494.180(f)(4)(i) through § 494.180(f)(4)(v) responds to the ''disruptive'' or ''challenging'' patient issue. We have also added language to § 494.70(b)(1) in response to comments, to clarify that patients must be informed of routine as well as involuntary discharge policies. As stated in the proposed rule preamble, we do not expect that a patient should be involuntarily discharged from a dialysis facility merely for failure to follow the instructions of a facility staff member. However, we recognize it may be necessary to discharge a disruptive patient in order to protect the rights and safety of other patients and staff in the facility. If, for instance, a patient physically harms or threatens other patients and/or staff, brings weapons or illegal drugs into a facility, or verbally abuses and disrupts the facility to a degree that the facility is unable to operate effectively, then the 30-day discharge notice policy could be abbreviated pursuant to § 494.180(f)(5). This issue is further discussed later in this preamble under the ''Governance'' condition.

Comment: One commenter noted that some facilities already have policies in place regarding discharge and transfer policies as well as policies regarding patient conduct, and questioned whether federal requirements were needed.

Response: We are aware that some facilities already have policies in place regarding discharge and transfer of patients. Many of these facilities have established protocols regarding how staff must deal with patient conduct. It is not our intent to create more prescriptive requirements in this area, but to ensure that all dialysis facilities review any established documentation and policies to make certain they meet the minimum discharge and transfer requirements set forth at § 494.180(f).

Comment: Two commenters recommended that we delete the phrase ''reducing or terminating ongoing care.'' The concern was that the phrase was too indefinite.

Response: We agree that the wording in the proposed rule was unclear. Therefore we have modified § 494.70(b)(2) to require that patients receive written notice 30 days in advance of an involuntary discharge following the procedures described in § 494.180(f)(4)(i).

Comment: One commenter recommended that we require posted patient rights to be written in English at a 7th to 9th grade level and translated into a patient's native language if possible. Many other comments suggested that we require facilities to have an ''alternate method'' to inform patients who cannot read posted information.

Response: The concerns raised in these comments have already been addressed at § 494.70(a)(2). The ''Patients' rights'' condition requires that all patients receive information in a way they can understand. Facilities have the flexibility to provide information to patients in the most appropriate manner based upon patient needs. The qualified professionals at the facility are capable of evaluating an individual patient's level of understanding and making a determination regarding the needs of that patient. We have retained the proposed language.

Comment: One commenter suggested that the criteria for transplantation be posted at the dialysis facility along with a copy of the patient rights, which we proposed at 494.70(c).

Response: Dialysis facilities have the flexibility to post transplant criteria within the facility. At § 494.70(a)(7), it is required that patients be informed about transplantation as a modality. Additionally, the ''Plan of care'' condition at § 494.90(d) of this final rule requires that patients and caregivers be provided with education and training on several topics, including transplantation. These requirements will provide patients and their caregivers with increased awareness of transplantation.

Comment: A commenter suggested that we add language that would specifically state that patients have the right to know the identity of their facility caregivers and the nature of their credentials. Another commenter suggested that facility staff be required to wear nametags.

Response: The issue of staff nametags should be addressed in facility-level policies and procedures. While it is desirable for staff to wear nametags, we would like to allow flexibility within this health and safety regulation. We would expect that facility staff introduce themselves; however, we do not believe that it is necessary or appropriate to add this prescriptive requirement to this final rule.

Comment: One commenter recommended that CMS use an ombudsman to build relationships with ESRD patients and their families.

Response: Section 923 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub.L. 108–173)(MMA), mandated the creation of the Medicare Beneficiary Ombudsman in section 1808(c) of the Act, to ensure that people with Medicare get the information and help they need to understand their Medicare options and to apply their rights and protections. A Medicare Beneficiary Ombudsman Open Door Forum has been established to provide an opportunity for beneficiaries, their caregivers and advocates, to publicly interact with the Medicare Beneficiary Ombudsman to discuss issues and concerns regarding ways to improve the systems and processes within the Medicare program. Information on the Office of the Medicare Ombudsman may be found at *http://www.cms.hhs.gov/center/ombudsman.asp*.

Comment: One commenter suggested that the language in the final rule include some mention of senile dementia and how it relates to consent forms.

Response: Dialysis facilities employ professionals who must assess whether a patient is competent to make medical decisions and assess patients' mental capacities in general. This issue is present across provider settings and we do not believe it is appropriate to implement a new provision of this nature within these conditions for coverage. Facilities may wish to address such issues and concerns in their own policies.

b. Patient Assessment (Proposed § 494.80)

We proposed to add a ''Patient assessment'' condition for coverage at § 494.80 that would make the ESRD facility, through the patient's interdisciplinary team, responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. This condition would define the interdisciplinary team to include, at minimum, the patient (or patient designee), a registered nurse, a physician, a qualified social worker, and a registered dietitian. The proposed rule would expand the existing requirements to specify the criteria that a facility must include in a comprehensive patient assessment. We believe that these criteria would be necessary in order to develop a specialized care plan that is based upon the nature of the patient's illness, the treatment prescribed, and patient needs. The frequency of patient assessment was also addressed in the proposed rule. We proposed that the facility conduct an initial

comprehensive assessment within 20 calendar days of the first treatment and that the facility conduct a follow up comprehensive assessment within 3 months after the completion of the initial assessment. We also proposed that the facility assess the adequacy of the treatment prescription at least monthly for hemodialysis and at least every 4 months for peritoneal dialysis. Finally, we proposed patient reassessment timeframes for both stable and unstable patients. We proposed that the facility perform comprehensive assessments at least annually when the patient is stable; if unstable, the facility must reassess monthly. In addition, the proposed rule also added criteria to specify which patients would be considered to be unstable.

We received more than 100 comments regarding the ''Patient assessment'' condition at § 494.80. Many commenters supported the condition as proposed, while others supported the condition with minor revisions.

Comment: A few commenters recommended we subsume standards (b), (c) and (d) of proposed § 494.80 ''Patient assessment'' condition into the ''Patient plan of care'' condition at § 494.90 and delete the assessment criteria at § 494.80(a). Some commenters opposed the assessment criteria at standard (a), stating that it was unnecessary to require assessment criteria because assessments using such criteria are already being performed in their facilities.

Response: We appreciate the support for § 494.80 ''Patient assessment.'' We purposely linked the ''Patient assessment'' and ''Patient plan of care'' requirements, as evidenced by the inclusion of both under subpart C ''Patient care.'' The ''Patient assessment'' condition provides a set of criteria for the evaluation of all ESRD patients. The condition promotes an interdisciplinary approach to evaluating and treating patients in order to achieve better outcomes. Measuring patient outcomes of care is our goal, and outcome measures are inherently linked to patient assessment tools. It is possible that these dialysis patient assessment criteria will lead to the development of a standardized assessment tool, which we hope that facilities would use in the future to meet QAPI requirements. We expect that quality-oriented facilities already are performing comprehensive patient assessments that meet these new conditions.

We are retaining the proposed condition for coverage in the final rule. A large number of commenters agreed that a comprehensive patient assessment for each patient is critical to developing an appropriate plan of care. The assessment criteria required at § 494.80(a) are necessary to ensure consistent assessments for all patients, ensuring that all important assessment areas are addressed for every patient. The comprehensive assessment is the tool used to develop a plan of care based upon patient needs. In addition, the comprehensive assessment criteria promote less fragmented care and will assist the facility's QAPI program as a clinical data source.

Comment: Two commenters suggested CMS mandate that a physician or an RN conduct the patient assessment. Other commenters suggested the final rule allow nurse practitioners and physician's assistants to conduct the physician portion of the assessment.

Response: The interdisciplinary team must include a physician and a registered nurse, and these individuals are responsible, along with other team members identified at § 494.80, for providing each patient with an individualized and comprehensive assessment. This final rule retains the proposed requirement at § 494.80 regarding the composition of the interdisciplinary team. We expect every patient to be assessed by the interdisciplinary team physician or ''physician extender'' (that is, a nurse practitioner, clinical nurse specialist, or a physician assistant (PA)), if a state practice act allows such physician extenders to conduct the physician portion of the patient assessment. Although a physician extender may conduct an assessment in some states, the physician providing ESRD care must participate in the assessment by reviewing and approving the assessment.

Comment: A few commenters recommended the addition of the term ''qualified,'' when referring to the social worker, and the term ''registered,'' when referring to the dietitian, who are members of the interdisciplinary team as required in the first paragraph at § 494.80.

Response: The dietitian and social worker specified under the ''Patient assessment'' and ''Patient plan of care'' conditions must possess the professional qualifications set forth at § 494.140(c) and § 494.140(d), respectively. We do not agree with the commenters that further clarification is necessary regarding the qualifications of the interdisciplinary team members. However, to further clarify the dietitian and social worker duties required in the ''Patient assessment'' condition, we have modified § 494.80(a)(6) to require that the assessment include evaluation of nutritional status by a dietitian, and modified § 494.80(a)(7) to require the assessment to include evaluation of psychosocial needs by a social worker.

Comment: Two commenters suggested that we specify in the final rule that the interdisciplinary team's nephrologist must be the facility medical director or treating nephrologist. The commenters were concerned that the proposed phrase at § 494.80, which would require ''a nephrologist or the physician treating the patient for ESRD'' to be a member of the interdisciplinary team was unclear. Commenters suggested that this phrase could mean that any nephrologist, not necessarily a nephrologist treating the patient, could participate on the interdisciplinary team.

Response: Because the public may interpret the proposed language to mean that any nephrologist may participate on the interdisciplinary team, as opposed to the patient's treating nephrologist, we have modified the introductory paragraph at § 494.80 to include ''the physician treating the patient'' and removed our reference to the nephrologists, since the term ''physician'' includes nephrologists.

Comment: A few commenters suggested clarification regarding the patient participation on the interdisciplinary team. The suggested modification was ''the patient or the patient's designee (if the patient chooses)'' in order to clarify that the patient not only has the choice to participate, but also has the choice to have a designee participate as part of the interdisciplinary team. Another commenter suggested that facilities be required to document patient participation and the reasons patients do not participate on the interdisciplinary team.

Response: Patients have the right to be informed about and participate, if desired, in all aspects of care, as required in the ''Patients' Rights'' condition at § 494.70(a)(5). The ''Patient assessment'' condition at § 494.80 states that the interdisciplinary team includes the patient or a patient designee if chosen by the patient. Patients must have the option to participate in the facility's interdisciplinary team. Conversely, the patient has the right not to participate or to designate another individual to participate on his or her behalf on the interdisciplinary team. Although patient participation on the interdisciplinary team is important and should be encouraged, we do not want to mandate patient participation. We have modified the provision at § 494.80, which proposed to require that the facility provide every patient the opportunity to participate with the

interdisciplinary team. The modified language in the first paragraph of § 494.80 clarifies that the patient may choose whether he or she wants to identify a designee to participate in the interdisciplinary team.

We note that the facility must demonstrate that the patient has been provided the opportunity to participate in the interdisciplinary team. The facility may develop policies and procedures regarding standard documentation of patient participation and may document the reasons for patient non-participation. If, for instance, a facility has a low level of patient participation in the interdisciplinary team, the facility may choose to document and monitor reasons for patient non-participation as part of a quality assessment and performance improvement plan.

Comment: We received two comments that suggested that the final rule specify that individual assessments be conducted by all members of the interdisciplinary team. Additionally, the commenters requested that the final rule clarify that face-to-face meetings between the patient and the interdisciplinary team would be required. Another commenter recommended that we eliminate team assessment altogether and only require use of individual assessments by each discipline.

Response: The entire interdisciplinary team is responsible for ensuring that each patient is individually assessed and his or her needs identified, as required at § 494.80. We agree that in order to conduct a clinical assessment, the patient must have face-to-face contact with the other interdisciplinary team members. We expect all professional members of the interdisciplinary team to complete the portions of the comprehensive patient assessment that are within their respective scopes of practice. It is not necessary for each professional team member to individually complete the entire comprehensive assessment and thereby duplicate efforts. Professional interdisciplinary team members might choose to conduct one-on-one interviews with patients to complete the assessments. The team may also opt to set up team meetings, which would include the patient, in order to collect the appropriate assessment information. We expect facilities to determine the best way to manage this process, and create policies and procedures to accurately and effectively collect patient assessment information. The assessment information is used to develop the patient's treatment plan and expectations for care, and thus it is critical for the members of the interdisciplinary team to participate.

Comment: One commenter recommended that the final rule be modified to include advance directive planning as part of the patient assessment at § 494.80(a).

Response: Patients are entitled to be informed about their right to have an advance directive, as required at § 494.70(a)(6). Additionally, if a patient has an advance directive, this information must be recorded in his or her medical record, as required at § 494.170(b)(2). In some cases, it may be appropriate for a patient to be assessed for advance directives and facilities should use their professional judgment to evaluate and determine if such an assessment is appropriate. We are not requiring advance directive planning as part of the patient assessment, but are allowing facilities the flexibility to include it in the patient assessment when deemed appropriate.

Comment: We received a comment recommending that language be added to the final rule to ''allow the Secretary to modify or update these 'elements' with new technology and knowledge.''

Response: We believe the commenter is referring to the assessment criteria found at § 494.80(a), and we also believe the commenter would like to see language that allows for updates without rulemaking. We have not modified this final rule to allow for automatic updates for assessment criteria because the Administrative Procedure Act (APA) requires rulemaking with public notice and comment if and when new regulatory requirements are proposed.

Comment: One commenter suggested the final rule at § 494.80(a)(1) be modified specifically to include chest auscultation, visual observance, gastrointestinal evaluation, access site evaluation, and patient symptoms between treatments as part of the evaluation of current health status and medical condition.

Response: Professional standards of practice require clinicians to perform appropriate clinical assessments and use their clinical judgment when caring for patients. The expectation is that these standards of practice will be employed by all clinicians. We have retained the proposed language at § 494.80(a)(1). Evaluation of current health status and medical condition, including co-morbid conditions, would include the techniques, specific evaluations and symptoms recommended by the commenter.

Comment: A few commenters recommended that the final rule include an assessment criterion for cardiovascular disease.

Response: Dialysis patients are at risk for cardiovascular disease, which is affected not only by individual risk factors, but also by renal bone disease, blood pressure and fluid management. These patients may have a number of co-morbid conditions and this final rule requires the interdisciplinary team to assess the patient's medical history, including any co-morbid conditions (§ 494.80(a)(1)). Since cardiovascular disease is a co-morbid condition we expect it would be assessed as appropriate for individual patients in order to comply with § 494.80(a)(1).

Comment: It was recommended by one commenter that ''intradialytic symptom frequency, causes, prevention, and tracking symptoms'' be added to this condition as new assessment criteria. Another commenter suggested that dialysis adequacy be specifically referenced in the assessment criteria.

Response: Patients must be assessed for the appropriateness of the dialysis prescription, blood pressure and fluid management at § 494.80(a)(2), which encompasses intradialytic symptoms and issues, such as cramping, as well as dialysis adequacy.

Comment: Many commenters suggested minor edits to the ''Patient assessment'' condition, but concurred with the condition as a whole and agreed with our belief that systematic patient assessment is essential to improving quality of care and patient outcomes. We received a comment from the Safe and Timely Immunization Coalition (STIC), which is facilitated by the Southeastern Kidney Council, Inc. (ESRD Network 6). This comment presented the benefits of immunization including prevention of illness and hospitalizations. The commenter stated that immunization is one of the most cost effective strategies to prevent unnecessary hospitalizations and deaths, and that immunization is currently a Government Performance and Results Act of 1993 (Pub. L. 103–62 (1993)) and Healthy People 2010 goal. According to the commenter, the current rates of immunizations for influenza, pneumococcal and hepatitis B immunizations nationwide are lower than 50 percent. STIC recommended adding influenza, pneumococcal, and hepatitis requirements to this final rule. The suggested requirements are consistent with the immunization requirements for long-term care facilities. The recommended provisions address: (1) The offering of influenza, pneumococcal and hepatitis B immunizations to the patient (or legal representative) at appropriate times and

frequencies; (2) a process for patient immunization refusal; and (3) documentation parameters.

Response: We agree with commenters that the systematic approach to patient assessment is essential for improving quality of care and patient outcomes.

We appreciate the work of STIC and their recommendations for specific immunization requirements. In order to promote the immunization initiative and the ongoing cooperative effort between CMS and the dialysis industry to screen patients for their immunization needs, we have modified the final rule at § 494.80(a)(3) to include immunization history as part of the assessment criteria. We believe it is reasonable for facilities to include immunization history as part of the comprehensive assessment at least annually so that immunization needs may be identified. However, we have not added the extensive provisions recommended by the commenter. If we determine that further immunization requirements are warranted, we will undertake rulemaking at a future date and provide the public the opportunity to comment on any new proposed provisions.

Comment: One commenter recommended that erythropoietin not be specifically referenced in the ''Patient assessment'' condition in the final rule, so as not to limit the use of other erythropoiesis-stimulating drugs.

Response: We agree with the commenter and in order to allow flexibility for other medications that stimulate erythropoietin, as well as new developments in the future, we have modified the final rule to eliminate specific references to erythropoietin, and instead will use the term erythropoiesis-stimulating agent(s).'' The new language at § 494.80(a)(4) reads: ''including administration of erythropoiesis-stimulating agent(s).''

Comment: We received several comments suggesting that bone disease be retained and added to the assessment criteria in the final rule.

Response: The proposed rule included bone disease as part of the assessment criteria. The final rule will retain the language at § 494.80(a)(5), which reads: ''Evaluation of factors associated with renal bone disease.''

Comment: We received several comments regarding the evaluation of nutritional status, which is required as part of the comprehensive patient assessment. Two commenters suggested we modify the final rule to add more specificity regarding nutritional status, suggesting the use of K/DOQI guidelines, to insure uniformity in assessment. One commenter suggested that serum albumin not be used as a sole indicator and another commenter suggested specific nutritional parameters for growth assessment for pediatric patients be added to the final rule.

Response: The K/DOQI guidelines are clinical practice guidelines developed by the NKF via a technical expert workgroup and consensus process (*http://www.kidney.org/PROFESSIONALS/kdoqi/guidelines.cfm*). In order to allow for flexibility and professional clinical judgment we are not adding specific criteria to the evaluation of nutritional status requirement in this final rule at § 494.80(a)(6). We discuss ''nutrition'' and nutritional indicators under the ''Patient plan of care'' (§ 494.90(a)(2)) condition discussion in the preamble below.

Comment: We received many comments suggesting revisions to the final rule regarding the evaluation of psychosocial needs. Many commenters recommended the addition of a standardized survey tool to be used in assessing the psychosocial status of dialysis patients, namely the SF–36 or another instrument advocated by National Kidney Foundation Life Options subgroup. One commenter suggested the final rule be modified so that § 494.80(a)(7) would specifically require ''evaluation of psychosocial needs, functioning and well-being using the SF–36 or other standardized survey.'' Two commenters suggested the final rule specify a list of psychosocial needs to be assessed, such as mood changes and coping with chronic illness. We received suggestions regarding additional forms that could be used for assessing psychosocial status. One commenter suggested that ''depression'' be added as a separate assessment criterion.

Response: In response to concern regarding the psychosocial status of dialysis patients, we have modified the ''Patient assessment'' condition and strengthened the ''Patient plan of care'' condition. At § 494.80(a)(7) we have added the phrase ''by a social worker'' to ensure that patients are being assessed by an MSW, as defined at § 494.140(d). Additionally, we are requiring at § 494.90(a)(6) that a standardized tool, chosen by the MSW, be used to monitor patient status, and that counseling be provided and referrals be made as appropriate. There is further discussion of the standardized tool under the ''Patient plan of care'' discussion below.

Comment: One commenter suggested that all patients be encouraged to first consider home dialysis options when evaluating modality and setting.

Response: We have emphasized increasing patient awareness of home dialysis options in this final rule. In § 494.70 we require that the patient has the right to be informed about all treatment modalities and settings, including home dialysis. We expect facilities to encourage patients to consider home dialysis if it is a suitable choice. In addition, we encourage the use of home dialysis under the ''Patient plan of care'' condition at § 494.90(a)(7)(i).

Comment: A commenter suggested the comprehensive assessment include an evaluation of self-care activities the patient performs. Another commenter remarked that the evaluation of a patient's potential for self-cannulation should be part of the assessment, and that documentation in the patient record should be required if the patient chooses not to participate. One commenter made a general observation that patients are not treated as adults in the facility.

Response: All patients are to be encouraged to participate in their own care, as ability and interest allows. Some patients may be able to self-cannulate, while others may not. Some may be able to weigh themselves or they may be charged with holding their access site to stop bleeding after completion of a course of dialysis. Regardless of the patient's level of participation, an evaluation of self-care activities is encompassed within the comprehensive assessment requirement at § 494.80(a)(9), which requires ''Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis) and setting (for example, home dialysis), and the patient expectations for care outcomes.''

Comment: We received many comments regarding the responsibility and basis for transplantation referral of dialysis patients. Some commenters remarked that ESRD facilities should not be responsible for referring patients for transplantation. Commenters explained that often dialysis units must cooperate with multiple transplantation centers that may have varied criteria and some transplantation centers do not have any criteria available on which a dialysis facility could base a referral. Another commenter suggested that referral for transplantation is the nephrologist's and patient's responsibility.

Response: The part 405, subpart U ESRD conditions for coverage required facilities to evaluate patients for transplantation referral as part of the long-term care program planning process. This final rule does not require transplantation referral as an activity separate from the short-term care plan, but rather, it is now encompassed within the plan of care. Referrals will continue to be a facility-level responsibility. We recognize the role of the physician as the leader of the interdisciplinary team; however, these regulations apply to the facility, and the interdisciplinary team is responsible for patient referral for transplant.

It is important for dialysis facilities and transplantation centers to make a concerted effort to communicate and cooperate. Two-way communication is required not only in this final rule, but also within the recently published Medicare Transplant Center conditions of participation. The March 30, 2007 transplant center final rule (''Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants'' (72 FR 15276)) requires kidney transplant centers to make transplant referral criteria available to any requesting dialysis center (see § 482.90(a)(4)). The purpose of using transplant center criteria is to remove and reduce the chances of referral bias and transplant referral disparities.

Comment: One commenter suggested that the final rule require a written agreement between transplant centers and dialysis facilities and that such agreement contain the transplant center criteria for patient referral.

Response: If a dialysis facility finds it useful to have a written agreement with the transplant center regarding communication and responsibilities of each entity, as well as transplant criteria, the dialysis facility has the flexibility to do so, but we do not believe we have sufficient cause to require such an agreement of all facilities.

Comment: We received many comments regarding the proposed requirement that the assessment include an evaluation of patient physical activity level and rehabilitation status (§ 494.80(a)(12) and § 494.80(a)(13)). Some commenters agreed with the proposed assessment criteria here, while others suggested modifications to the final rule. Commenters remarked that the interdisciplinary team members are not qualified or trained to assess a patient's physical activity level or rehabilitation status. One commenter suggested we modify the final rule to specify evaluation of developmental progress and educational needs as part of the rehabilitative assessment for pediatric patients.

Response: We agree with commenters that the proposed language at § 494.80(a)(13), which would require the facility to evaluate the vocational and physical rehabilitation status and potential of patients, is beyond the scope of a facility's responsibilities. The professionals who are part of the interdisciplinary team do not have complete knowledge and training necessary to accurately and fully assess physical activity level or physical rehabilitation status and potential. Therefore, we have modified the final rule at § 494.80(a)(13) to require the interdisciplinary team to evaluate the patient for referral to vocational and physical rehabilitation services. Facilities are expected to evaluate whether the patient should be referred for services as appropriate, not perform a complete physical therapy or rehabilitation assessment in the facility. Evaluation and referral of developmental progress and educational needs may be appropriate for some patients; however, the final rule will not be modified to require that these needs be evaluated for all patients. If, during the assessment process, either of these issues is identified by the interdisciplinary team, we expect the patient will be referred to the appropriate professional for further evaluation.

Comment: One commenter suggested that the final rule require the assessment elements laid out at § 494.80(a)(11) through § 494.80(a)(13) (support systems, physical activity level, and rehabilitation services) be completed by a social worker using a standardized assessment instrument that measures physical, social, and emotional status.

Response: Facilities have the flexibility to designate staff with the appropriate expertise to complete the comprehensive assessment. The social worker may possess the greatest expertise related to these areas; however, another team member might perform the physical activity level assessment. At § 494.80(a)(7), a social worker is required to assess the psychosocial needs of patients, and § 494.90(a)(6) of the final rule requires the plan of care to address psychosocial status using a standardized mental and physical assessment tool, chosen by the qualified social worker. As discussed previously, we are not requiring facilities to use any specific assessment tool.

Comment: A few commenters sought clarification on the meaning of the phrase ''new patient'' at proposed § 494.80(b), ''Frequency of assessment for new patients.'' The commenters asked whether ''new patient'' meant a patient new to dialysis or a patient new to a particular dialysis unit. Another commenter asked if ''new patient'' referred to a patient receiving his or her first treatment in an outpatient dialysis unit.

Response: In order to clarify the meaning of ''new patient,'' we have modified the title of § 494.80(b), so that it now reads: ''Frequency of assessment for patients admitted to the dialysis facility.'' We intend for all dialysis patients new to any particular outpatient dialysis facility be categorized as ''new patients'' and have a comprehensive assessment within the specified 30-day timeframe even if they are transferring from another dialysis facility. This means a comprehensive assessment must be done on all transfer patients, as well as those new to dialysis, within the first 30 days.

Comment: We received more than 50 comments regarding the frequency of assessment and the timeframe for completion of patient assessments. A few commenters agreed with the proposed timeframe for completing the patient assessment; however, the majority of commenters were concerned that the 20-day proposed timeframe did not allow enough time to complete a thorough comprehensive assessment. Many commenters stated that completion of the patient assessment within 20 days would be ideal but is impractical for staff that often cover multiple units and/or cover large geographical areas; such a requirement would be particularly impractical in rural areas. Commenters also stated that the proposed timeframe is unrealistic for MSWs carrying large patient caseloads. Other commenters suggested 20 days would not be enough time for all team members to participate, specifically those who work in part-time positions. Other commenters were concerned that the 20-day timeframe was inadequate for complete evaluation of all assessment criteria, including nutritional status, physical activity level or vocational or physical rehabilitation status. Commenters offered many suggestions regarding the deadline to complete the assessment. Some suggested alternatives that included time periods ranging from 30 to 60 days, and assessment timelines based on the number of dialysis sessions ranging from 6 to 13 sessions. Other suggestions included a split assessment with part 1 completed within 20 to 30 days or 9 sessions, and part 2 at 3 months. Commenters also suggested completing

the assessment and plan of care within 30 days, or allowing medical justification for the assessment time period to exceed 30 days.

Response: We agree with many of these commenters. A comprehensive initial assessment is the basis for an effective plan of care and for achieving desired patient outcomes. We also recognize dialysis facilities may have difficulties when conducting assessments on patients who face a wealth of challenges, including frequent hospitalizations; however, these difficulties should not outweigh the need to complete a comprehensive initial assessment within a reasonable period of time. If a patient has received dialysis for a 1-month period, or 13 hemodialysis treatments, that in-center patient has likely been physically present in the facility for at least 40 hours. We are therefore revising the deadline. We believe that, by allowing facilities 30 days or 13 hemodialysis treatments to complete the assessment (whichever is later), we are providing a reasonable timeframe for every member of the interdisciplinary team to assess the patient before developing the treatment plan. We have modified the final rule at § 494.80(b)(1) ''Patient assessment'' and at § 494.90(b)(2) ''Patient plan of care'' so that the interdisciplinary team has a timeframe of 30 days or 13 outpatient hemodialysis sessions, whichever is later, for completion of the assessment and implementation of the plan of care. Because some assessment criteria may take a longer period of time to evaluate, such as nutritional status and vocational and physical rehabilitation status, we expect that these areas would be more fully covered during the follow-up comprehensive reassessment that we are requiring for stable patients within 3 months after the completion of the initial assessment, as required at § 494.80(b)(2) and discussed below.

Comment: We received more than 50 comments on the proposed 3-month follow up comprehensive reassessment for dialysis patients. Half of the commenters supported the requirement, arguing that a follow-up assessment is necessary in order to evaluate the level of patient adherence to the treatment plan, determine whether the care plan is effective, and track the patient's overall adjustment to dialysis. One commenter supported the 3-month timeframe, stating, ''many patients are too sick and/or depressed to participate in life-altering decisions regarding their care and treatment'' during the initial assessment. Two commenters supported the 3-month reassessment but suggested that it be a ''focused'' reassessment used exclusively to determine whether changes would be needed in the plan of care.

The other half of the commenters opposed the proposed requirement, stating that the requirement was redundant, burdensome and of ''questionable value.'' Some commenters suggested that follow-up reassessments be completed after 6 months to relieve burden, especially in rural areas. Some commenters suggested the 3-month reassessment timeframe would be impractical because many new patients do not stabilize for the first 6 months of dialysis. Some commenters suggested that we modify the final rule to require a follow-up reassessment within 36 hemodialysis treatments rather than within the proposed 3-month timeframe. One commenter suggested that monthly progress notes would eliminate the need for the 3-month follow-up reassessment.

Response: We recognize that patients who are new to dialysis need time to adjust and adapt to the treatment. Initially, patients may experience anxiety while learning self-care skills, modifying their diet, changing their behavior, and perhaps dealing with access issues. The 3-month comprehensive reassessment enables the interdisciplinary team to evaluate, among other things, the patients' adherence to treatment plans; the accuracy of the patient's plan of care; and the patient's educational needs, rehabilitation needs, nutritional needs, quality of life and adjustment to the dialysis regimen. We recognize the burden this 3-month reassessment places on the interdisciplinary team. However, the burden has been significantly reduced in this final rule by eliminating the previous requirement that the team review the care plans and associated patient assessments of all *stable* patients every six months, which was previously required in part 405, subpart U. This rule does not preclude facilities from performing an assessment 6 months after the initial assessment, if they desire.

Comment: We received several comments regarding the assessment of the efficiency of the treatment prescription for hemodialysis and peritoneal dialysis. One commenter believed that proposed § 494.80(c) merely repeated § 494.90(a)(1) and recommended that the final rule combine the two.

Response: We disagree with the commenter regarding redundancy of the ''Patient assessment'' and ''Patient plan of care'' provisions. The requirement at § 494.80(c) mandates the frequency of assessment of the effectiveness of the treatment prescription for both hemodialysis patients and peritoneal dialysis patients, while § 494.90(a)(1) requires the interdisciplinary team to develop a patient plan of care to address the dose of dialysis and provide the necessary care and services to achieve and sustain the prescribed dose of dialysis. These conditions are also in keeping with our payment regulations (Medicare Claims Processing Manual, Chapter 8, 50.1) (*http://www.cms.hhs.gov/manuals/IOM/list.asp*).

Comment: One commenter suggested § 494.80(c), which addresses the frequency of dialysis adequacy monitoring, be modified to require facilities to ''monitor fluid status.'' The commenter cited a study that argued Kt/V levels did not correlate with mortality or morbidity and that better methods of measuring intravascular volume and related blood pressure changes are needed.

Response: Proposed § 494.80(a)(2) would require the interdisciplinary team to evaluate fluid management needs. We have retained this provision in this final rule. We have also added, ''manage the patient's volume status'' at § 494.90(a)(1), under the ''Patient plan of care'' condition.

Comment: One commenter proposed that a Kt/V measurement should be done every 2 months and that urea reduction rate could be used in alternate months. The commenter argued that Kt/V measurement was excessively burdensome for both patients and staff.

Response: Monthly monitoring of dialysis adequacy for hemodialysis patients is consistent with current dialysis facility practice and Medicare payment policies. We are not making any change to § 494.80(c) based on this comment.

Comment: One commenter suggested the final rule be reworded at § 494.80(d)(1) to clarify what kind of annual reassessment must be completed, as required in this condition.

Response: We appreciate the comment; however, § 494.80(d) states clearly that the reassessment must be completed in accordance with the standards specified in paragraphs 494.80(a)(1) through (a)(13). We do not believe that further clarification is needed. The proposed language has been retained in the final rule.

Comment: We received a comment that suggested the final rule require ''monthly reassessments for all stable patients using a simple tool.'' Another commenter remarked that annual assessments for stable patients are not enough and that co-morbid conditions

may necessitate assessments that are more frequent.

Response: While we are requiring stable patients to be comprehensively reassessed at least annually, we recognize that appropriate monitoring of patients may require ongoing assessments in various areas. We expect that patients would be monitored on an ongoing basis and expect progress notes would be entered in the patient's medical record as needed. The interdisciplinary team has the flexibility to use its professional judgment regarding on-going monitoring methods as appropriate for their patients, as specified in the patient plan of care.

Comment: We received many comments regarding the monthly reassessments for unstable patients. Many commenters requested we clarify what we meant by ''unstable patients'' and provide a definition for ''unstable'' in the final rule, as well as identify what the reassessment for such patients would specifically need to include. A few commenters said ''unstable'' should be clarified to state that all four criteria listed at § 494.80(d)(2)(i) through § 494.80(d)(2)(iv) must be present at once in order for the patient to be considered ''unstable.'' Another commenter suggested § 494.80(d)(2)(iv) be modified to add ''and/or'' so that presence of any one of the three criteria listed in (iv) (poor nutritional status, unmanaged anemia, and inadequate dialysis) would deem the patient ''unstable.'' A couple of commenters recommended modifying the final rule to allow each facility to provide its own definition of ''unstable'' as part of their facility policies.

A few commenters recommended that nutritional status should not be linked with anemia management or dialysis adequacy at § 494.80(d)(2)(iv). One commenter suggested nutritional status should stand alone, as should unmanaged anemia. One commenter recommended the final rule clarify ''unmanaged anemia'' and defer to the most recent KDOQI anemia clinical practice guidelines. A couple of commenters asked whether the requirement at § 494.80(d)(2)(iv) required all three criteria to be present simultaneously. Another commenter strongly recommended that the final rule clarify that all three parameters of (iv), poor nutritional status, unmanaged anemia, and inadequate dialysis be present to justify the determination that the patient was ''unstable.'' Another commenter suggested that ''poor nutrition'' should not be deemed a marker for instability, because facilities have minimal influence over poor nutritional status, which is a chronic problem.

We received many comments from social workers suggesting additional assessment criteria which would indicate that patients were ''unstable,'' and therefore, trigger the requirement for monthly reassessments. These suggestions included hemoglobin less than 11 gm/dL for more than 8 weeks, frail patients, reduced physical and mental component summary scores, physical debilitation, diminished emotional well-being, loss of employment, intradialytic symptoms, blood pressure, use of certain types of hypertensive medications, dry weight changes, chronic heart failure admissions, depression, and significant change in psychosocial needs.

Response: The comprehensive reassessment process can be seen as part of a cycle. Through the use of patient assessment, accurate and timely patient information is reflected in the plan of care. As the assessment changes, the plan of care must be revised accordingly. Once the patient is determined to be unstable, a monthly reassessment is necessary to update the plan of care appropriately. Existing regulations at part 405, subpart U required the professional care team to review the plan of care for an unstable patient at least monthly. The proposed rule aimed to add clarification and guidance as to how to classify a patient as unstable, and we specified at § 494.80(d)(2) the minimum criteria necessary to consider a patient unstable. A patient is unstable if he or she has had extended or frequent hospitalizations, or a marked deterioration in health status, or a significant change in psychosocial needs. In addition, a patient is unstable when he or she is determined by the interdisciplinary team to have poor nutritional status, unmanaged anemia, and inadequate dialysis concurrently. Unstable patients must be reassessed in accordance with § 494.80(d), which specifies use of the assessment criteria at § 494.80(a)(1) through § 494.80(a)(13). While a comprehensive reassessment for patients classified as unstable is required, it is possible that patient status may not change in all parts of the assessment. Patient status, whether changed or unchanged, should be clearly reflected in the new assessment.

This final rule allows facilities the flexibility to use their professional judgment to develop more stringent policies regarding the definition of ''unstable'' patient based on their unique patient population and patient characteristics and to insert additional assessment criteria, such as those offered by the commenters.

Comment: One commenter was concerned that facilities have previously developed their own definitions of ''unstable patient'' that ultimately classify very few patients as unstable. The commenter suggested that this trend should be discouraged.

Response: The proposed rule at § 494.80(d)(2) aimed to specifically address these concerns by establishing minimum criteria by which to identify patients considered ''unstable.'' As stated above, facilities continue to have the flexibility to develop their own policies and procedures with regards to how they define ''unstable'' patient, as long as that definition meets the minimum requirements put forth in this final rule.

Comment: One commenter remarked that it is unclear how monthly reassessments of stable patients coordinate with the ''monthly unstable care plans.'' The commenter questioned if patients would be considered ''unstable'' if care plan goals were not met.

Response: Patients are considered unstable if they meet any of the criteria listed at § 494.80(d)(2). Implementation of the initial and revised plan of care is discussed in the ''Patient plan of care'' section of the preamble below. The implementation of an updated plan of care, which results from a new patient assessment, is addressed at § 494.90(b)(2).

c. Patient Plan of Care (Proposed § 494.90)

We proposed a new condition for coverage entitled ''Patient plan of care,'' which would require the interdisciplinary team to develop and implement a written, individualized comprehensive plan of care that specified the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and would have included measurable and expected outcomes and estimated timetables to achieve these outcomes. Proposed components of the patient plan of care included dose of dialysis, nutritional status, anemia, vascular access, transplantation status, and rehabilitation status. This proposed condition for coverage called for documentation of a plan for transplantation, or, in the alternative, the patient's decision not to accept transplant referral, or documentation of the reason for the patient's nonreferral. We proposed implementation of the plan of care within 10 days of completion of the initial or updated patient assessment. We would no longer require the separate short-term and

long-term care plans required, biannually and annually, respectively, by part 405, subpart U of our rules. This proposed condition for coverage would also have required that the facility would have to adjust the plan of care if the expected outcome was not achieved. We proposed that the dialysis facility would have to ensure that all dialysis patients were seen by a physician providing the ESRD care at least monthly, that this visit was documented, and occurred periodically while the patient was receiving dialysis. Under the proposed rule, the interdisciplinary team would have been required to track the results of each kidney transplant center referral, monitor patient status, and communicate with the transplant center at least quarterly. The proposed ''Patient plan of care'' condition included a patient education and training standard, which would have required, as applicable, education and training for patients and facility members or caregivers on the aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation. Further discussion of § 494.90 provisions may be found in the proposed rule (70 FR 6205).

We received more than 100 comments regarding the ''Patient plan of care'' condition. The majority supported the proposed ''Patient plan of care'' condition.

Comment: Dozens of commenters made recommendations regarding the composition of the interdisciplinary team that would develop the plan of care. Several commenters agreed with the proposed interdisciplinary team definition and some suggested that the team definition wording at § 494.80 be carried over to § 494.90. Two commenters supported excluding the medical director from the interdisciplinary team, while others thought the medical director team role should be retained from part 405, subpart U, or changed to a team supervisory role. Commenters disagreed as to whether the home dialysis physician role on the interdisciplinary team should have been deleted in the proposed rule. One commenter stated that some patients need a physical therapist and psychiatrist on the interdisciplinary team. Another two commenters stated it would be ideal to have a vascular access coordinator on the interdisciplinary team, although this could be a cost issue. A number of commenters suggested that a pharmacist be included as a member of the interdisciplinary team.

Response: We are specifying the multidisciplinary team composition in § 494.90 of the final rule by cross-referencing the wording used at the beginning of § 494.80 (introductory text). The final rule language at § 494.80 reads as follows: ''The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian * * *.'' We do not agree there is a need to require that the medical director, the home dialysis physician or other professional staff be members of the interdisciplinary team. The medical director role has been strengthened at § 494.150 so that the medical director is responsible for the delivery of patient care and outcomes in the facility. In this role, the medical director may choose whether to be a member of the interdisciplinary team and participate in interdisciplinary team activities. The patient's right to be informed about home dialysis was strengthened both in the ''Patients'' rights' (§ 494.70(a)(7)) and ''Patient assessment'' (§ 494.80(a)(9)) conditions, so that the patient could be informed of home dialysis options whether or not a home dialysis physician was included in the multidisciplinary team.

Patients needing physical therapy or psychiatric services should be referred for these services, as we would not necessarily expect the dialysis facility to employ these professionals as staff members. Facilities may want to have a vascular access coordinator. While we encourage this, we will not mandate it, as dialysis facilities should have the flexibility to use other approaches and staff as interdisciplinary team members in ways that best meet the needs of their patient population.

We have addressed comments related to a pharmacist's role at § 494.140 ''Personnel qualifications'' discussion below. We have defined in regulation the minimum staff that must be part of the team in order to meet basic dialysis patient care needs. This regulation does not preclude the use of an expanded interdisciplinary team, and dialysis facilities always have the flexibility to add staff to the interdisciplinary team.

Comment: Many commenters agreed with the proposed modification to the provision specifying the role of the transplant surgeon in the development of the patient's plan of care. A few commenters opposed eliminating the requirement that the transplant surgeon's signature be part of the plan of care, while some of the comments supported transplant surgeon involvement via a designee.

Response: The previous ESRD conditions required a transplant surgeon to participate in the long-term care program planning process. The interpretive guidelines used by surveyors provided that a transplant surgeon designee could be used, and this designee was often a transplant nurse or the attending dialysis nephrologist. We proposed that while the transplant surgeon would not be a required member of the interdisciplinary team, the team must use criteria from the transplant center to determine whether a patient was a transplant referral candidate. The majority of comments supported this approach; therefore, we will retain the proposed requirement, which does not include the transplant surgeon. We are requiring use of transplant center criteria for assessing potential transplant candidates (§ 494.80(a)(10)), including transplantation status, as a component of the patient plan of care (§ 494.90(a)(7)(ii)), and the transplantation referral tracking standard (§ 494.90(c)).

Comment: A few commenters recommended further clarification of the term ''current evidence-based community-accepted standards'' at proposed § 494.90, and some suggested that this be defined as the K/DOQI standards. Some felt that the use of the word ''community'' could allow wide variation throughout the country as different communities embraced different standards, some of which might not be evidence-based.

Response: The first provision of the proposed ''Patient plan of care'' condition required that the plan of care ''include measurable and expected outcomes and estimated timetables to achieve these outcomes.'' The outcomes specified in the ''Patient plan of care'' condition must allow the patient to achieve ''current evidence-based community-accepted standards.'' The phrase ''community-accepted standards'' was intended to mean nationally-accepted professional standards of practice accepted by the renal community at large. ''Community'' was not intended to mean small local geographic groups of people having standards unique to that group or area. We have modified § 494.90 to better clarify our meaning and have replaced the phrase with new wording, ''current evidence-based professionally-accepted clinical practice standards.''

Comment: One commenter recommended that a phrase be added to the first paragraph in § 494.90 of the ''Patient plan of care'' condition to clarify that community-accepted standards must reflect joint decision-making between the patient and the

interdisciplinary team to individualize optimal goals for patient.

Response: We have designated the patient as a member of the interdisciplinary team (if the patient desires) and expect that the patient would share in the goal-setting team decisions. We do not agree there is a need to modify the provision as suggested.

Comment: We received a few comments opposing the plan of care timetables in § 494.90 because commenters believed that the patient response to therapy would be impossible to predict. A commenter recommended that we clarify that the facility would not be responsible for setting and meeting timetables for meeting the patient's medical and psychosocial needs; the commenter argued that such policy would constitute micromanagement that added no value to patient care. The commenter stated there was no matrix (or method) in the literature that allowed prediction of a patient's response time. A commenter stated it was beyond the scope of practice for a dialysis center to set a timetable for patients to achieve ''measurable and expected outcomes,'' especially those with ESRD for more than 1 year, since problems are complex and professionals cannot predict how long they will take to solve.

Response: It is common practice for a plan of care to include the following elements for each patient problem or medical/nursing need identified: Goal, action plan, and target date to either meet the goal or check the patient's progress toward that goal. We recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control, such as demographics, the systemic effects of the underlying renal disease, and patient preferences and adherence. Further, we recognize that health care delivery is dynamic and that not all patients may be achieving, for example, the expected delivered dose of dialysis at any specific point in time. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation, and any opportunities for improvement in the patient's health should be identified. Care plans commonly include time frames and care plan goals are more meaningful when the facility identifies a target date to achieve a goal or reassess the patient's status. Therefore, we have adopted the provision as proposed.

Comment: A few commenters were concerned about the patient's ability to refuse to comply with the plan of care, which could nullify team efforts to meet the plan of care goals. One commenter suggested that CMS allow facilities to demonstrate that a patient's failure to comply with the treatment regimen justified failure to meet criteria within the plan of care. Another commenter recommended that the dialysis adequacy regulatory language be more flexible to account for patients who terminated treatment early, despite team intervention.

Response: These patient compliance concerns were discussed in the February 4, 2005 proposed rule (70 FR 6209). As noted above, we recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation for the patient's inability to achieve the desired outcomes, and the team must identify any opportunities to improve the patient's health. This clarification has been added to the final rule at § 494.90(b)(3).

The patient is part of the team and should be working to meet the plan of care goals. We are requiring the interdisciplinary team to adjust the patient's plan of care to achieve revised goals if initial outcomes are not achieved. If a therapeutic goal is not met due to patient non-compliance, then interventions must be implemented to achieve better patient compliance. If reasonable measures have been taken and lack of patient compliance still prevents the goal from being met, the facility must document the interventions, the results of the interventions, and the plan to preserve patient health and safety within the limitations of poor patient compliance. Patient choices that create barriers to meeting the targets should be documented and addressed to a reasonable extent by the team. We are not requiring patients to meet plan of care goals as a condition for coverage of facility services.

Comment: We received several comments regarding § 494.90(a)(1), ''Dose of dialysis.'' Most commenters recommended using the K/DOQI adequacy standards for this requirement, and several, including the National Kidney Foundation, recommended that we add the specific K/DOQI guidelines as minimal standards to the plan of care requirements. Some commenters suggested we include patient volume status (that is, a measurement of body fluid removal) in the adequacy requirement. A few commenters opposed establishing specific targets in the plan of care requirement because they stated that would be too prescriptive and rigid, future advances may outdate targets, facilities would have to risk-adjust, and not all patients would be able to achieve 100 percent of the targets. Commenters suggested alternatives, including using guidelines of practice or consensus standards (like AAMI and CDC guidelines), and encouraging, but not requiring, that specific targets be met.

Response: The majority of commenters supported adding language to § 494.90(a)(1) to specify that the K/DOQI dialysis adequacy guidelines must be targeted for all patients. We agree that the KDOQI adequacy guidelines are the current evidence-based professionally-accepted clinical practice standards. We have added to § 494.90(a)(1) a reference to the 2006 KDOQI targets (that is, Kt/V of 1.2 for hemodialysis or weekly 1.7 for peritoneal dialysis); we are also allowing dialysis facilities to meet ''an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis that would allow for future advances in dialysis adequacy measurement.

While there may be a need to risk-adjust when measuring facility-wide performance, the ''Patient plan of care'' condition addresses individual patient care and allows for unique patient characteristics to be considered in the development of the plan of care goals, alleviating the need to risk-adjust. As discussed previously in this preamble, if a patient does not meet the plan of care goals, appropriate interventions must be employed and if the patient still cannot meet the goals, a proposed explanation of why goals were not met must be entered into the plan of care. The rule does not require patients to meet plan of care goals as a condition for coverage, but facilities must demonstrate that they are attempting to meet those goals to the extent possible.

Volume control, important to blood pressure management and cardiac health, is an essential component of dialysis care that requires ongoing attention from the care team. Therefore, we are incorporating it into the ''dose of dialysis'' plan of care element. We have modified § 494.90(a)(1) to read, ''The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.''

Comment: We received many comments regarding § 494.90(a)(2), the nutrition component of the ''Patient plan of care'' condition. Several commenters supported the inclusion of nutrition as a plan of care element. Two commenters objected to the use of serum albumin as a marker of nutritional status, saying it was a poor indicator. Other nutritional indicators favored by commenters include subjective global assessment (SGA), normalized protein catabolic rate, weight, height and appetite, body mass index (BMI), body surface area, lab values, prealbumin and cholesterol, and the use of multiple nutrition measures, and urea kinetic modeling. One commenter recommended that the nutrition plan of care include target outcomes to meet/exceed the K/DOQI clinical practice guidelines. Another commenter stated that if the target albumin level was not met, alternate indicators (adequate dialysis and normalized protein catabolic rate) should be allowed, as albumin is affected by inflammation and chronic disease.

Response: Serum albumin levels are closely linked to morbidity and mortality. According to the K/DOQI clinical practice guidelines (CPG), serum albumin is a valid and clinically useful measure of protein-energy nutritional status in maintenance dialysis patients, even though it may fall in the presence of inflammation and stress. Several commenters supported inclusion of BMI or body weight as a required nutritional indicator. Dialysis patients are weighed at least 6 times per week and inclusion of body weight does not increase burden to facilities. A monthly assessment of body weight allows facilities to calculate BMI (when the height is known), and track changes in body mass.

We agree that the use of multiple markers is necessary to adequately assess nutritional status. For example, the KDOQI CPG encourages facilities to perform SGAs bi-annually as they are considered to be a valid and clinically useful measure of protein-energy nutritional status in dialysis patients (CPG 9). The CPGs also state that catabolic rate or protein equivalent of total nitrogen appearance are valid and clinically useful measures of net protein degradation and protein intake in maintenance dialysis patients (K/DOQI CPG 8). Serum cholesterol and serum prealbumin are valid and clinically useful markers of protein-energy nutritional status in hemodialysis patients (K/DOQI CPG #4 & 6). Facilities may use additional markers and assessments as deemed appropriate by the registered dietitian and physician. We are retaining in § 494.90(a)(2) the requirement that the interdisciplinary team monitor serum albumin (a visceral protein) and body weight at least monthly as indicators of nutritional status. In addition, we are adding language to § 494.90(a)(2) to require that ''Additional evidence-based, professionally-accepted nutrition indicators may be monitored, as appropriate.''

Comment: Some commenters objected to the language in § 494.90(a)(2) that requires the interdisciplinary team to ''provide the necessary care and services to achieve and sustain an effective nutritional status,'' because Medicare does not cover nutritional supplements. One suggestion was to change the wording so that the facility ''monitors'' the patient's nutritional status. Another commenter suggested that facilities be allowed to give out supplements without being cited for providing beneficiaries with an impermissible ''enticement.''

Response: Facilities must provide nutrition assessment, counseling, and ongoing monitoring, and must review with the patient monthly laboratory blood test results relating to the dialysis patient's nutritional intake and nutritional status. The provision of nutritional supplements by the dialysis facility is not expected or required. To clarify this, we have revised the wording in § 494.90(a)(2) to read, ''provide the necessary care and counseling services * * *.'' Depending on the facts and circumstances of a particular case, a gift of nutritional supplements by a provider to a beneficiary of a federal health care program could violate the prohibition on beneficiary inducements (section 1128A (a)(7) of the Social Security Act), 42 U.S.C. § 1320a–7a(a)(7)) or the anti-kickback statute (1128B(b), 42 U.S.C. § 1320a–7b(b)). Questions regarding whether a particular arrangement may violate these statutes should be directed to the HHS Office of Inspector General.

Comment: We received many comments regarding the anemia management component of the ''Patient plan of care'' condition. While there was some support for § 494.90(a)(3) (now § 494.90(a)(4)) as written, many commenters recommended that we require that the KDOQI anemia CPGs be plan of care targets. One commenter urged that we consider having the healthcare team consider the new 2006 KDOQI CPGs as they develop the plan of care. One commenter stated the hematocrit and hemoglobin targets of 33.0 percent and 11 g/dl were too low and that a hematocrit of 36 percent should be the minimum target.

Response: The proposed rule included references to the KDOQI minimum target hemoglobin and hematocrit levels of 11 g/dL and 33 percent, respectively, at proposed § 494.90(a)(3) (now § 494.90(a)(4)). Although new 2006 KDOQI anemia CPGs modified the 2000 version, target hemoglobin and hematocrit CPGs continue to be evaluated as new scientific evidence emerges. We note that the FDA issued a November 16, 2006 alert to provide new safety information for erythropoiesis-stimulating agents based on information reported in two clinical studies in patients with chronic renal failure treated with an unapproved regimen of erythropoiesis-stimulating agent(s). In addition, on March 9, 2007, the FDA issued a stronger warning, entitled a ''Black Box'' warning (see *http://www.fda.gov/bbs/topics/NEWS/2007/NEW01582.html*). Clinical research data continue to emerge and the FDA continues to analyze this information.

In addition, the NKF convened a KDOQI workgroup in 2007 to review new anemia management information and develop an update to the NKF–KDOQI anemia management guidelines. The revised anemia management guidelines were published on September 10, 2007 (see *http://www.kidney.org/professionals/kdoqi/pdf/KDOQI_finalPDF.pdf* or the *American Journal of Kidney Diseases*, *Vol. 50(3)*, *September 2007:* pp. 471–530) and included one clinical practice recommendation and one clinical practice guideline for dialysis and nondialysis patients with chronic kidney disease receiving erythropoiesis-stimulating agent(s) therapy. They are as follows:

1. ''The selected Hgb target should generally be in the range of 11.0 to 12.0 g/dL;'' (clinical practice recommendation) and

2. ''The Hgb target should not be greater than 13.0 g/dL'' (clinical practice guideline).

The KDOQI recommendation and guideline also discussed the ''need to maintain flexibility in medical decision making given the breadth of variability between patients' individual needs, values, functional status, disease burden, prognosis, and responsiveness to erythropoiesis-stimulating agent(s) therapy.''

As such, the appropriate minimum hemoglobin/hematocrit targets for dialysis patients may vary. Therefore, the interdisciplinary care team must assess each patient to identify his or her unique needs for anemia management,

considering renal community evidence-based professional standards of practice, such as those published by the FDA or the NKF's KDOQI guidelines.

Because the current science is evolving and it is probable that more information regarding dialysis patient anemia management needs and hemoglobin and hematocrit values will be forthcoming, we have not included hemoglobin/hematocrit target levels in the final rule. The plan of care must, however, reflect that individual patient anemia management is consistent with current renal community evidence-based professional standards of practice.

Comment: A few commenters stated that the proposed requirements for anemia management in § 494.90(a)(3) are not consistent with payment policy, since physicians could not start Epogen until hematocrit was below 30 percent. One commenter stated that the proposed requirement would push hematocrits above 36 percent and add to reimbursement problems (when the hematocrit goes above 37.5 percent). Another commenter noted that payment affects hemoglobin/hematocrit targets.

Response: The final rule does not specify a specific hemoglobin level. This change allows physicians and clinicians managing the patient to determine the hemoglobin/hematocrit level appropriate for each patient based upon the patient's comorbidities and clinical characteristics. We note that the FDA labeling for erythropoiesis-stimulating agent(s) (*http://www.fda.gov/cder/foi/label/2007/103234s5122lbl.pdf*) does not specify specific target hemoglobin, but warns prescribers to use the lowest dose of erythropoiesis-stimulating agent(s) to gradually increase the hemoglobin levels sufficient to avoid the need for red blood cell transfusion. In addition, the anemia management section in the final regulation decreases the focus on erythropoiesis-stimulating agent(s) and instead, at § 494.90(a)(4), focuses on the patient's overall anemia management needs: ''The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The dialysis facility must conduct an evaluation of the patient's anemia management needs.'' This evaluation would determine whether the patient would benefit from supplemental iron, erythropoiesis-stimulating agent(s), blood transfusions, or other medical interventions.

Comment: One commenter stated hemoglobin levels should be used, and not hematocrit levels, as the hemoglobin levels are more accurate and are not affected by blood volume.

Response: The KDOQI CPGs do include a preference for hemoglobin readings over hematocrit levels and many dialysis facilities have been focusing on hemoglobin levels when managing anemia, rather than hematocrit levels. Some facilities multiply the hemoglobin by three to arrive at a comparable hematocrit level. Currently, Medicare payment systems allow both hematocrit and/or hemoglobin levels to be reported. Therefore, to allow flexibility in this health and safety rule, we will allow use of either the hemoglobin or the hematocrit.

Comment: A commenter suggested that we remove specific references to ''erythropoietin'' to allow for possible future advances in technology. Another commenter recommended that anemia management be individualized without the use of a range of parameters (that is, a sliding scale) necessary for delivering medication.

Response: We agree with the commenter that a more general term should be used rather than ''erythropoietin.'' We have revised § 494.90(a)(4) by removing the term ''erythropoietin'' and adding the term ''erythropoiesis-stimulating agents'' to allow for new technology developments.

Standing physician orders are used in some dialysis units to improve efficiency and responsiveness to changes in the patient's anemia markers. We do not agree that there is a need to prevent facilities from using these types of tools to manage anemia in dialysis patients, provided the medication dose administered and lab tests obtained are approved by the physician and are appropriate for the individual patient. The physician is responsible for ordering medications and laboratory tests and may or may not prescribe standing orders or the use of an algorithm. However, medication type and quantities billed to Medicare must be consistent with the physician's orders.

Comment: We received many comments regarding the vascular access component of the patient plan of care. While there was support for including a vascular access plan of care component, several commenters requested clarification of what type of vascular access monitoring would be required. Some noted that a clinical physical exam, which included observation, auscultation and palpation, would be different from mechanical surveillance that could include transonic flow measurements. The latter, according to commenters, would require a change in payment policy. One commenter recommended referencing K/DOQI Vascular Access CPGs #10, 11, and 12 for specifics regarding monitoring, while the NKF suggested that monitoring include a clinical physical exam at least monthly to detect problems or persistent abnormalities that should prompt referral for access angiography. Another commenter asked what CMS meant by its proposed requirement that facilities ''provide necessary care and services to sustain vascular access,'' and stated that a facility could only evaluate, monitor, recommend, educate, and refer, but not provide all the services and care that might be needed.

Response: The vascular access monitoring that must be included in the patient plan of care is limited to a clinical physical exam, and we expect that persistent abnormalities should prompt a referral, which is in keeping with the K/DOQI Vascular Access CPGs. This physical monitoring includes clinical observation, auscultation, and palpation of the access. Additional information can be gained by comparing the patient's expected Kt/V (given the current dialysis prescription) to the actual Kt/V. When the actual Kt/V is significantly lower than the expected Kt/V, the facility should investigate reasons for the discrepancy, including the patency of the vascular access. The proposed ''necessary care and services'' provision in § 494.90(a)(4) of our regulation would be limited to those vascular access actions that are reasonably expected within the dialysis facility, (generally, vascular access monitoring, and appropriate and timely referral). We have modified proposed § 494.90(a)(4), now § 494.90(a)(5), which now reads in part, ''The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access.'' The current composite payment includes payment for clinical access monitoring. When intervention is indicated, Medicare covers certain diagnostic procedures.

Comment: A commenter stated that the plan of care should address issues related to vascular access outcomes and the RN should be responsible for access, initiating treatments and monitoring care. The commenter also suggested that vascular access treatment should be restricted to RNs or trained LPNs, because surgeons often complain of vascular access problems in patients under their care, which they believe is related to inadequate vascular access training and care.

Response: We appreciate the comment, however, it is not practical to limit cannulation and all access care to

RNs and trained LPNs. In many units, PCTs perform vascular access tasks under the direction of the licensed nursing personnel. We have strengthened patient care dialysis technician certification and training requirements at § 494.140(e). Only PCTs with proven cannulation competency should be inserting hemodialysis needles, under the direction of the RN.

Comment: Two commenters suggested that we require a facility to document the reason a fistula is not being used to provide vascular access, as well as when applicable, a plan to place an arteriovenous fistula in eligible patients.

Response: Current standards of practice recognize the health and economical benefits of arteriovenous fistulas over catheters or grafts used for hemodialysis. Vascular accesses must be patent over long periods of time and efforts should be directed towards obtaining and maintaining the most beneficial access type possible for each patient. While not all patients may be able to obtain a viable arteriovenous fistula, which generally lasts significantly longer than other access types, each hemodialysis patient should be assessed for possible arteriovenous fistula placement. To ensure adequate care planning for arteriovenous fistulas, we have added a phrase to the vascular access plan of care component at § 494.90(a)(5), to require the facility to evaluate ''whether the patient is a potential candidate for arteriovenous fistula placement.'' The interdisciplinary team must enter documentation into the medical record to demonstrate that this requirement has been met; this documentation may include reasons why a fistula is not being used in a particular patient's case.

Comment: A commenter recommended that evaluation of the hemodialysis patient for the appropriate vascular access type should be removed from the ''Patient plan of care'' condition, as this would be a nephrologist's responsibility. Another commenter asked whether the vascular surgeon's determination of what kind of access the patient needs (per K/DOQI Vascular Access CPG #10) would meet the patient plan of care requirement to evaluate the patient for the appropriate vascular access type.

Response: The interdisciplinary team, led by the nephrologist, must consider any vascular access determinations made by the vascular surgeon, but the team may not abdicate its role of promoting the placement of the safest access type possible for their patient.

Comment: Several commenters did not agree with the proposed role of the dialysis facility interdisciplinary team as related to transplantation referral. One commenter stated that transplant referral should not be in the plan of care condition because it is a transplant center responsibility. Several commenters stated that accountability for transplant referral rests with the nephrologist. Two commenters stated that the plan of care should simply include documentation of the patient's transplant status. Another commenter stated that if an eligible patient declines a transplant referral, this should be documented in the plan of care as an informed decision.

Response: The proposed requirement regarding the role of the dialysis facility interdisciplinary team in the transplant referral process originated with the existing requirement in part 405, subpart U (§ 405.2137(a)) that required the completion of a long-term care program that addressed the selection of a suitable treatment modality (that is, dialysis or transplantation) and dialysis setting for each patient. The intent was to ensure each patient received the appropriate modality of care and the appropriate care within that modality. The professional team, not solely the nephrologist, has historically been accountable for developing a plan of care that addresses whether the patient was a transplant candidate.

We proposed to clarify what would have to be included in the plan of care to include the plan for transplantation if the patient accepted the referral, the patient's decision if an eligible patient declined the transplantation referral, or reasons that the patient was not being referred as a transplantation candidate, as determined during the assessment. Many long-term care programs across the country address these issues currently and it is reasonable that these topics be addressed in any valid plan of care.

Facilities may want to develop their own policy identifying the role of the interdisciplinary team members in performing the actual transplant referral. The team member may be the nephrologist or another team member. In any case, the facility will be held accountable for ensuring that appropriate modalities are employed in treating chronic kidney disease patients. We are adopting the proposed transplant referral requirements at § 494.90(a)(7)(ii) in this final rule.

Comment: We received many comments regarding the proposed rehabilitation component of the ''Patient plan of care'' condition at § 494.90(a)(6), which read, ''The interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years).'' Many commenters supported inclusion of rehabilitation in the plan of care, while one commenter disagreed. Many commenters stated that the provision of necessary care and services for rehabilitation was beyond the scope of services offered by the dialysis facility. A few of these commenters stated that a requirement to provide rehabilitation services would constitute an unfunded mandate, and some commenters noted that social workers are not trained to do rehabilitation. One commenter recommended deletion of § 494.90(a)(6) (now § 494.90(a)(8)) and suggested that rehabilitation referrals be addressed under social services. Many commenters suggested a rewording of the requirement to be more consistent with the capabilities of the dialysis facility, and provided this wording: ''The interdisciplinary team must assist the patient to achieve appropriate level of rehabilitation and refer the patient to necessary services.''

Response: We concur with comments that the provision of the necessary care and services for rehabilitation is beyond the range of services offered by the majority of dialysis facilities. Physical therapy, occupational therapy, and academic tutoring services (for example) cannot realistically be provided by the facility staff. Therefore, in response to comments, we have changed the wording of the ''rehabilitation status'' component, now at § 494.90(a)(8), to read, ''The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.''

Comment: A few commenters suggested that a staff person be identified who would be responsible for rehabilitation. One commenter suggested that the social worker has a major role while another commenter recommended that the medical director be responsible for ensuring that the team assist patients in rehabilitation and in making referrals.

Response: This final rule makes the interdisciplinary team responsible for the patient plan of care, including rehabilitation. Referrals may be made by the appropriate team member, which may be the physician and/or the nurse or social worker. The role of the medical director, as described in § 494.150, is to

be responsible for the delivery of patient care and outcomes in the facility; this would include rehabilitation outcomes.

Comment: One commenter suggested that rehabilitation referrals be made before starting dialysis, when there is the most potential for rehabilitation progress.

Response: While it may be desirable in some cases to provide a rehabilitation referral to the patient before the start of dialysis, this may not be possible because of patient illness associated with the symptoms of uremia, as well as issues related to payment for rehabilitation services.

Comment: A few commenters made suggestions regarding patient plan of care rehabilitation outcomes. One commenter stated that the final rule should clarify rehabilitation outcomes as broadly as possible, and success should be defined differently for each patient. Another commenter suggested adding sub-criteria for rehabilitation outcomes, since the proposed rehabilitation requirements were not measurable as written. A third commenter recommended that the optimum rehabilitation outcome would be to return the patient to his or her former occupation. Another commenter suggested that for pediatric patients, the rehabilitation goal should be to help the patients get a high school diploma/high school equivalency diploma (GED), and those interventions and any reasons for a decline in rehabilitation potential should be documented. A few commenters recommended that we add functional status to the rehabilitation section. One commenter stated that a shift in rehabilitation focus to functionality (activities of daily living) would be more appropriate, because the age of many patients would suggest that rehabilitation might not be realistic for them. Another commenter suggested that we make maximizing physical/mental functioning scores a rehabilitation goal, and aim to help patients maintain or improve vocational status as measured annually, using the employment categories on the CMS–2728 Medical Evidence form at *http://www.cms.hhs.gov/cmsforms/downloads/cms2728.pdf*.

Response: The introductory language to the ''Patient plan of care'' condition calls for the establishment of ''measurable and expected outcomes and estimated timetables to achieve these outcomes.'' This requirement will allow for individualized plans that lead to desirable outcomes for patients in all care areas listed in the patient's plan of care, including rehabilitation. Outcomes listed in the plan of care could include such targets as the return of the patient to a former occupation, attainment of a certification of education, return to normal activities within the patient's household, a certain level of functionality, or any another outcome that the team has determined is appropriate for the patient. Dialysis facilities have the flexibility to choose appropriate rehabilitation outcome targets, and we will not narrowly define them in this final rule.

Comment: Two commenters stated that any rehabilitation services to which a patient might be referred would be time-limited, and the patient may not reach his or her full rehabilitation level; they stated that the regulation would need to allow for this.

Response: If, while pursuing a rehabilitation goal, the team encountered limits on the patient's eligibility for services (for example, a limited number of physical therapy sessions), the plan, goals and timetables would need to be adjusted and the reason noted in the patient's record, as required at § 494.90(b)(3).

Comment: One commenter suggested that the care team be required to discuss with the patient whether to seek physical therapy, occupational therapy, counseling or vocational rehabilitation referrals.

Response: The patient is a member of the interdisciplinary team and, as such, should participate in team discussions regarding rehabilitation potential and goals.

Comment: A commenter recommended that we require a separate rehabilitation assessment initially and again every 3 to 6 months.

Response: The frequency of the rehabilitation assessment will be the same as the frequency of the comprehensive assessment, since this is a component of the assessment. (See § 494.80(b).)

Comment: We received many comments suggesting modifications to the components of the patient plan of care. Many commenters suggested that we add ''mineral metabolism/bone disease'' as a required component of the patient plan of care and referred to the NKF K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease (American Journal of Kidney Disease 42:S1–S202, 2003 (supplement 3)). Two commenters specifically suggested that we incorporate the K/DOQI CPGs for bone metabolism and disease in CKD patients.

Response: In response to comments and evidence supporting the importance of mineral metabolism management to the health of dialysis patients, we will add mineral metabolism to the list of required components of the plan of care by inserting the following language at § 494.90(a)(3): ''Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.'' Care and services are limited to those normally provided by the dialysis facility and would include appropriate referrals outside the dialysis facility when appropriate. Current professional practice standards include management of renal bone disease in dialysis patients, and we agree that mineral metabolism and bone disease management is well within the purview of the dialysis facility.

Comment: Many commenters supported adding a requirement for the interdisciplinary team to document in the medical record or plan of care the reasons a patient was not referred to home care, if applicable. Other commenters suggested adding medication therapy management and advance directives as additional plan of care components.

Response: The patient must be assessed at least annually for modality choice and level of participation in the dialysis care process. We agree with commenters that it is appropriate to have a plan of care component that corresponds with the treatment modality assessment required at § 494.80(a)(9) and § 494.80(a)(10), and it is appropriate to document the barriers to home dialysis. Therefore, we have added home dialysis to § 494.90(a)(7)(i), coupling home dialysis with transplantation status (proposed § 494.90(a)(5), now § 494.90(a)(7)(ii)) under a ''modality'' plan of care component. This new ''Modality'' plan of care provision reads, ''Modality: (i) *Home dialysis.* The interdisciplinary team must identify a plan for home dialysis or explain why the patient is not a candidate for home dialysis.'' This provision requires that, based on the most recent assessment, the plan of care must be revised to reflect modalities for which the patient is a candidate and the patient's preferences regarding modality.

Advance directives were added under the ''Patient's rights'' and ''Medical records'' conditions and therefore we will not require advance directives within the plan of care. Facilities have the flexibility to address advance directives within the plan of care when they deem it appropriate. Medication therapy management may be included within the action plan for various components of the plan of care.

Comment: A commenter suggested that the plan of care address cardiovascular health, and referred to the NKF K/DOQI Clinical Practice

Guidelines for Cardiovascular Disease in Chronic Kidney Disease (American Journal of Kidney Disease 45:S1–S154, 2005 (supplement 3)). The commenter stated that the NKF recommends that electrocardiograms be performed in all patients at the initiation of dialysis, once patients have achieved dry weight, and at 3 yearly intervals thereafter. In addition, appropriate blood pressure management is an important part of dialysis care and contributes directly to cardiovascular health.

Response: Cardiovascular disease is a concern for dialysis patients and is affected by renal bone disease, blood pressure, and fluid management as well as any other risk factors the patient may have. Dialysis patients often have a number of co-morbidities. The patient's medical history and co-morbidities are to be assessed as required at § 494.80(a)(1). Any problems identified by the comprehensive assessment are to be addressed in the patient plan of care as required at § 494.90. Since very little support came from commenters specifically to add a cardiovascular disease component to the plan of care, we have not added this requirement. However, dialysis-related cardiovascular health problems must be addressed in the plan of care whenever it is appropriate for an individual patient, as determined by the interdisciplinary team. Although core components of the plan of care are listed in this final rule, the interdisciplinary team has flexibility to add areas to the plan of care as identified in the comprehensive assessment.

Comment: We received many comments regarding whether a social services component should be required in the ''Patient plan of care'' condition. Most of the comments recommended that social services be part of the plan of care and referred to current research regarding social work services. Commenters stated that studies have shown that social work intervention improves patients' quality of life, their adherence to the ESRD treatment regimes and fluid restrictions, and improves medication compliance. Another example of improved outcomes provided by a commenter is that social work interventions can reduce patients' blood pressure and anxiety levels.

Commenters suggested including emotional and social well-being criteria in the final rule. Some commenters recommended including functional status measures that they believe correlate with better survival and hospitalization rates. Other commenters recommended requirements that would specify psychosocial criteria along with MSW tasks and responsibilities, and which would require that MSWs provide information and training to patients. Some commenters suggested adding specific language that would address measurable improvement in physical, mental, and clinical health outcomes * * *,'' ''psychosocial status and appropriate referral for services * * *,'' and would ''provide the necessary care and services to achieve and sustain effective psychosocial status * * *.'' Many commenters suggested that we require use of a tool to assist in measuring psychosocial status. Tools suggested include the Zung Self-Assessment Depression Scale or Hamilton Anxiety Scale, and a quality-of-life tool such as the SF–36, or SF–12 (version 2.0 tool), that commenters state are used to measure depression, functional status, and predict mortality and morbidity. Commenters cited research supporting social work interventions that they believe would contribute to meeting patient care team goals.

Response: In response to the large number of comments, and in light of current academic research supporting social service interventions to improve patient care, we are adding a social services component, called ''psychosocial status'' to the plan of care requirements at § 494.90(a)(6). We are requiring that a standardized tool, chosen by the social worker, be used to monitor patient status, and that counseling be provided and referrals be made as appropriate. This new requirement reads, ''The interdisciplinary team must provide the necessary monitoring and social work interventions, including counseling and referrals for social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.''

The standardized tool should be a professionally accepted, valid, reliable tool, such as the SF–36, and should relate to the patient's functional health and well-being. The tool must be used as a monitoring aid that assists in determining the patient's psychosocial status. The SF–36 model uses metrics that measure physical health as related to functional level and presence of pain, and mental health as related to social functioning, emotional and mental health. Reliability and validity studies have been performed for this instrument. More information about the SF–36 may be found in numerous articles or on the Web at *http://www.sf-36.org/tools/sf36.shtml.* The SF–12 survey form was derived from the SF–36 form and scales the 36 question survey down to a 1-page, 2-minute version. However, we are not specifying which tool must be used in order to allow flexibility and to limit the amount of burden. The choice of which standardized tool to use is best left to the facility social worker.

Comment: Although most comments recommended that social services be part of the plan of care, two commenters disagreed, stating that social workers have too big a caseload and are not capable of providing professional counseling services. One commenter stated that until there is consensus on outcomes, CMS should not include an outcomes-based social service requirement in the plan of care. Commenters supporting social services in the plan of care submitted a lengthy list of references that highlight the importance of social services as related to improved patient outcomes.

Response: In the previous conditions (§ 405.2162) as well as in this final rule (§ 494.180(b)), dialysis facilities are required to have adequate staff available to meet the care needs of their dialysis patients. This requirement applies to the provision of social services as well. Facilities may want to assess the caseloads of social workers to ensure there are adequate staff to provide the appropriate level of social services, including counseling. Social workers who meet the qualifications at § 494.140(d) are capable of providing counseling services to dialysis patients. Furthermore, Medicare payment for social worker counseling services is included in the dialysis facility composite rate.

We are setting forth some process requirements within the ''Patient plan of care'' condition because measurable outcomes in all areas are not yet available. When evidence-based or consensus outcome measures and standards become available, we may consider whether some process requirements may be removed from the conditions for coverage in the future.

Comment: We received a comment recommending that consistent language be used for all plan of care elements so that for all care plan areas the dialysis facility ''must provide the necessary care and services to achieve and sustain an effective (treatment program).''

Response: Requiring the facility to provide all necessary care and services for all elements of the patient plan of care may overstep the facility's scope of practice in some areas, as pointed out by several commenters.

Comment: One commenter questioned the need to list components of the plan of care, since a qualified care team

would develop an appropriate plan, which would include measurable and expected patient outcomes conforming to community-accepted standards. The commenter stated this would not need to be mandated, nor should it.

Response: Although quality-oriented facilities may develop meaningful plans of care that include measurable outcomes, we do not agree that all facilities adequately develop and implement such a plan of care. This patient-centered condition serves to protect the health and safety of dialysis patients and to ensure that adequate patient care services are provided.

Comment: A commenter suggested that when referring to the interdisciplinary team implementing the plan of care at § 494.90(b)(1)(i) the phrase ''inclusive of the patient'' be added.

Response: The interdisciplinary team definition specifically includes the patient, and has been added to the first paragraph of this condition. We have added the phrase ''including the patient if the patient desires'' to § 494.90(b)(1)(i) to clarify that we expect that the patient will want to participate in devising the plan of care.

Comment: We received many comments regarding the proposed requirement at § 494.90(b)(1)(ii) suggesting that the patient sign the plan of care. A few commenters recommended the plan of care be signed by the patient's attending physician as well as the patient.

Response: The patient plan of care must be completed by the interdisciplinary team (§ 494.90(b)(1)(i)). It is standard practice for all team members, including the treating physician, that develop the plan of care to sign it, as they would for any other entries into the medical record. Therefore, we are changing the wording at § 494.90(b)(1)(ii) to reflect that all team members must sign the plan of care.

Comment: Commenters agreed with the proposed rule requirement that the plan of care be signed by the patient or the patient's designee. One commenter stated that at least one facility, to his or her knowledge, limits patient involvement exclusively to signing the care plan; the staff orders the patient to sign and the RN on-duty becomes offended if the patient actually reads the care plan. The commenter further noted that patients should be able to indicate the date they signed the care plan. Another commenter noted that the proposed rule did not require the patient to be involved in the development of the care plan, but only to sign it. This commenter was concerned that only paper compliance would be achieved with such a provision, and that enforcement regarding patient involvement would be difficult. One commenter recommended that facilities be required to conduct periodic patient care conferences. The commenter further stated that deleting survey tag V174 would be detrimental to quality of care and CMS should prevent a ''pass around the paper'' meaningless care plan development process.

Response: The role of the patient is central to providing quality dialysis care. Paper compliance without substantive compliance is unproductive. Specifically, the patient member of the interdisciplinary team has a role in converting the comprehensive assessment into a meaningful plan of care. Whenever possible, the patient (or designee) should assist in the identification of goals and in formulating the action plan to achieve these goals. The patient must be involved in care planning and actively participate in care plan development and review.

Survey tag V174, referred to by the commenter, required regularly scheduled conferences, with participation by the staff involved in the patient's care, to evaluate the progress each patient is making towards the goals in their long-term care program and patient care plan. However, this final rule also allows the facility flexibility to choose the methods to ensure patient participation. One means of providing an opportunity for participation is to have the patient attend the meeting in which the plan of care is developed and updated. This final rule makes very clear that the patient is part of the care team and can participate in the assessment and the plan of care activities if the patient desires to do so. While we have not required monthly care plan meetings specifically, the facility must demonstrate that there is an opportunity for patient involvement and participation. The facility has the flexibility to design a process. The patient signature on the plan of care is not sufficient to demonstrate patient participation. The new interpretive guidelines for this regulation will include direction to surveyors regarding enforcement of this provision.

Comment: A few commenters were concerned about dialysis facility responsibility for patient participation in cases where the patient chooses not to participate. Some commenters suggested that there be a provision in this final rule for situations in which the patient refused to sign the plan of care. The commenter suggested that in such cases, documentation provided by the facility explain that the patient had refused to provide a signature.

Response: We agree that as long as the patient has been provided sufficient opportunity to participate with the interdisciplinary team, the dialysis facility should not receive a citation for non-compliance with these conditions when the patient has refused to participate or sign the plan of care. We have modified the language at § 494.90(b)(1)(ii) to indicate that the facility must document a patient's refusal to sign the plan of care, along with the reason the signature was not provided.

Comment: We received many comments regarding the time period for commencing implementation of the patient plan of care (§ 494.90(b)(2)). The proposed rule specified that the plan of care would have to be implemented within 10 days of any comprehensive assessment. While there was some agreement with this proposal, many commenters stated that 10 days was too short. Some commenters suggested that we combine the assessment and plan of care time period to 30 days. Commenters suggested a myriad of alternative timeframes for implementing the plan of care, such as requiring implementation within 15 days of assessment completion, within 90 days of starting dialysis, within a certain number of dialysis treatments (to allow for the possibility of patient hospitalizations), or at the first team meeting following completion of the assessment. The reasons facilities gave for needing a longer plan of care implementation time included the shortage of staff, needing time for referrals and schedule coordination, the need for interpreters, accommodating monthly care plan meetings, and the difficulties involved in bringing the multidisciplinary team together monthly.

Response: We believe we must balance the health and safety needs of the patient against the staffing limitations of the facilities. The case loads of staff and constraints of facility processes should not outweigh the need to develop and implement the plan of care within a reasonable period of time. If a patient has received in-center dialysis for a 1-month period or 13 (thrice-weekly) hemodialysis treatments, that patient has likely been physically present in the dialysis facility for at least 40 hours. We believe that this should provide sufficient time for the interdisciplinary team to have completed an assessment and developed a plan of care that is ready for implementation. Thirty days is a reasonable timeframe for the initial

assessment and implementation of the plan of care in order to protect the health and safety of patients and prevent harm. Facilities may want to re-evaluate their processes, resources, and adequacy of staff if they find the 30-day deadline to be too difficult to meet. We have modified the requirement at § 494.90(b)(2), so that the interdisciplinary team has a timeframe of the latter of 30 days or 13 hemodialysis treatments from the date of admission to complete the assessment and implement the plan of care. This provision now addresses commenter concerns regarding time lapses when a patient is in the hospital. Referrals are considered to be a part of the implementation of the plan of care and would not be a reason to allow extended time periods to complete and implement the plan of care. In addition, we will allow a 15 day time period for the facility to implement any patient plan of care revision due to completion of a monthly assessment (done for unstable patients) or an annual assessment (completed for stable patients) (§ 494.90(b)(2)).

Comment: Many comments addressed proposed § 494.90(b)(4), which would require the dialysis facility to ensure that the patients are seen at least monthly by a physician providing ESRD care. Some commenters supported this provision and a few suggested that the visit could take place in the physician's office. Other commenters disagreed with the requirement but agreed with the intent, saying that physicians should see their dialysis patients at least monthly. Many commenters strongly disagreed with the provision, stating that the facility should not be accountable for physician visits. A few commenters stated that the payment G-codes provided enough incentive for facilities and that therefore this physician visit requirement was not needed. Other commenters suggested there was no evidence of any benefits that could be linked to monthly visits, and this would be especially burdensome for rural dialysis facilities. One commenter recommended that an exception be available for facilities in the Pacific Islands. Two commenters suggested that CMS had no authority to mandate these monthly physician visits according to section 1801 of the Social Security Act, which prohibits the federal government from exercising any supervision or control over the practice of medicine.

Response: We believe that it is in the best interest of the patient for dialysis facilities to ensure that a physician (or other practitioner, such as a PA, nurse practitioner, or clinical nurse specialist) visits each month. The Dialysis Outcomes and Practice Patterns Study (DOPPS) data demonstrate that physician contact correlates with the quality of care. The G-codes, established in the final rule, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2004'' published November 7, 2003 (68 FR 63196, 63216), provide payment to physicians in incremental amounts depending on whether the patient was seen 1, 2–3, or 4 times during a given month. Although the payment G-codes provide some incentive for attending physicians to see their dialysis patients more often, physicians may still choose not to see their patients for a month or more. In this case, the patient still receives dialysis for which the facility receives payment. We do not believe that requiring monthly visits infringes on how physicians practice medicine and note that physician organizations that provided comment on the proposed rule supported the provision. We are retaining the proposed provision at § 494.90(b)(4) to ensure that patients receive face-to-face physician (or, as discussed below, ''physician extender'') visits at least monthly.

Comment: A few commenters suggested that physician assistants be allowed to perform monthly visits, while one commenter favored allowing a nurse practitioner to perform monthly visits.

Response: In response to comments, we have added nurse practitioners, clinical nurse specialists, and physician assistants as options for compliance with the provision requiring monthly visits by a physician. CMS has previously issued instructions regarding physician visits and payment via G-codes and these instructions clarify that a physician assistant, clinical nurse specialist, or a nurse practitioner may provide visits to dialysis patients instead of a physician. Physicians may use nurse practitioners, physician assistants, and clinical nurse specialists, who are able under the Medicare statute to furnish services that would be physician services if furnished by a physician and who are eligible to enroll in the Medicare program, to deliver some of the visits during the month.

Comment: We received many comments regarding proposed § 494.90(c), ''Transplantation referral tracking,'' which would require the interdisciplinary team to track the results of each kidney transplant center referral and monitor the status of any facility patients who are on the transplant wait list. In addition, this standard would require the team to communicate with the transplant center regarding patient transplant status at least quarterly or more frequently if necessary. Some commenters supported this standard as proposed and many commenters stated the dialysis facility should not be accountable for transplantation referral tracking once the referral has been made. Commenters who disagreed with this proposed provision stated that other parties have this tracking responsibility, including the transplant center, the transplant candidate, and/or the physician. Two commenters stated that this requirement creates a burden for dialysis facilities.

Some commenters acknowledged that the proposed (now final) transplantation center conditions of participation, published on March 30, 2007, included a proposed requirement for transplant centers to communicate with dialysis centers regarding transplant candidate status. A few commenters suggested that dialysis facility responsibility be limited to maintaining a list of patients on the transplant wait list. Several commenters stated that some transplant centers did not communicate with the dialysis facility, or that it was difficult to get information from the transplant center. One commenter suggested penalties for transplant centers that did not communicate with dialysis facilities, while another commenter suggested that incentives be provided to transplant centers to share information monthly on transplant candidates' work-up and listing status.

Response: Our intent is to ensure that the interdisciplinary team is aware of where the patient is in the referral and transplant evaluation process so that patients do not get ''lost'' along the way. We do not expect that the transplant referral tracking responsibilities borne by the dialysis facilities would be redundant with the responsibilities of the transplant center. We would expect the interdisciplinary team to be aware of whether the patient has completed the evaluation process, is wait-listed, ineligible for wait listing, or is awaiting living donation. Moreover, the dialysis facility is expected to alert the transplant center about changes in the patient's condition that would affect whether a patient was able to receive kidney transplantation. The transplantation center conditions of participation published on March 30, 2007 (72 FR 15198) require kidney transplant centers to communicate transplant patient status to the dialysis facility at § 482.94(c)(1) and § 482.94(c)(2) so that there is two-way communication.

Comment: A few commenters who agreed that there was a need for dialysis facility and transplant center communication did not agree with the

proposed quarterly frequency of this communication. One suggestion was to remove the ''quarterly'' language and replace it with ''when there is a change.''

Response: We agree. In response to comments, we have changed the frequency of required communication with the transplant center at § 494.90(c)(3) so that the regulation will require the interdisciplinary team to contact the transplant center ''at least annually, and when there is a change in transplant candidate status.'' Although the proposed ESRD conditions for coverage called for quarterly communication with the transplantation center, the transplantation center final rule (at § 482.94(c)(1)and (2)) requires that the transplant center notify the dialysis facility of the patient's transplant status only when there are changes in such status (72 FR 15276). Our purpose here is to provide a means by which up-to-date information can be made available to the transplant team so that eligible patients are wait-listed and so that patients offered a donor kidney are in a position to accept the transplantation. The dialysis team also needs up-to-date information so that the team can choose the most appropriate ESRD modality and setting for the patient and assist the patient in understanding the process used to obtain kidney transplantation.

Comment: Commenters made several additional transplant recommendations. One commenter suggested that an RN with specific transplant related duties is needed to act as transplant coordinator.

Response: While dialysis facilities may find it beneficial to have an RN transplant coordinator assist in transplant referral tracking, we do not believe it should be a requirement. We are allowing flexibility so that the tracking may be done by staff members chosen by the dialysis facility.

Comment: One commenter suggested that the dialysis facility and the transplant center have a written agreement with each other.

Response: If a dialysis facility finds it useful to have a written agreement with the transplant center, the dialysis facility has the flexibility to pursue this, but we do not believe it is necessary and will not require it.

Comment: One commenter suggested that there should be an internet database to facilitate communication between transplant centers and dialysis facilities.

Response: While there may be some benefit in having an internet database to facilitate communication between transplant centers and dialysis facilities, we will not burden dialysis facilities with developing such an internet database. We believe an active and ongoing communication and coordination process will suffice currently. As electronic health records become a reality in the future, there is the possibility that these records could facilitate dialysis facility and kidney transplant center communications and exchange of information.

Comment: One commenter suggested that the transplantation requirements should be consistent with the recommendations of the 2005 ESRD Network technical expert panel (TEP) that worked on developing transplant referral clinical performance measures. Another commenter stated that conditions for transplant center, physician and patient communications should be based on the study and endorsement of the American College of Physicians and physician organizations.

Response: The TEP referred to by the commenter was charged with developing dialysis facility-specific kidney transplant referral clinical performance measures. These measures would track steps in the transplant referral process. TEP membership included transplant surgeons, nephrologists, and dialysis facility representatives. The TEP recommended that this final rule include the proposed transplantation provisions at 494.90(c) in order to facilitate implementation of the kidney transplant referral CPMs they developed. We have adopted the proposed transplant provisions and believe this will alleviate the concerns of the commenters.

Comment: A few commenters responded to our query as to whether we should specify actions (that is, transplant referral activities and monthly blood draws for antigen/antibody testing) that must be included in the transplantation action plan. Two commenters stated that monthly transplant blood drawing should not be the responsibility of the dialysis facility. One commenter supported the concept that facilities should support patients in the process of a work-up for a transplant, which would include tracking tests, communication with transplant coordinators/surgeons, etc.

Response: We will not specify actions that must be included in the patient plan of care under the transplantation component, but encourage dialysis facilities to assess the circumstances and include appropriate actions in the plan of care as needed.

Comment: We received several comments supporting inclusion of the ''Patient education and training'' standard at § 494.90(d). Some commenters recommended the addition of other training topics, including patient education regarding arteriovenous fistulas, advance directives, and more. A commenter recommended that we require documentation in the medical record that patients were informed of the risks and benefits of various types of vascular access consistent with ''Fistula First'', and provide funding for this if needed.

Response: We agree that it is a reasonable expectation that dialysis patients be educated regarding the risks and benefits of various access types due to the impact of a vascular access on the patient's morbidity and mortality risks. Comments on this and other sections of these conditions strongly support adding a requirement ensuring that patients must be educated regarding the risks, benefits, and outcomes of various access types. These comments are in keeping with the National ''Fistula First'' quality initiative. Additionally, the Institute of Medicine (IOM) has encouraged the empowerment of patients to improve the quality of the healthcare system. Therefore, we have added new language to the ''Patient plan of care'' condition at § 494.90(d), Patient education and training, requiring that the plan of care include education and training on the benefits and risks of various vascular access types. We have also added infection prevention and personal care, and home dialysis and self-care training to this provision in response to comments as discussed under the ''Infection control'' and ''Care at home'' sections of the preamble.

Comment: One commenter believes that education for all life changes associated with dialysis is an unfunded mandate that will require additional personnel skilled in this training. The commenter also stated that patient education regarding employment, rehabilitation and transplantation is beyond the scope of the dialysis center nurses and technicians.

Response: Patient education is included in the Medicare composite rate paid for dialysis. We expect that the interdisciplinary team has the skills and expertise needed to educate dialysis patients about aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.

d. Care at Home (Proposed § 494.100)

We proposed a separate condition for coverage for care at home requirements, which were previously located in four existing sections of 42 CFR part 405, subpart U. The requirement that services to home patients be at least equivalent to those provided to in-center patients was retained from existing § 405.2163. We addressed home

dialysis training in the proposed rule and proposed requiring the interdisciplinary team to provide training to the patient and/or the designated caregiver before the initiation of home dialysis. We proposed that the home training be provided by a facility approved to provide home dialysis services and that home and self-care training would have to be conducted by an RN. The proposed training would have to address specific needs of patients in several subject areas, including the nature and management of ESRD, techniques associated with the treatment modality, nutritional care plans, emotional and social well-being, methods to detect, report and manage potential complications, how to access and use available resources, how to self-monitor health status, how to handle emergencies, infection control precautions, and proper waste and disposal procedures. We also proposed a home dialysis-monitoring standard, which would have required the dialysis facility to document that the patient and/or caregiver received and demonstrated adequate comprehension of the training; retrieve and review self-monitoring data and other information at least every two months; and maintain this information in the medical record. We proposed to retain many of the existing regulations regarding home dialysis support services; however, the proposed support services standard was strengthened by requiring home dialysis patient consultation with the interdisciplinary team. The team also would have been held responsible for the development and periodic review of the patient's plan of care based upon the comprehensive assessment, and for addressing the patient's needs and achieving the expected outcomes of care. The proposed rule also would have expanded existing requirements to monitor the quality of water used by home hemodialysis patients. The proposed rule specifically included onsite evaluation of the water system, as well as adherence to applicable AAMI guidelines and immediate correction of any problems with the water treatment system. If problems could not be immediately corrected the facility would have to arrange for backup dialysis until the home dialysis water quality could be restored. At § 494.100(c)(1)(vi), the proposed rule would retain existing requirements that the dialysis facility be responsible for ''Purchasing, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.'' The proposed rule also would have required facilities to plan for and arrange for emergency back-up dialysis services when needed. We also proposed that the facility maintain record-keeping systems that ensured continuity of care; this would have also been retained from existing provisions found at § 405.2163(e)(3).

Comment: Many commenters strongly supported the requirement that home dialysis patients receive services that are at least equivalent to those provided to patients in facilities. One patient remarked he felt his peritoneal dialysis care was not equivalent to in-center hemodialysis. Another commenter said home dialysis needs more attention in the final rule.

Response: We appreciate the positive response from commenters. All the ESRD conditions for coverage must be met regardless of whether the setting is in-center or at home. We have added language to clarify this in the first paragraph of § 494.100, to require that dialysis facilities meet all applicable conditions of this part. We would expect that under these new regulations, dialysis facilities would make any necessary changes to ensure that all patients receive the same quality of care regardless of the location of the service. We have increased the home dialysis focus of these conditions by making ''Care at home'' a separate condition for coverage.

Comment: A few commenters recommended that a new section be added to our regulation, to address patients performing self-care dialysis in the facility, and address policies and procedures for self-care in the facility. These commenters believed that stringent regulation and oversight was needed for self-care. One commenter suggested there should be requirements for self-care training for both patients and facility staff and that self-dialysis training should include treatment monitoring, machine monitoring, needle procedures, and infection control.

Response: We encourage self-care, both at home and within the facility, whenever the patient has the ability. Self-care can be supported in-center by Medicare-certified outpatient dialysis facilities. Dialysis facilities that provide self-care must meet these conditions for coverage and protect patient safety. We do not agree that additional regulations are needed regarding self-care.

Comment: One commenter remarked that the requirements as written would require all patient training to be completed before the initiation of home dialysis, and the commenter suggested that this was not practical because patients would lose interest in performing home dialysis before the instruction was complete.

Response: As required at § 494.100(a), the interdisciplinary team must oversee the training provided to the home dialysis patient and the designated caregiver before the initiation of home dialysis. Patients should not begin home dialysis before adequate training is complete and competency has been determined. We have maintained the language of the proposed rule.

Comment: One commenter agreed that initial home training should be conducted by a qualified RN. Some commenters remarked that the requirement for an RN to train home dialysis patients was excessively stringent and that an LPN was qualified to train these patients. Another suggested that an RN be responsible for home training but still have the ability to delegate parts of the training program to a trained LPN or PCT. Two commenters suggested the final rule allow PCTs, under the supervision of an RN, to provide patients with some or all home care training, with a final review and evaluation done by an RN. One commenter strongly opposed the provision at § 494.100(a), which required that the interdisciplinary team be responsible for providing self-dialysis training to home patients.

Response: The existing requirement at § 405.2162(c) mandates that an RN be in charge of self-care training. We believe that an RN, as an experienced health professional, fully understands the complexity and rationale for the dialysis process, and is the best-suited expert to conduct self-care training to patients. The requirement serves to protect the health and safety of the patient. Therefore, we have retained the proposed RN requirement in the final rule at § 494.100(a)(2), which stipulates that the RN must conduct the home training. The RN may use other members of the clinical dialysis staff to assist in providing the home training. However, the RN is responsible to ensure that the training is in accordance with the requirements at § 494.100.

In addition, we have modified the provision at proposed § 494.100(a), which would have required that the interdisciplinary team be responsible for providing the self-dialysis training to home patients, to clarify that the role of the interdisciplinary team is to oversee the home dialysis training.

Comment: Several commenters suggested that training topics should be determined by the facility rather than regulation. Some commenters suggested removing at least two of the proposed training topics (proposed

§ 494.100(a)(3)(iii), implementation of a nutritional care plan, and § 494.100(a)(3)(iv), how to achieve and maintain emotional and social well-being), since these topics are proposed to be covered in the ''Patient plan of care'' condition.

Response: Patient education and training are addressed in the ''Patient plan of care'' condition, which now requires that the care plan include education and training regarding home dialysis and self care, as appropriate, at § 494.90(d). All dialysis patients, whether home or in-center, are to receive counseling regarding nutrition and psychosocial well-being (§ 494.90(a)(2) and (6), respectively). We concur with the comments and believe it is redundant to include these topics under the self-care training standard at § 494.100(a). Therefore, we have removed ''implementation of a nutritional care plan'' at proposed § 494.100(a)(3)(iii) and ''how to achieve and maintain emotional and social well-being'' at proposed § 494.100(a)(3)(iv).

Comment: One commenter suggested removing the specific level of hemoglobin and hematocrit and replacing it with reference to evidence-based standards.

Response: We have modified the final rule at § 494.100(a)(3)(ii) because the proposed language was redundant. The ''Patient plan of care'' condition at § 494.90(a)(4) requires that the interdisciplinary team develop a plan of care that addresses anemia, and specifies the hemoglobin and hematocrit targets. In the final rule at § 494.100(a)(3)(ii), we have eliminated specific numerical values for hematocrit and hemoglobin but require that the patient be instructed on how to administer erythropoiesis-stimulating agent(s) in order to achieve and maintain a target level hemoglobin or hematocrit, as written in the patient's plan of care at § 494.90.

Comment: A few commenters suggested that the 2-month timeframe for monitoring home patients was excessively rigid and burdensome. Two of those commenters suggested a quarterly reporting timeframe that would coincide with monitoring. Two commenters suggested we change the timeframe to require monthly reporting.

Response: The goal of the standard at § 494.100(b)(2) is to have facilities effectively monitor the care of home dialysis patients to achieve desired outcomes. Monitoring patient records allows dialysis facility staff to compare the prescribed regimen to actual dialysis results. Home patients do not see facility staff as frequently as in-facility patients do and so we believe the 2-month monitoring schedule is reasonable.

Comment: One commenter agreed with the proposed rule but pointed out that home patients do not always provide documentation regarding their care at home. Another commenter remarked that non-compliant patients may not provide the required data and other information necessary for staff to carry out the mandatory review. This commenter suggested we add language that would enable staff to be in compliance on the basis of having made a ''good faith effort.''

Response: The home dialysis patient is part of the interdisciplinary team and should be working to meet the home dialysis plan of care goals. If home dialysis patients exhibit non-compliant behavior and/or their care plan goals are not met, then facilities must intervene. If facilities take reasonable measures and lack of patient compliance remains a problem, then the interdisciplinary team must document the interventions to address patient non-compliance, the results of the interventions, and the plan to protect patient health and safety within the limitations of poor patient compliance.

Comment: Several commenters remarked on the differences between hemodialysis and peritoneal dialysis modalities in the home setting. The commenters suggested that peritoneal dialysis visits only be required when medically indicated, since the water treatment issues associated with hemodialysis do not exist for these patients. Two commenters suggested that home monitoring visits be at the discretion of the interdisciplinary team. One commenter suggested that the proposal be revised to allow home visits ''as appropriate.'' Another commenter suggested that the final rule state whether the interdisciplinary team would be required to perform an assessment at a team meeting. Another commenter asked for clarification on whether the staff must visit a patient's home periodically. A commenter suggested that a physician be required to visit home patients only as medically indicated, while another commenter asked whether the physician would be required to see the home patient monthly. One commenter suggested we add a requirement that the home consultation be with ''all'' of the team members as needed. Two commenters suggested that ''periodic monitoring'' include ''at least annually.'' Other commenters suggested that the final rule specifically state that all home patients must be visited in the home at least periodically after home training is completed.

Response: Many of these concerns from commenters would be addressed in the patient's plan of care at § 494.90, which requires an appropriate plan of care based upon medically indicated needs, treatment, and services. Patient needs identified in the plan of care should drive the frequency of home visits of the interdisciplinary team members, including the physician. Regular contact with facility staff offers the patient an ongoing support service and an avenue for communicating questions and concerns. Our regulations require periodic monitoring and home visits by a team member as part of the patient plan of care; they are necessary in order to protect patient health and safety. We would expect that each home care patient, in addition to being visited, would have regular contact with dialysis facility staff. The initial home visit allows dialysis facility staff to ensure that the home patient has an acceptable environment in which to perform safe dialysis, and ensure there is adequate storage of supplies, etc. The dialysis facility should ensure that care being provided to home-care patients be equivalent to care provided to other facility patients.

Comment: A commenter suggested that we require at § 494.100(c)(1)(i) that home patient monitoring be completed as needed and only if geographically feasible, in accordance with the patient's plan of care. Another commenter remarked that facility staff should not be required to make home visits if patients live in dangerous areas or if it is unsafe for staff.

Response: Support services at standard (c) are required for all home patients, regardless of the setting or geographical location. At § 494.100(c)(1)(i), dialysis facility staff are required to periodically monitor the patient's home adaptation and visit the patient's home setting in accordance with the plan of care. All patients have the right to receive equal care that protects their health and safety, and CMS cannot establish a mandate that would allow discrimination in any form.

Comment: Two commenters remarked that while the proposed rule provides a new level of protection for the patient, the requirements would make home dialysis more expensive, which could be a deterrent for dialysis facilities to offer home dialysis. One commenter noted that weekly home hemodialysis water testing for new systems was too expensive, as was monthly bacteria testing. The commenter remarked that the final rule should recognize differences between hemodialysis and peritoneal dialysis, and that it is not

necessary to monitor water quality/dialyzer reuse with certain new home dialysis technologies. One commenter suggested that for preconfigured, 510(k) cleared systems designed, tested and validated to yield AAMI quality water and dialysate, that we should merely require the facility to monitor water quality in accordance with the systems' FDA-approved labeling under § 494.100(c)(1)(v). Another commenter remarked that AAMI recommendations were never intended for home hemodialysis, stating that home water quality should be monitored but not with the same frequency as in a facility setting. One commenter also asked how the conditions would stay current if the referenced guidelines were changed or updated.

Response: The subject of water quality was addressed in our discussion under § 494.40, where all related issues, including home dialysis issues, were thoroughly discussed. In accordance with that discussion, we have revised the final rule at § 494.100(c)(1)(v)(A) and § 494.100(c)(1)(v)(B), to require that the facility monitor the quality of water and dialysate used by home hemodialysis patients and conduct onsite evaluations and testing of the water system in accordance with the recommendations specified in the manufacturers instructions and the system's FDA-approved labeling for preconfigured systems designed, tested and validated to yield AAMI quality water and dialysate. Bacteriologic and endotoxin testing must be performed at least quarterly, or on a more frequent basis as needed, to ensure that the water and dialysate are within AAMI limits. We are requiring at least quarterly cultures and endotoxin testing to ensure that as new technologies come into use, the facility monitors home hemodialysis water systems so that patient safety is protected. As data and information become available regarding the long-term use and safety of new technologies, we may, in the future, re-evaluate the required frequency of water testing for these systems based on the scientific evidence.

Comment: One commenter agreed with the proposed rule that the dialysis facility should provide all support services regardless of whether or not any durable medical equipment is provided by that facility. Another commenter suggested adding the following language to the final rule at § 494.100(c) for Method I patients: ''The dialysis facility must purchase or lease and deliver the necessary home dialysis supplies and equipment.'' Two commenters remarked that equipment rental should be included in the proposed list of requirements at § 494.100(c)(2)(iii), as some providers rent dialysis equipment.

Response: We appreciate the positive comments regarding the need for facilities to provide support services for the home patient. Home dialysis patients who receive all equipment, supplies and support services from their ESRD facility are considered ''Home Dialysis Method I.'' Under ''Method II,'' a durable medical supply company provides all necessary equipment and supplies to the home dialysis patient, and a dialysis facility provides support services to the patient. In order to be responsive to commenters, we have added the terms ''renting'' and ''leasing'' to the final rule at § 494.100(c)(1)(vi), which now requires services provided by the facility to include, ''Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.''

Comment: One commenter suggested that we add a requirement that a home dialysis provider have its own in-center facility within 35–50 miles of the patient's home, or an agreement with a designated backup in-center provider, including on-call availability of a nurse to permit a home patient to have access to care when equipment fails or in an emergency.

Response: In the proposed rule at § 494.100(c)(1)(vii), facilities are required to identify a plan and arrange for emergency back-up dialysis services in the event that they may be needed. We believe this requirement addresses the commenter's concern, while providing flexibility for facilities. Emergency preparedness is also addressed in the final rule at § 494.60(d), which requires facilities to implement processes and procedures to manage medical and non-medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public.

Comment: One commenter stated that requiring facilities to deliver supplies and equipment to home patients would give an unfair advantage to Method II suppliers, especially for a clinic serving a large geographic area. Another commenter recommended that we consider allowing facilities to ''arrange'' for installation and maintenance of supplies and equipment, as it is standard industry practice for the manufacturer to install dialysis equipment.

Response: It appears these commenters may have misinterpreted some of the proposed rule language at § 494.100(c). The part 405, subpart U requires self-dialysis support services to be furnished either directly, under agreement or by arrangement with another ESRD facility (§ 405.2163(e)). We have added language to § 494.100(c)(1) of the final rule to clarify that, ''A home dialysis training facility must furnish (either directly, under agreement or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company.''

As noted above, home dialysis patients who receive all equipment, and supplies from one durable medical equipment supplier and all other support services from their dialysis facility have opted for ''Home Dialysis Method II.'' Facilities are accountable for arranging and providing services and supplies to their patients as required. To allow maximum flexibility for facilities to carry out this requirement, facilities are permitted to determine the most effective and efficient way for them to operate within the context of the final rule.

Comment: One commenter suggested the proposed rule at § 494.100(c)(1)(vii) (identifying a plan and arranging for emergency backup) be modified to require that emergency backup dialysis services must be at a location convenient to the patient's home.

Response: We do not believe it would be beneficial to mandate emergency back up dialysis services that are convenient to the patient's home. The term ''convenient'' may have a wide range of interpretations and depending on how it is interpreted, could become an access to care barrier that reduces the availability of home dialysis. Some patients choose home dialysis because they live in a remote area where in-center dialysis is not available. If we required that back up dialysis for all home patients must be ''convenient'', this may cause dialysis facilities to discontinue home dialysis for patients who live in these remote areas for whom there is no convenient dialysis facility. We expect providers to work with patients, other providers and ESRD Networks to best meet the needs of patients. Facilities must have a reasonable emergency plan to deal with patients in need of backup dialysis services.

Comment: Two commenters suggested we delete proposed § 494.100(c)(1)(iii) through § 494.100(c)(1)(vii) because most of the requirements are already required of the facility with respect to all patients receiving care and services through the facility.

Response: The support services provision in the proposed rule at § 494.100(c)(1)(i) through § 494.100 (c)(1)(vi) would retain and expand existing part 405, subpart U requirements, as discussed in the ESRD proposed preamble (70 FR 6212). We also proposed the addition of § 494.100(c)(1)(vii), which would require the facility to plan for and arrange for emergency backup dialysis services when needed. Support services for home care patients are required by section 1881 of the Act and are necessary to ensure proper care and support. We have added a clarification to § 494.100(c)(1) to state that any home dialysis training facility must also ''furnish either directly, under agreement, or by arrangement with another ESRD facility.''

Comment: Some commenters suggested that separate sections were needed for home hemodialysis and peritoneal dialysis. One commenter remarked that this was necessary due to water quality issues. Another suggested that hemodialysis was more complex and that the proposed rule, as written, would impose an undue burden on peritoneal dialysis care.

Response: Hemodialysis water quality was addressed in the ''Care at home'' condition at § 494.100(c)(1)(v) in the proposed rule. The language in the final rule has been modified and is now consistent with the requirements in the ''Water and dialysate quality'' condition at § 494.40. The language at § 494.100(c)(1)(v)(A) and § 494.100(c)(1)(v)(B) requires that services include, ''Monitoring of the quality of water and dialysate used by home hemodialysis patients, including conducting an onsite evaluation and testing of the water and dialysate system in accordance with: (A) The recommendations specified in the manufacturers' instructions; and (B) the system's FDA-approved labeling for preconfigured systems designed, tested, and validated to yield AAMI quality water and dialysate; in addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.'' We have added a reference to dialysate in our final rule to be consistent with the AAMI RD52 guidelines that we have incorporated by reference. The interdisciplinary team is required to educate the patients or caregivers about water quality problems as required by § 494.100(a)(3)(iii).

Comment: One commenter remarked that Medicare should ''cover separately billable medication and biologicals for home patients, as it does for in-center patients, to improve their clinical outcomes.''

Response: This regulation does not address payment issues. The matter has been referred to the appropriate CMS coverage staff for consideration.

Comment: One commenter recommended that CMS contract with a Network to form a TEP to study current guidance for care at home and make recommendations.

Response: A TEP was convened in Baltimore on January 20 and 21, 2006, after the close of the proposed rule's comment period, to assist ESRD Network 9/10 in developing recommendations for providing staff-assisted dialysis in a long-term care facility. TEP members, including patients and professionals, represented various ESRD stakeholders involved in or impacted by dialysis in the LTC facility. The TEP's final recommendation to CMS was to suggest creation of a new model of care for staff-assisted dialysis in long-term care facilities, as the current method of home dialysis in such facilities did not appropriately meet the need. The final report ''Delivery of Dialysis Treatment Within the Long Term Care Facility'' can be found on The Renal Network Web site at *http://www.therenalnetwork.org/PF/LTC_feedback.html*.

Comment: We received many public comments regarding the issue of institutional dialysis or dialysis in a nursing home setting, which was discussed in the proposed rule preamble. Dozens of members from the renal, hospital, and nursing home industries commented and many were opposed to the current existing (2004) nursing home dialysis policy, which can be viewed at *http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter04-24.pdf* and *http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter04-37.pdf*. The majority of commenters had major concerns with this issue and expressed frustrations with existing payment systems. Commenters were concerned with the financial feasibility of providing dialysis to these patients at a certified dialysis facility within the nursing home or under the home dialysis model. Commenters believe that the reimbursement system should be adjusted for care provided in this setting. Accountability is another concern, as commenters were not clear regarding the division of responsibilities between the skilled nursing facility and the ESRD facility. Still other commenters stated that these patients should not be categorized as home-care patients because the majority are frail and often elderly, cannot participate in their own care, and cannot be trained. Many commenters suggested that CMS convene a Technical Expert Panel to address the issue of dialysis for nursing home residents and craft a separate rule following publication of this final rule.

Response: The proposed rule solicited comment regarding ''whether the current dialysis regulations need to be modified to protect this vulnerable (nursing home) population * * *'' (70 FR 6213). Commenters clearly believe that current regulations pertaining to the provision of dialysis to nursing home patients need to be revised. However, it is not clear now how we could best improve our health and safety regulations to meet our goal of providing safe, high quality, efficient dialysis care to vulnerable nursing home patients. Therefore, we are not issuing nursing home dialysis regulations in this final rule. Given the complex programmatic and fiscal issues associated with a new nursing home dialysis model, we intend to consider rulemaking as well as alternative actions in the future. Until that time the current policy (S&C–04–24 and S&C–04–37) will remain in effect.

e. Quality Assessment and Performance Improvement (Proposed § 494.110)

The February 4, 2005 proposed rule included a new condition that would require dialysis facilities to develop, implement, maintain, and evaluate an effective, data-driven, interdisciplinary QAPI program. This ongoing internal quality oversight program would focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The QAPI program would include adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries and medical errors identification, hemodialyzer reuse, (if applicable), and patient satisfaction and grievances. The dialysis facility would be required, not only to monitor its performance, but also to take actions that would result in sustained performance improvements. Priorities would have to be set for performance improvement activities, taking into consideration the prevalence and severity of identified problems and affect on clinical outcomes or patient safety. We proposed that any identified problems that threatened the health and safety of patients would be immediately corrected. We also proposed retaining the part 405, subpart U requirement that dialysis facilities participate in ESRD Network activities and pursue Network goals.

We received a large number of comments on the QAPI condition. The comments generally supported a QAPI condition. One commenter applauded the proposed requirement for prioritizing QAPI improvement activities and requiring facilities to have a plan for immediate correction of problems that might jeopardize patient health and safety.

Comment: A few commenters requested clarification of the term ''interdisciplinary team'' as used in subpart C.

Response: As stated earlier, we have clarified the meaning of ''interdisciplinary team'' under the ''Patient assessment'' (§ 494.80) and ''Plan of care'' (§ 494.90) conditions. The first sentence of the QAPI condition in the proposed rule required an ''interdisciplinary'' QAPI program. We have modified this requirement in the final rule to make clear that the professional members of the interdisciplinary team (physician, RN, social worker, and dietitian) must participate in the QAPI program. The facility has the option of including facility patients when appropriate. The first sentence of § 494.110 now reads, ''The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team.''

Comment: Two commenters were concerned that there was no mechanism to update QAPI measures, and suggested that CMS develop such a mechanism.

Response: QAPI measures were not proposed; however, QAPI topics were proposed at § 494.110(a)(2). Facilities may use indicators and measures of their choice as appropriate and necessary to implement the data driven QAPI program. We may update the QAPI topics as needed in future revisions of the ESRD conditions for coverage. Facilities may add topics to their QAPI program as needed to meet the unique needs of their facility.

Comment: A commenter suggested that if face-to-face QAPI meetings are expected, this should be specifically required in the regulation.

Response: The facility has the flexibility to develop and implement QAPI via processes of their own choosing, as long as the efforts result in a multidisciplinary, data-driven QAPI program that achieves improvement and meets the criteria stated in § 494.110. This might include face-to-face meetings or additional and alternate activities. We have not modified the regulatory language to specify processes or face-to-face meetings.

Comment: Two commenters suggested that we consider increasing the Network role in QAPI oversight.

Response: The Network role regarding the quality of ESRD care is defined at section 1881(c) of the Act, and implemented at 42 CFR 405.2112 and in the ESRD Network contract. We expect the ESRD Networks and the facilities to work collaboratively for the benefit of the patients that are being served. These conditions for coverage do not affect the ESRD Network role or requirements. The requirements regarding dialysis facility cooperation with its ESRD Network have been consolidated at § 494.180(i), as discussed under that section of this preamble.

Comment: A commenter stated that standard facility continuous quality improvement programs should satisfy QAPI requirements.

Response: We expect that some quality-oriented dialysis facilities already have in place effective full-scale quality improvement programs that would meet QAPI requirements.

Comment: Many commenters suggested additional QAPI topics that should be required, including: Infection control, renal bone disease, psychosocial status, transplantation, mortality reviews, staffing policy, errors, fluid status, staff education, home dialysis, surveillance of water treatment, venous catheter use reduction, fistula use, depression, hospitalizations, cardiovascular health, patient suggestions for QI and safety, and growth and development for pediatric patients under the age of 18. A large number of the comments supported inclusion of infection control and renal bone disease. Two commenters suggested that we omit the specific QAPI elements because while they are currently appropriate, they should not be codified.

Response: The proposed QAPI elements included adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries and medical errors identification, hemodialyzer reuse program, and patient satisfaction and grievances. The majority of comments strongly supported the QAPI topics that we proposed to be included in the facility QAPI program. We have added ''mineral metabolism and renal bone disease'' to the list of QAPI topics in this final rule at § 494.110(a)(2)(iii) due to its importance to quality dialysis care, its association with cardiac health, and the strong support received from commenters. Renal bone disease and mineral metabolism are routine components of dialysis facility QI programs and are easily monitored via lab values. CMS has recently pilot tested mineral metabolism/bone disease clinical performance measures and has added these as new ESRD clinical performance measures. We have also added ''infection control'' at § 494.110(a)(2)(ix), as discussed above in connection with § 494.30 ''Infection control'' condition. This QAPI component retains the same specificity and detail provided in the proposed rule under § 494.30. We believe that infection control is crucial to protecting patient health and safety. We do not intend to understate the importance of this issue simply because it was relocated in this final rule.

Fistula use and reduction in venous catheter use is encompassed by the vascular access topic, which is already included in the QAPI required topics. Therefore, we are not making any additional changes. Dialysis facilities should focus on the vascular access problems that have been identified as a priority for their facility.

Surveillance of the water system is already required by this final rule; the ANSI/AAMI RD 52 water purity guidelines, incorporated by reference in the ''Water and dialysate quality'' condition for coverage at § 494.40(a), specify surveillance and quality assurance procedures.

We encourage dialysis facilities to include social services and other suggested QAPI topics in their program when appropriate, but are not requiring these additional topics. The facility should identify additional QAPI components when it prioritizes improvement activities in accordance with standard § 494.110(c). We expect the dialysis facility to devote the needed resources to its QAPI program, which will be based on such prioritization of facility needs.

Comment: We received several comments on various aspects of proposed § 494.110(b), which includes monitoring performance improvement, taking actions that result in performance improvements, and tracking performance to sustain improvements. One commenter stated that when evaluating performance, new patients should be excluded for the first 3 months. Another commenter suggested that the facility be examined before requiring an improvement plan, in order for the surveyor to evaluate patient characteristics and to decrease risk of facilities ''cherry picking'' the healthiest patients. A commenter stated that patients will not be able to meet targets for albumin and anemia, and certain categories of patients should be excluded from the quality measure patient population. One commenter

suggested that it should be sufficient that facilities address the quality issues, while another stated that the facility can only address actionable issues. Some commenters said a risk adjustment is needed, but one commenter disagreed with a need for risk adjustment. Other commenters stated that patient non-compliance is a factor in meeting QAPI goals.

Response: The intent of § 494.110(b) was explained in the preamble of the proposed rule (70 FR 6217) where we stated, ''We will specifically expect a facility whose treatment outcomes vary significantly from accepted standards to identify the reasons for poor outcomes and implement improvement projects to achieve expected outcomes.'' The QAPI program is meant to have a facility-wide scope that seeks opportunities for improvement, whereas the ''Patient plan of care'' condition focuses on individual patient care. Since the QAPI program is an internal facility function, facilities may use their own risk adjustors and incident or prevalent patient designators within their QAPI programs as needed. However, both adjusted and unadjusted QAPI data must be available for our review. This QAPI condition does not require facilities to report QAPI data, although information about quality measurement and improvements would need to be available to the surveyor who assesses whether the QAPI program met the requirements of this condition. The risk adjustment aspect is discussed under the ''minimum facility-wide standards'' discussion below.

The QAPI requirement provides the facility with flexibility in identifying the QAPI goals and actions to undertake. We would expect the facility to undertake activities that are expected to improve health outcomes, and prevent and reduce medical errors.

We recognize that patient adherence to the treatment plan can be a factor in meeting facility QAPI goals. The issue of patient compliance was discussed earlier in this document under the ''Patient plan of care'' condition portion of the preamble. We addressed the need for interventions when the plan of care goals are not met and the required documentation of any barriers preventing the goals from being met. It is possible that some facilities may find during their prioritization of improvement activities that patient compliance trends need to be addressed within the QAPI program.

Comment: Several commenters supported a requirement for dialysis facilities to use a common patient experience of care or satisfaction tool. They stated that this would allow comparable information and spur improved performance, although one commenter stated this could be costly and burdensome. Two commenters support the use of a common tool that allows facilities to add unique facility-chosen questions. A few commenters supported a patient satisfaction survey, but not use of a common tool. While there was predominant support for the inclusion of patient satisfaction in the QAPI program requirement, few commenters specified their position on whether CMS should mandate the use of a common survey tool (that is, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)).

One commenter said that CMS should only specify that a survey be done and within specified intervals. Another commenter, opposing a common patient satisfaction tool requirement, stated regional differences may skew results. A large dialysis organization (LDO) stated they preferred their own patient satisfaction tool, which is used to benchmark and allows modifications to the questions over time. The LDO further stated that ICH CAHPS is not operational, and that pilot tests need to be reviewed. A few commenters recommended that a ''quality of life'' aspect be included in a patient survey.

Response: We are requiring that dialysis facilities include patient satisfaction as a component of their QAPI program. At this point in time we are strongly encouraging facilities to use the standardized ICH CAHPS tool to assess in-center hemodialysis patient experience of care, but we are not requiring use of this instrument. As the renal community becomes more experienced with using the ICH CAHPS instrument and recognizes benefits associated with its use, we would expect to see widespread voluntary use.

Providing patient experience-of-care information to beneficiaries is a priority for CMS as a component of our transparency initiative. Many of the questions in the Core ICH CAHPS Instrument are questions that were taken directly from existing surveys used by dialysis facilities that responded to our call for measures. A rigorously tested instrument, based on input from stakeholders and facilities, would supply valuable feedback to facilities for improving quality of dialysis care.

Creation of a standardized patient experience-of-care survey for dialysis patients is directly responsive to calls for CMS and the Secretary to collect this type of information in a variety of reports. The Office of the Inspector General (OIG) Report, entitled ''External Review of Dialysis Facilities'' (June 2000), recommended that CMS ''require dialysis facilities to monitor patient satisfaction'' particularly, as a way of bringing forth patient concerns that may not be captured by the current complaint systems. Likewise, in a Report to the Congress entitled ''Improving Payment for End-Stage Renal Disease Services'' (March 2000), the Medicare Payment Advisory Commission (MedPAC) recommended that CMS collect and analyze information on a regular basis on ESRD patients' satisfaction with the quality of and access to care. This recommendation was reiterated in MedPAC's report to the Congress ''Modernizing the Outpatient Dialysis Payment System'' (October 2003), which recommends that, ''The Secretary should also monitor patient satisfaction with care and other access indicators to determine whether patients face obstacles in obtaining needed care.'' Furthermore, the importance of a patient focus in the provision of healthcare services was emphasized in the IOM 2001 report, ''Crossing the Quality Chasm,'' that established patient-centered care as one of the industry's six aims for quality improvement. The IOM dimensions of patient-centered care include respect for patients' values, preferences, and expressed needs; coordination and integration of care; information, communication, and education; physical comfort; emotional support; involvement of family and friends; continuity and transition; and access to care. The ICH CAHPS survey instrument addresses all these areas in either the Core Instrument or supplemental questions.

Consumer testing of the DFC Web site, conducted on behalf of CMS by the Research Triangle Institute during 2002 and 2003, revealed that consumers most frequently requested patient satisfaction information or patient opinions about the care given in dialysis facilities to gauge the quality of care provided in a dialysis facility. The data collected from the core items in a common tool will allow consumers to make ''apples to apples'' comparisons among dialysis facilities. In addition, such information would allow dialysis facilities to benchmark their performance at local, regional, and national levels.

The ICH CAHPS core instrument and supplemental questions have been placed in the public domain. Any hemodialysis facility interested in using the survey should contact Charles Darby at *Charles.Darby@ahrq.hhs.gov.* The Agency for Healthcare Research and Quality welcomes input on experiences

that dialysis facilities may have in implementing the survey.

Comment: We received many comments regarding CMS use of facility-specific standards for enforcement of the conditions for coverage. While commenters supported CMS regulations that would hold facilities accountable for their performance via clinical data, there was much disagreement regarding the implementation approach.

Several commenters responded to our proposed rule preamble discussion (70 FR 6218) regarding the use of NKF K/DOQI clinical practice guidelines as the facility-specific minimum standards to be used for enforcement. One commenter recommended that CMS adopt evidence-based NKF–K/DOQI clinical practice guidelines for adequacy, anemia, and vascular access as facility-wide targets for enforcement. The commenter suggested that if problems were found, facilities could be required to provide a plan to improve care with active Network involvement. Two commenters supported minimum clinical standards using K/DOQI, stating that this could provide a basis for quality improvement and patient education on expected outcomes or goals. One commenter supported facility-wide measures without risk adjusters, arguing that no patient should be exempt from the coverage of evidence-based minimum threshold values, and pointing out that the purpose of QAPI is to identify and solve problems.

Most of the comments submitted on this minimum standards issue did not support immediate implementation of facility-level standards and thresholds in this final rule. The NKF communicated concerns about CMS use of their K/DOQI guidelines for enforcement without addressing factors such as case mix, effects of patient non-compliance, biologic variability, third party reimbursement, large numbers of outliers, and the inflexibility of the CMS regulation process. Another commenter suggested that CMS should be careful to avoid overly prescriptive language, requirements that create new indirect costs, and requirements that hold units accountable for things they cannot control. A commenter stated that some K/DOQI clinical practice guidelines are opinion-based, and some requirements apply to non-reimbursable practices and that only evidence-based criteria covered by Medicare should be considered for inclusion in the conditions for coverage.

A few commenters stated that not all patients would be able to meet the numerical outcome targets and should not be expected to meet them. Other commenters were concerned about unintended consequences. A commenter suggested that ''cherry-picking'' and other inadvertent consequences will result without an effective case-mix adjuster to avoid disadvantaging facilities that have a challenging case mix. The commenter further stated that the current Medicare Modernization Act case-mix adjuster (used to determine Medicare payment) is inadequate, disadvantages frail elderly patients, and that minimum standards should not be considered until an effective case-mix adjuster has been developed. Many commenters objected to implementation of facility-level performance standards without the use of case-mix adjusters and objected to using clinical practice guidelines written for individual patient care as facility-wide standards.

Some commenters noted that the NKF workgroups that developed the K/DOQI clinical practice guidelines never intended that they would be used for enforcement and pointed to the K/DOQI disclaimer regarding appropriate use of the clinical practice guidelines. A commenter stated that more study is needed to link existing evidence to intended outcomes. Another commenter stated that CMS needs to differentiate between standards and clinical guidelines. A commenter suggested that ''dynamic'' numerical standards do not belong in ''static'' federal regulations. The commenter also noted that no methodology exists to update numerical values, that serum albumin should not be a target marker, and that these values are often out of the facility's control for the majority of ESRD patients.

Commenters urged CMS to avoid direct extrapolation of standards from existing guidelines until voluntary consensus organizations develop real evidence-based standards and link a standard to a desired outcome. Many commenters supported minimum facility-level clinical performance standards development via a voluntary consensus process that allowed input from the renal community at large. Several commenters specifically supported the National Technology Transfer and Advancement Act of 1995 (NTTAA) process proposed at § 494.180(h)(3)(iv) as the voluntary consensus process to use. A commenter urged CMS to develop flexible, evidence-based standards with a methodology for periodic review. Another commenter endorsed the concept of using commonly agreed upon clinical standards, but was very concerned that frequent rulemaking would be required. One commenter questioned the need for minimum standards in these conditions given the difficulty of updating the conditions for coverage. Another commenter also stated that CMS should not link QAPI expectations to ''static standards.''

One commenter stated that the minimum facility standards proposal is focused totally on lab-based outcomes and this focus ignores more important clinical issues such as blood pressure treatment and cardiovascular disease risks that are not tied intimately to information technology systems and laboratory test outcomes. While multiple laboratory results may be available, other important factors such as the percentage of patients on ACE (angiotensin converting enzymes) inhibitors or beta-blockers are not readily available. Another commenter stated that there is an overdependence on K/DOQI in the proposal.

Although commenters agreed that CMS should hold dialysis facilities accountable for clinical outcomes and performance, the majority did not agree with implementing facility-level clinical performance standards based on the NKF K/DOQI clinical practice guidelines without a case-mix adjuster and without recognition of other factors that affect clinical outcomes.

Response: These conditions for coverage are an important component of the overall CMS quality improvement strategy. We intend to hold dialysis facilities accountable for the quality of care provided to patients using performance measures and clinical data. Commenters pointed out some factors that may impact a facility's ability to meet K/DOQI targets for 100 percent of their patients. While certain dialysis patient populations may have some unique characteristics, efforts should be made by dialysis facilities to meet clinical practice guidelines or come as close as possible to meeting those guidelines for all patients. This is required by the ''Patient plan of care'' condition at § 494.90. We do not intend for the implementation of facility-level clinical performance standards to negatively impact access to dialysis care and we do not hold facilities accountable for outcomes beyond their control. Currently we do not have a case-mix adjuster or other analytical means to ensure comparability between facility performance levels. We would like to address the concerns voiced by commenters before facility-level minimum standards are implemented. In response to comments, we will develop facility-level clinical performance standards via a voluntary consensus standards process indicated at § 494.180(h)(3)(iv). Once developed, these facility-level clinical performance

standards will be published in the **Federal Register** as a proposed rule.

Comment: A few commenters responded to our preamble discussion (70 FR 6218) regarding how current NKF–K/DOQI clinical practice guidelines could be used as minimum standards and what statistically-based thresholds could be employed.

One commenter who was not in favor of using the K/DOQI guidelines as minimum facility-level standards provided suggestions for possible statistical methodologies: using 2 standard deviations below the mean; or, using the 25th percentile for skewed distributions or alternatively using percentiles; however, using a set percentage cut-off as a standard would be arbitrary with no basis in science or evidence. Another commenter suggested that facility-specific ''clinical care measures should never appear on the oversight radar unless a certain percentage of patients fail to meet a particular measure.'' Another commenter recommended that facility-specific standards using K/DOQI be identified as goals and expectations ''for more than 80 percent'' of all patients. This commenter related concern about how minimum standards would be applied when facilities are surveyed and stated that the final rule must acknowledge that 100 percent of patients cannot achieve K/DOQI target minimums.

One commenter suggested that CMS set minimum outcome goals, then move up the thresholds incrementally, with annual readjustments. Another commenter suggested that facilities could develop a corrective action plan when a pre-determined portion of patients failed to meet selected clinical standards. This could be percentile-based or some other methodology but would have to be developed in collaboration with the dialysis industry.

Another commenter recommended a focused review by the servicing Network's Medical Review Board prior to implementation of a corrective action plan, to determine whether there may have been reasonable justification for poor performance. The focused review should be consistent with population studies, which are statistically sound, and not on percentile thresholds. A commenter suggested that K/DOQI clinical practice guidelines were developed only to ''inform and enhance decision-making,'' and believed that any process should include a review by Network Medical Review Boards prior to CMS taking enforcement action.

One commenter had a number of concerns. The first concern was that it would be impossible to predict if patients could achieve clinical outcomes. Another concern was that the proposal could create a potential paperwork burden. A third concern was that no improvement plan should apply unless a significant number of patients were involved. Another concern was that the proposal ignored issues like missed sessions and patient non-compliance. The commenter also suggested that an improvement plan could not guarantee better outcomes, and that the renal community should develop clinical standards and CMS should then incorporate them by reference into its regulations.

A commenter stated that the minimum standards proposal confuses process with outcomes. While a facility can order adequate dialysis, Epogen, iron, etc., it could not guarantee that numerical targets would be met. Documenting interventions and why goals were not met should be sufficient, not the mandatory requirements proposed.

Response: According to the 2006 Annual Report, End-Stage Renal Disease Clinical Performance Measures Project (*http://www.cms.hhs.gov/CPMProject*), which is based on data from October 2005 through December 2005 for hemodialysis patients and October 2005 through March 2006 for peritoneal dialysis patients, reports national rates of meeting K/DOQI based performance measures using a representative sample, 91 percent of hemodialysis patients are meeting the dialysis adequacy target, and 81–84 percent of dialysis patients have a hemoglobin of 11 g/dL or better are meeting the anemia targets. In determining facility-level minimum standards, we would not want to set our thresholds well below established performance levels that could serve to undercut current performance levels.

We have not included minimum facility-level clinical standards in this final rule. We intend to develop minimum facility-level clinical standards for enforcement using a voluntary consensus standards process, as proposed at § 494.180(h)(3)(iv).

f. Special Purpose Renal Dialysis Facilities (Proposed § 494.120)

We proposed to retain with modifications the ''Special purpose renal dialysis facilities'' condition from § 405.2164. This condition addresses the needs of patients who need dialysis on a short-term basis because of emergency conditions, or because they are staying at remote vacation camps. We proposed that such dialysis facilities would be approved to furnish dialysis services at special locations and that such vacation camps would have to be operated under the direction of a certified renal dialysis facility that would assume full responsibility for the care provided to patients. The proposed rule retained the limited 8-month approval period and the service limitation found at § 405.2164. We proposed that a special purpose facility would be approved as a vacation camp by demonstrating compliance with proposed § 494.30, most provisions of § 494.40, § 494.50, § 494.70(a) and § 494.70(c), § 494.100(c)(1)(v), § 494.130, § 494.150(c) and § 494.150(d), and § 494.170. We also proposed that a special purpose facility certified due to emergency circumstances could provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility and was approved by demonstrating compliance with specified proposed conditions for coverage that included § 494.20, § 494.30, § 494.40, § 494.50, § 494.60, § 494.70(a) through § 494.70(c), § 494.130, § 494.140, and § 494.150, § 494.170, and § 494.180. The part 405, subpart U requirement, that a special purpose unit consult with the patient's physician, was retained; we added a provision that this consultation must occur before initiation of dialysis in a special purpose unit. Additionally, we proposed to require the special purpose unit to document care provided to the patient and forward that documentation to the patient's regular dialysis facility within 30 days.

Comment: Many commenters submitted suggestions and recommendations regarding requirements and/or certification for special purpose dialysis facilities, and several commenters made positive remarks regarding the proposed requirements and inclusion of vacation camps within this condition, including the 8-month approval period for special purpose facilities, as required at § 494.120(a). A commenter applauded the specific mention of vacation camps in this regulation, but advised that these vacation camps should be certified as ''safe environments'' for campers, while another commenter suggested the deletion of vacation camps from the final rule. One commenter suggested that the personnel requirements for the ESRD facility medical director, for those furnishing nursing services, and for patient care and water treatment technicians be met by the special purpose dialysis facility vacation camp if on-site dialysis is performed.

Another commenter suggested that the final rule requirements also address backup emergency care, and further suggested that the closest hospital and/

or children's hospital be notified and a process for emergency transportation be identified. One commenter suggested that ''certified facilities not be held accountable for services provided outside their domain.''

Response: We appreciate the positive comments on the proposed language regarding special purpose dialysis facility vacation camps. While we received a suggestion to delete vacation camps in the final rule, the majority of comments regarding vacation camps were positive. Thus, we will adopt vacation camp requirements in the final rule at § 494.120. We also received some positive remarks regarding the approval period of 8 months, discussed at proposed § 494.120(a), which will also be adopted in the final rule. We agree with the commenter that vacation camps should be a safe environment for campers. The facilities must comply with the conditions for coverage set out at § 494.120(c) to ensure that the vacation camp environment protects the health and safety of campers.

This condition addresses the possible needs of patients who, because of emergency conditions, or because they are staying at a remote vacation camp providing such services, need dialysis on a short-term basis. The commenters' concerns regarding certain personnel requirements, as well as responsibility and accountability for vacation camps, is addressed at § 494.120(c)(1). This standard mandates that special purpose dialysis services, provided at a vacation camp facility, be operated under the direction of a certified renal dialysis facility. The certified renal dialysis facility assumes full responsibility for the care provided to patients. Vacation camps must demonstrate compliance with the conditions for coverage set out at § 494.120(c)(1)(i) through § 494.120(c)(1)(viii), including infection control, water and dialysate quality, reuse of hemodialyzers, patients' rights, laboratory services, medical director responsibilities, medical records, and home monitoring of water quality. We agree with the commenter that it is important to take into consideration emergency backup care in vacation camps. Vacation camps will be held responsible for the care of their patients under § 494.120(c)(1), including emergency care when required; however, we will not specifically mandate that vacation camps notify hospitals and develop emergency transportation plans in this final rule. We believe that the requirement at § 494.120(c)(1) provides adequate protection for patients at vacation camps.

Comment: A commenter supported the requirements for emergency circumstance facilities, noting that recent natural disasters underscored the necessity for such facilities. Another commenter agreed with changes in the proposed rule that would make access to care for a patient in a disaster situation more readily available. One commenter suggested the proposed language at § 494.120(c)(2) was too restrictive and that the final rule should be revised by requiring such facilities to comply with the specified conditions ''where feasible.'' The commenter suggested that adding ''where feasible'' would be necessary in the event of a large emergency affecting a broad geographical area.

Another commenter suggested the requirement at § 494.120(c)(2)(i) regarding compliance with Federal, State, and local laws and regulations would be redundant for a facility that is quickly converted to a special purpose facility under emergent circumstances. The commenter suggested the adoption of State and local codes, as well as the International Code Council (ICC) requirements, in lieu of the LSC, would eliminate this problem of redundancy in many states. The ICC is an association dedicated to building safety and fire prevention, and they develop the codes used to construct residential and commercial buildings, such as health care facilities. Most U.S. cities, counties and states that adopt codes choose those codes developed by the ICC.

Response: In the event of a large disaster, section 1135 of the Act gives the Secretary the authority to waive regulatory requirements during national emergencies. During natural or man-made disasters, the proposed regulation at § 494.120(c)(2) allows for more flexibility than part 405, subpart U of our previous regulations in managing emergent circumstances. These facilities must comply with a condensed number of conditions, which include: § 494.20, compliance with Federal, State and local laws and regulations; § 494.60, physical environment; abbreviated sections of § 494.70, patient's rights; § 494.140, personnel qualifications; § 494.150, medical director; and § 494.180, governance. While we expect that special purpose facilities will comply with these requirements, we understand that there may be instances where this may not be possible and a waiver might need to be granted; however, we do not agree that the suggested language ''where feasible'' should be added to the final rule.

Comment: Two commenters agreed that physician contact during a disaster is ideal; however, they stated it may be impossible. These commenters recommended the addition of a provision to allow another physician to provide emergency care in extenuating circumstances at § 494.120(d). One commenter suggested we modify the requirement in the final rule to indicate, ''Standing orders or the patient's current orders may be followed until the time a physician may be reached.'' Another commenter suggested the wording in the final rule be changed to require ''nephrologist contact'' as opposed to ''physician contact.''

Response: We agree that it may not be possible to consult with the patient's physician during a disaster. To allow greater flexibility, in the event of disasters or emergencies, we have modified the wording in the final rule at § 494.120(d) to indicate that the facility must contact the patient's physician ''if possible'' prior to initiating dialysis in the special purpose renal dialysis facility. Additionally, we will retain the requirement for ''physician contact'' as proposed, because we believe this language will allow more flexibility for facilities.

Comment: It was suggested by a commenter that we modify the final rule to require forwarding of documentation of care at the special purpose facility to the patient's regular facility within 1 day of the last scheduled treatment, as opposed to 30 days as proposed at § 494.120(e). The rationale given was that hospitals as well as transient dialysis clinics must transfer patient care records within one day.

Response: It is the responsibility of the special purpose facility to communicate to the patient's permanent dialysis facility regarding the patient's status, and we recognize that it would be most desirable for this information to be forwarded in less than 30 days. However, we must also keep in mind that some circumstances may prevent such communication timeframes. For example, we have learned through recent events, such as Hurricane Katrina in 2005, that 30 days may not allow enough time for special purpose facilities to forward all documentation to the patient's permanent facility. Because we recognize this possible limitation, we have added language to allow greater flexibility for facilities. At § 494.120(e) the language has been modified in the final rule to require information be forwarded ''if possible'' within 30 days.

g. Laboratory Services (Proposed § 494.130)

We proposed to retain the existing requirements governing laboratory services previously set out at

§ 405.2163(b), with minor revisions. The dialysis facility must provide or make available laboratory services to meet the needs of their patients, and these services must be furnished by or obtained from a facility that meets the requirements for laboratory services in accordance with 42 CFR part 493.

Comment: One commenter recommended that we add language in the final rule to specify that facilities must have an agreement with a primary or secondary laboratory that meets the Certified Laboratory Improvement Amendments of 1988 (CLIA) requirement.

Response: CLIA certification is addressed at § 494.130 by reference to part 493. It states that all Medicare-certified laboratories performing laboratory tests be certified under CLIA. Therefore, we have adopted the language as proposed.

Comment: One commenter suggested the addition of language to the final rule saying that to ''ensure that composite rate lab tests for each ESRD beneficiary are accounted for in a single, centralized database for proper application of ESRD laboratory billing rules, composite rate lab tests performed by any other laboratory must be billed through the primary laboratory.'' Another commenter suggested adding language to specify that in the event a facility uses a secondary laboratory, it must enter into an agreement with the facility or the facility's primary laboratory to bill the facility or the primary laboratory for laboratory tests that are subject to ESRD laboratory billing rules. One commenter suggested we require a facility's primary laboratory to be the single laboratory permitted to bill Medicare for tests listed as composite rate laboratory tests. Another commenter suggested that local laboratories (in close proximity to an ESRD facility) should be able to bill for tests through a ''primary laboratory.'' One commenter remarked that the final regulation should address problems with Health Maintenance Organizations (HMOs) and mandate that required testing be conducted in laboratories equipped to do such testing. The commenter stated that HMOs often refuse referrals to properly equipped laboratories affiliated with the patient's ESRD unit.

Response: The commenters' concerns are related to Medicare payment for services and are therefore outside the scope of this rule. The commenters' concerns have been forwarded to the appropriate officials within CMS for consideration.

Comment: One commenter suggested the regulation require that primary laboratories agree to furnish the dialysis facility with laboratory test data electronically upon request so that the data can be submitted to ESRD Networks.

Response: The ESRD Conditions for Coverage cover dialysis facilities and do not extend to testing laboratories. Facilities must provide for or make available laboratory services to meet the needs of the ESRD patient. Laboratory services must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter (§ 494.130). However, dialysis facilities may enter into business agreements with laboratories willing to provide requested data electronically.

Comment: One commenter stated ''convenience'' lab draws need to be addressed in the final rule.

Response: We believe the commenter is referring to those laboratory tests, such as histocompatability tests, ordered by a patient's outside physician, which could be drawn in the ESRD facility while a patient is undergoing dialysis treatment. Drawing additional laboratory tests while the patient is undergoing treatment is convenient for the patient; individual facilities have the flexibility to determine if this is a service they wish to offer.

4. Subpart D (Administration)

a. Personnel Qualifications (Proposed § 494.140)

To avoid placing substantive requirements within the definitions section as written in part 405, subpart U (at § 405.2102), we proposed a separate condition to set forth requirements for dialysis facility staff qualifications. We proposed that the dialysis facility medical director be a physician who has completed a board approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis. We did not retain transplantation experience as a qualification, which was previously set out at § 405.2102(d), because this rule applies to dialysis centers and not to transplantation centers. We proposed to carry forward the part 405, subpart U waiver provision for instances when a physician meeting the medical director qualifications is not available. We proposed that the facility nurse manager be an RN and a full time employee, as required under part 405, subpart U, and have at least 12 months of clinical nursing experience and an additional 6 months of dialysis experience. We proposed that the self-care home dialysis training nurse be an RN with at least 12 months of nursing experience and an additional 3 months of dialysis experience in the modality for which he or she would provide training. We proposed new qualifications for the charge nurse, who would be required to be an RN or licensed practical nurse (LPN) with 12 months of nursing experience, including 3 months of dialysis experience. We also proposed new qualifications for the staff nurse, who would have to be an RN or LPN and meet the State practice requirements. The proposed qualifications for the facility dietitian included the registered dietitian (RD) credential and at least one year of professional work experience as a RD. We proposed social worker qualifications that would require the social worker to have a master's degree in social work from a school of social work accredited by the Council on Social Work Education. Our proposed social worker qualifications did not include the grandfather clause (see § 405.2102, ''Qualified personnel'' paragraph (f)(2)), which allowed non-master's prepared social workers who were employed for at least two-years as of September 1976 to hold dialysis facility social worker positions when there was a consultative relationship with a master's prepared social worker. We proposed to recognize patient care dialysis technicians for the first time in the proposed conditions for coverage, and set forth proposed qualifications. We proposed that patient care dialysis technicians have a high school diploma or equivalency and at least 3 months experience under the direct supervision of an RN, and that they complete a training program that would include specified topics and be approved by the medical director and governing body. We proposed that the clinical staff meet State practice requirements (§ 494.140) and be licensed according to State provisions (§ 494.20 and § 494.140(e)(1)). We proposed new qualifications for the water treatment system technicians, who would complete a training program approved by the medical director and governing body. Personnel qualifications that were not carried forward from part 405, subpart U, included those for the chief executive officer, medical record practitioner, and the transplantation surgeon.

We received more comments (more than 150) on the proposed ''Personnel qualifications'' condition for coverage at § 494.140 than on any other condition.

Comment: A large number of commenters suggested that the title of this condition be changed to ''Personnel qualifications and responsibilities'' and

that the specific responsibilities of all members of the interdisciplinary team be included. Commenters suggested that the medical director and patient be excluded from assignment of responsibilities under the ''Personnel qualifications'' condition. Some commenters said that since medical director responsibilities were included at § 494.150, other team member responsibilities should be listed in the regulation as well. Some commenters stated that it would be helpful if clinical social worker responsibilities were listed in regulation; they state that social workers are unable to provide clinical social services to patients because they are often tasked with clerical work that fills the majority of their time.

Response: We have sought to be less prescriptive in this rule in order to allow dialysis facilities flexibility in meeting Medicare requirements. We expect that as professional caregivers, members of the interdisciplinary team are aware of their discipline's professional standards of practice and provide quality care to their patients in keeping with those standards. Under the ''Patient assessment'' and ''Patient plan of care'' conditions (§ 494.80 and § 494.90), we require that members of the interdisciplinary team complete a comprehensive assessment followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the registered dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. Specifically, the dialysis facility must ensure that the social worker provides timely psychosocial assessments and social work interventions in accordance with the plan of care in order to meet these conditions for coverage. We are also requiring at § 494.140 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. We do not agree that all the responsibilities of the entire interdisciplinary team need to be enumerated in regulation.

Comment: Many commenters objected to the change in medical director qualifications, as proposed in standard § 494.140(a), and recommended that the medical director be board-eligible or board-certified, as previously required at § 405.2102(e). These commenters included patient organizations, dialysis organizations, as well as physicians. One commenter stated that nephrology is a recognized sub-specialty, which requires specialized knowledge and training and that removing the ''board eligible or board-certified'' requirement could affect the continued existence of this sub-specialty. Another commenter said this ''board-certified'' requirement is the accepted industry standard for evidence of proficiency in a specialty. A commenter stated that to lower standards could jeopardize patient care across the nation and that board eligibility and certification needs to be recognized. Other commenters object to lowering of standards for this important position, except on a case-by-case basis. One commenter recommended that the medical director be required to be a nephrologist. Two commenters supported our proposed medical director qualifications.

Response: Many commenters communicated quality-of-care concerns regarding our proposed deletion of the requirement under former § 405.2102 that the facility medical director be ''board-eligible'' or ''board-certified'' in internal medicine or pediatrics. Our goal is to improve quality of care via this final rule and to ensure that the medical director has the appropriate qualifications. Therefore, in response to comments, we have revised the proposed requirement in the final rule, so that the medical director must be ''board-certified'' in internal medicine or pediatrics by a nationally recognized professional board at § 494.140(a). We are not including the term board-eligible,'' as it is no longer used, defined, or recognized by the American Board of Internal Medicine (*http://www.abim.org/cert/policies_ssneph.shtm*). We have retained the proposed requirement that the medical director complete a board-approved training program in nephrology.

Comment: A commenter recommended that the time period during which a physician is in a training program and providing care to dialysis patients should satisfy the 12-month experience requirement for medical directors. Another commenter requested clarification of whether or not experience gained during a training program could count towards the 12 months of experience for medical director qualifications. The commenter noted that if this time were not counted, then nephrologists completing their training programs could not become a medical director for at least 12 months.

Response: The required 12 months of experience caring for dialysis patients may include experience gained while a physician is enrolled in a nephrology-training program. This will be reflected in the interpretive guidelines for this regulation.

Comment: A commenter requested further clarification of the process that would allow a physician who does not meet the medical director requirements at § 494.140(a)(1) to serve as the medical director as permitted at § 494.140(a)(2).

Response: A physician who does not meet § 494.140(a)(1) requirements may only serve as the medical director when a qualified physician is not available, and when approved by the Secretary as required at § 494.140(a)(2). This provision was retained from part 405, subpart U. A dialysis facility seeking to place an alternate physician in the role of the medical director must contact their CMS Regional Office to make a request for the Secretary's approval.

Comment: While most commenters supported the proposed RN qualifications at § 494.140(b), one commenter suggested an increase in RN experience requirement, to 2 years of clinical and 1 year of dialysis experience. Another suggested that the RN experience qualification be reduced to 6 months. One commenter asked whether one RN could fulfill all four roles listed under nursing services (§ 494.140(b)) if he or she met all the qualifications.

Response: Very few commenters disagreed with the proposed experience qualifications for RNs; therefore, we will adopt the requirement for 12 months of nursing experience and 3 to 6 months of dialysis experience (depending on the role of the RN) in this final rule. A single RN may fulfill multiple nursing roles in the dialysis facility if he or she possesses the appropriate qualifications for each role and if this does not jeopardize the facility's ability to meet the staff requirement at § 494.180(b)(1).

Comment: A few commenters suggested a revision of the qualifications for the charge nurse. A commenter suggested that 12 months of experience for charge nurses be changed to 6 months because the nursing shortage necessitates not eliminating new nursing graduates from the hiring pool. Another commenter stated that 3 months of dialysis experience should not include ''orientation time,'' as 3 months of experience is barely adequate. Two commenters stated that they believe the 3 months of dialysis experience to be inadequate and recommended that the requirement be changed to at least 6 months, since some States, such as California, have no

minimum training requirements; the commenters believe that this endangered patients.

Response: There was disagreement among commenters regarding the proposed qualifications for charge nurses, with some commenters advocating longer experience requirements and others suggesting shorter experience requirements. Our goal for this provision is to ensure that a qualified nurse who can adequately protect patient safety acts as the charge nurse. We believe that the level of experience for charge nurses as stated in the proposed rule (12 months experience in providing nursing care, including 3 months of dialysis nursing care) is reasonable. Given that there is disagreement among commenters and no evidence was presented supporting a modification, we have adopted the charge nurse experience requirements as proposed at § 494.140(b)(3)(ii).

Comment: Many commenters objected to the proposed charge nurse qualifications, which commenters state would allow a licensed practical nurse to serve as a charge nurse, because state practice boards generally do not allow an LPN to supervise an RN. Some commenters stated that the level of responsibility for the charge nurse requires an RN, and LPNs are not qualified for this position. Other commenters stated that experienced dialysis LPNs are very capable individuals. Two commenters stated that due to the nursing shortage, an LPN should be allowed to act as the charge nurse only when an RN is not available. Another commenter stated that the nursing shortage should not be used to justify use of unqualified personnel. One commenter stated that LPNs could function as charge nurses without any RN supervision on-site, and another stated that the LPNs at her facility have more experience than the RNs. One commenter noted that LPNs are used more frequently by LDOs.

Response: We have revised the requirement formerly found at subpart U (§ 405.2162), so that an RN must be present in the facility, and an LPN could still act as a charge nurse if he or she met the proposed qualifications. We did not intend for a LPN to supervise an RN, as suggested by the commenters.

The RN must be present in the facility when patients are being treated, as required at § 494.180(b)(2). An LPN might act as the charge nurse but would not necessarily be supervising an RN. All dialysis nurses must adhere to their state practice requirements. We have modified § 494.140(b)(3)(iii) to clarify this by adding language to indicate that, if the charge nurse is a licensed practical nurse or licensed vocational nurse, that he/she must work under the supervision of a registered nurse when required by the State nursing practice act provisions.

Comment: A few commenters objected to proposed § 494.140(b)(1)(i), which requires the nurse manager RN to be a full-time employee of the facility, and recommended deletion of this requirement. Two commenters said it was unrealistic to require the nurse manager to be employed full-time because small rural units are only open part-time. Some units share the same nurse manager. A commenter stated that requiring a full-time employee as nurse manager would not be a good use of a scarce resource.

Response: The full-time requirement is not a new provision (refer to former § 405.2162(a)). Dialysis facilities should already be fully compliant with this provision. In the case of small dialysis facilities that are not open for at least 40 hours per week the ''full-time nurse'' would be employed at all times the facility is open. For example, a dialysis facility that is only open for 24 hours per week would only need to employ the nurse manager for 24 hours per week to satisfy this requirement. We have retained this requirement as proposed.

Comment: We received a few comments regarding the qualifications of the self-care training nurse.

Response: Please refer to the earlier discussion of self-care training nurse qualifications found under the discussion of § 494.100 in this preamble.

Comment: A commenter suggested that we change the position title ''self-care training nurse'' to ''self-care or home training nurse'' in order to specify that self-care nurses can train patients for in-home or in-facility dialysis.

Response: We agree, and have modified the position title at § 494.140(b)(2) to clarify that ''self-care'' includes home dialysis. The new position title is ''self-care and home dialysis training nurse.''

Comment: A commenter suggested that staff nurse requirements be the same as those proposed for PCTs, which are at least 3 months experience, following a training program that is approved by the governing body.

Response: We agree that the requirements should be similar. We have eliminated the experience requirements for both staff nurses (§ 494.140(b)(4)) and PCTs (§ 494.140(e)). Each professional, however, will be required to meet the training requirements appropriate to their specialty.

Comment: One commenter suggested that a statement be added to the final rule that would mandate that there could be no contract nurse(s) filling the roles of the nurse manager, self-care training nurse, or the charge nurse.

Response: We agree, and are adopting the proposed requirement at § 494.140(b)(1)(i) that the nurse manager be a full-time employee of the facility, which means this position cannot be filled by a contracted nurse. The self-care and home dialysis training nurse and the charge nurse positions do not have this restriction and may be either employees or contractors. Employees are subject to the following directions of an employer relative to what needs to be done and how it should be done. Contractors, on the other hand, are generally not held to how a job is done and the methods that are used. A nurse manager fills a critical role and it is important that his or her actions meet the needs of the facility's governing body. If a nurse under contract fills these roles, he or she must have the proper qualifications and complete the orientation for the position as required in this final rule at § 494.180(b)(3).

Comment: A commenter suggested we specify that RNs have training in the care of patients with chronic disease and physical, emotional, and psychosocial issues.

Response: We would expect that RNs have received training in each of these areas as part of their nursing curriculum. We do not agree there is a need to specify this training in regulation.

Comment: One commenter suggested that advance practice nurses should serve as ''case managers'' and be reimbursed for this role.

Response: This rule does not preclude the use of advance practice nurses in dialysis facilities, but we do not feel we should be this prescriptive because of the degree of regulatory burden imposed upon facilities. In addition, this final rule does not address reimbursement issues.

Comment: We received more than 15 comments on dietitian qualifications at § 494.140(c). The majority of commenters agreed and supported our proposal to require a ''minimum of one year's professional work experience in clinical nutrition as a registered dietitian''. One commenter suggested that the American Dietetic Association (ADA) registration is not enough and minimum experience criteria are needed.

The ADA agreed with the proposed qualifications for dietitians. The ADA noted that registered dietitians (RDs) also possess clinical knowledge and

skills to manage anemia and bone disease and to conduct urea kinetic analysis. The ADA stated that according to the Commission on Dietetic Registration, there are more than 72,000 RDs nationwide, and the supply of RDs is well established.

One commenter stated that 1 year of registered dietitian professional work experience in clinical nutrition is acceptable, but 2 years would be ideal. Newly hired RDs without renal experience should have a training period of at least 2 weeks with an experienced renal dietitian. This commenter also noted that the role of the dietitian has expanded and recommended that the responsibilities of dietitians include monitoring adherence and response to diet, and recommending interventions for improving nutritional status. The commenter provided examples of the expanded role of the dietitian, which included anemia manager, and bone and urea kinetic modeling manager, to improve clinical outcomes.

One commenter agreed with the proposed 1-year experience requirement since quality care depends on renal training and specialization, but said facility managers point to the difficulty of finding sufficient numbers of experienced dietitians. This commenter suggested that the one year of experience be preferred but not required.

Three commenters disagreed with the proposed 1-year professional experience requirement. One commenter stated the 1 year of professional work experience is unnecessary; only registration with the Commission on Dietetic Registration is needed. This commenter stated that instead, mentoring and direction from an experienced renal dietitian is needed. The commenter stated that the experience requirement would diminish the pool of qualified dietitians. Another commenter also stated that adding a year of experience as a requirement for RDs would create even more of a RD shortage and is not necessary given their extensive education.

Another commenter suggested that we delete ''as a registered dietitian'' from regulations text, so that experience obtained prior to becoming a registered dietitian could be counted, and professional work experience gained during an internship would apply. This commenter further suggested that all dialysis dietitians be required to participate in training from experienced dietitians.

Three commenters recommended that the dietitian qualifications match the medical nutrition therapy (MNT) regulation requirements, which call for a bachelor of arts degree or higher, an academic program in nutrition or dietetics, 900 hours of supervised dietetics practice, and being licensed or certified as a dietitian or nutritional professional by the State in which the professional is practicing. One of these commenters agreed with requiring a minimum of 1 year's professional work experience as a registered dietitian.

Response: The dietitian qualifications in subpart U at § 405.2102(b) specify at least 1-year experience in clinical nutrition. In this final rule, we redesignated proposed § 494.140(c)(3) as § 494.140(c)(2), which requires 1 year of professional work experience in clinical nutrition as a registered dietitian. Renal nutrition is a specialized area within the practice of dietetics. The dialysis facility dietitian must be able to perform independently complex nutritional assessments, evaluate laboratory results, and assist the interdisciplinary team in managing anemia, renal bone disease, and performing kinetic modeling. A typical therapeutic diet for a hemodialysis patient has multiple restrictions and is limited in sodium, phosphorus, potassium, fluid, and includes specified amounts of protein. Many patients must follow additional dietary restrictions such as low cholesterol or diabetic limitations. We believe that a registered dietitian would need at least one year of experience to perform this specialized work. The majority of commenters recognized the specialized work of a RD in the dialysis setting.

The MNT dietitian qualifications at 42 CFR 410.134 require the MNT provider to be a registered dietitian with the Commission on Dietetic Registration or to have a bachelor's degree or higher in nutrition or dietetics, 900 hours of supervised experience and state licensure, if applicable. The MNT dietitian qualifications allow a nutritionist who is not a registered dietitian to provide medical nutrition therapy. By contrast, dialysis dietitians must be registered dietitians under both the previous ESRD regulations and the proposed rule. We have not removed the registered dietitian qualification requirement, as we find no reason to do so.

We do not have evidence that there is a shortage of registered dietitians that necessitates deletion of the clinical experience requirement. While mentoring programs are desirable, we did not propose them and have not added this requirement to the final rule. Registered dietitians must be oriented to the facility and their work responsibilities (§ 494.180(b)(3)) and have an opportunity for continuing education and related development activities (§ 494.180(b)(4)).

Comment: Two commenters suggested including the word ''clinical'' in the ''professional work experience'' phrase so that foodservice experience does not apply.

Response: The proposed rule at § 494.140(c)(3), (now § 494.140(c)(2)), requires dietitians ''have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.'' This wording would preclude a dietitian who only has foodservice professional experience from qualifying for a position as a dialysis dietitian. We do not agree that a change in wording is needed here because clearly, the experience must be in ''clinical nutrition.''

Comment: One commenter recommended that dietitian-to-patient caseloads be limited to 90–100 patients per dietitian.

Response: We address adequate staffing under the ''Governance'' condition for coverage at § 494.180(b). Some States have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue. Dialysis dietitian caseloads must not prevent RDs from providing care consistent with national standards of practice for dietitians. National standards have been published by the ADA entitled ''Standards of Practice in Nutrition Care and Updated Standards of Professional Performance'' in April 2005 (Kieselhorst, K.J., Journal of the American Dietetic Association, Vol. 105, No. 4, April 2005).

Comment: One commenter suggested that dietetic technicians be included in the final rule. The commenter stated that she strongly supported the use of dietetic technicians, registered (DTRs) under RD supervision and that DTRs are nationally certified and have education requirements similar to the RDs.

Response: We do not agree that RDs and DTRs have similar education requirements. According to the ADA, DTRs must complete at least a 2-year associate's degree while an RD must complete a minimum of a bachelor's degree at a U.S. regionally accredited college or university. A DTR must complete a dietetic technician program accredited and approved by the Commission on Accreditation for Dietetics Education (CADE), including 450 hours of supervised practice experience. An RD must complete a CADE accredited supervised practice program that typically runs 6 to 12 months in length. RDs and DTRs also have different continuing education requirements.

This final rule requires an RD to be a member of the dialysis facility interdisciplinary team, perform patient assessments, and participate in patient care planning and the QAPI program. The RD may use a DTR to provide assistance under RD supervision, but it is the RD who must meet these conditions for coverage. Therefore, we have not added DTRs to the ''Personnel qualifications'' condition.

Comment: We received more than 70 comments regarding social worker qualifications. The vast majority of commenters supported the proposed social worker qualifications, which require a master's degree in social work from a school of social work accredited by the Council on Social Work Education.

Commenters stated that dialysis patients have highly complex needs and require care from an MSW who has a ''specialization in clinical practice'' education. Commenters made the following statements in support of an MSW with a specialization in clinical practice. They stated that the nephrology social workers must be skilled in assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes, and must be able to design interventions with the patient, the family, the medical team, and community systems at large to maximize the effectiveness of ESRD treatment. The additional training received by MSWs enables them to perform these complex professional tasks and ensure effective outcomes that have a direct relationship to morbidity and mortality. Masters-prepared social workers are trained to use validated tools, such as the SF36 (the Medical Outcomes Study 36-item short-form health survey) and the KDQOL (Kidney Disease Quality of Life), to improve care and to monitor the outcomes of directed interventions. Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation, using highly developed social work intervention skills obtained in a master's level curriculum. The masters in social work degree provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum that offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate degrees or other mental health credentials do not offer this specialized and comprehensive training. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice, while the masters degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance. These commenters provided references and citations along with these comments.

A few commenters suggested that the master's degree qualification be eliminated because it is difficult to recruit MSWs in some rural areas. A commenter stated that in California a licensed clinical social worker requires 2 years of supervision and two examinations, which makes it difficult to get a licensed clinical social worker license. Another commenter suggested that we keep the MSW requirement but include an ''exceptions process'' for units that cannot hire an MSW. Some commenters stated that bachelor's prepared social workers are competent as long as they are supervised by an MSW.

Response: We appreciate the large degree of support for the MSW qualification for social workers. We have revised the MSW requirement in § 494.140(d)(1) by adding ''specialization in clinical practice,'' as specified in part 405, subpart U, as the majority of comments supported this. The consensus among the commenters is that this level of knowledge and skill is needed to deal with an increasingly older, sicker, more complex dialysis patient population.

Comment: One commenter recommended that we delete § 494.140(d) in its entirety or delete any preamble references to MSWs performing counseling, long-term behavioral and adaptation therapy, and grieving therapy. The commenter stated that such counseling exceeds the expertise of MSWs, and that patients should be referred outside the units for this service. The commenter also claimed that an ''expansion'' of counseling requirements represents a potential $18 million burden to his large dialysis organization.

Response: The ''Personnel qualifications'' condition for coverage at § 494.140 does not specify tasks or responsibilities for dialysis facility social workers, but only their education and qualifications. The proposed rule preamble discussion provided examples of social worker services that facilities might offer, including counseling services, long-term behavioral and adaptation therapy, and grieving therapy (70 FR 6222) that would require the education and training of an MSW. The proposed rule's preamble discussion is consistent with part 405, subpart U social worker requirements at § 405.2163(c), which state that ''Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient.'' Social services needed for each patient should be determined during the assessment and identified in the plan of care.

Only one commenter suggested § 494.140(d) be deleted in its entirety, while a very large number of comments supported this requirement, and the consensus was to retain MSWs in dialysis units. MSWs are trained and competent to counsel patients. The social worker professional standards of practice (*http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf*) do include patient and family counseling within the scope of services provided by a social worker. MSW services, which include counseling, is incorporated into the Medicare composite payment rate and should not be outsourced or separately billed.

Comment: We received a large number of comments regarding our proposed deletion of the master's degree ''grandfather clause'' for social workers. Many commenters agreed with eliminating the ''grandfather clause'' because ''30 years was more than enough time for dialysis social workers to obtain masters degree.'' Commenters stated that MSW and BSW tasks could be broken out into separate job descriptions so that BSWs may assist MSWs. Commenters said that there was no MSW shortage.

A larger number of commenters suggested that we retain the ''grandfather clause'' for non-MSWs so that currently employed non-MSWs working as dialysis social workers do not lose their jobs. Some commenters suggested that experienced non-MSW social workers were competent and had much to offer dialysis patients. A few commenters recommended that we continue the grandfather clause until the year 2015 to allow current non-MSWs who met the subpart U requirements to finish out their careers.

Response: According to the definition of ''Qualified personnel'' at § 405.2102, a non-masters degree social worker may serve as an ESRD social worker (under § 405.2102(f)(2), qualified personnel) when he or she ''has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition'' (that is, has completed a course of study with

specialization in clinical practice at, and holds a masters degree from a graduate school of social work). This subpart U grandfather clause only applies to non-MSWs who have been practicing social work since 1974, and any ESRD social workers who do not have 2 years of experience prior 1976 must have a masters degree.

While we believe the number of non-masters-degree social workers still practicing over the past 32 years is small, we do not intend that these long-time employees should become unqualified for their jobs because of deletion of the ''grandfather clause.'' In response to comments we will adopt the proposed ''grandfather clause'' and add the existing provision from subpart U to the final rule at § 494.140(d)(2) to read as follows: ''Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1) of this part.'' The grandfather clause may not be applied to social workers who do not meet the 1976 experience criterion. Bachelors-prepared social workers may function as assistants to the MSW. The MSW is the staff member who must satisfy these conditions for coverage.

Comment: A few commenters suggested that we eliminate the proposed § 494.140(d)(2) requirement, ''Meets the practice requirements for social services in the State in which he or she is employed.''

Response: Adherence to State scope-of-practice requirements is an appropriate minimum requirement for a federal health and safety regulation. This final rule supports compliance with State regulations. The final rule provision for meeting applicable scope-of-practice board and licensure requirements for dialysis facility personnel has been moved to the beginning of § 494.140 to avoid redundancy within the standards for each of the dialysis facility staff members.

Comment: Several commenters suggested that we add a social worker licensure requirement to § 494.140(d)(2).

Response: The proposed rule at § 494.20 required licensure for all staff. To prevent confusion regarding whether licensure is required under personnel qualifications, we have moved the requirement to the beginning of § 494.140, to read: ''All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.''

Comment: Many social workers as well as some commenters who are not social workers suggested that a new social worker aide personnel standard be added to the final rule. The rationale given was that this new staff member could perform many of the clerical tasks (admissions, billing, transportation, transient patient paperwork, determining insurance coverage) often assigned to social workers, so that the social worker would be freed up to perform clinical social services, such as counseling, that would result in improved patient care and better outcomes. Many commenters stated this position should be required for dialysis facilities with more than 75 patients.

Response: This final rule requires each facility to have adequate staff to meet patient needs. Paragraph § 494.180(b)(1) applies to all dialysis staff, including social workers. The use of ancillary staff is not precluded by this regulation. Some dialysis facilities do employ staff to assist the social worker with clerical tasks, while other facilities may employ more than one social worker. Each facility should assess their staffing needs and determine appropriate staffing levels. While we agree that using an MSW to perform clerical tasks and manage patient financial information may not be the most effective or efficient use of trained and licensed professional clinical staff, we are not requiring that dialysis facilities employ social worker aides. We encourage dialysis facilities to use staff resources in the most effective and efficient manner to provide quality care to dialysis patients.

Comment: Many commenters suggested that the final rule state that MSWs could not be assigned non-MSW tasks. These commenters object to the number of clerical tasks that are assigned to social workers.

Response: Dialysis facilities have the flexibility to assess facility-staffing needs and use staff as necessary. This final rule requires social workers to provide appropriate clinical services to dialysis patients under the ''Patient assessment'' and ''Patient plan of care'' conditions for coverage (§ 494.80 and § 494.90 respectively). The social worker must also participate in the facility QAPI program (§ 494.110). The facility must have a sufficient social services staff to meet dialysis patient needs as required at § 494.180(b)(1), which applies to all dialysis staff, including social workers. We would expect that any tasks assigned to the social worker would not compromise the social worker's ability to meet his or her obligations to patients and these conditions for coverage. We have not added restrictions regarding staff assignments to this final rule.

Comment: Many commenters recommended that we specify a maximum MSW caseload or an MSW-to-patient ratio.

Response: As discussed above, adequate staffing is addressed under the ''Governance'' condition for coverage at § 494.180(b). Some states have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue.

Nephrology social workers should adhere to the professional standards of practice for social workers. The National Association of Social Workers published ''NASW Standards for Social Work Practice in Health Care Settings'' in 2005. These professional practice standards may be found at *http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf*. The National Association of Social Workers and Council of Nephrology Social Workers jointly published ''NASW/NKF Clinical Indicators for Social Work and Psychosocial Service in Nephrology Settings'' in October 1994, which may be found at *http://www.socialworkers.org/practice/standards/nephrologysettings.asp*. In addition, the NKF has published the 2003 Council of Nephrology Social Workers ''Standards of Practice for Nephrology Social Work.'' These standards of practice include guidelines for clinical practice, a description of the nephrology social work role, as well as staffing information.

Comment: A commenter suggested that the final rule state that different facilities can share the same renal dietitian or social worker.

Response: Neither part 405, subpart U nor the proposed rule precludes facility sharing of renal dietitians and social workers, as long as each facility has adequate staff and staff hours to meet patient needs and provide care consistent with professional practice standards. Please refer to § 494.180(b)(1), which applies to all dialysis staff.

Comment: We received a very large number of comments on § 494.140(e), addressing patient care dialysis technician qualifications. Commenters generally supported the addition of technician qualifications and training requirements to the conditions for coverage.

More than 20 commenters, including the National Kidney Foundation, American Association of Kidney Patients, American Kidney Fund, CNSW, some of the ESRD Networks, the National Association of Nephrology

Technicians/Technologists, the Renal Support Network, and various ESRD suppliers and professionals, recommended that we require PCTs to be certified. Commenters stated that PCTs are now the predominant caregivers in ESRD facilities. Certification is necessary to protect patient health and safety in view of the ongoing nursing shortage. Commenters stated that certification is the first step towards minimal competency, and is the national trend; California, Arizona, Oregon, and Ohio now require PCT certification. Commenters state that a standardized curriculum and examination is desirable to improve quality of care.

Kidney Care Partners (KCP), which represents a coalition of renal stakeholders, including the large dialysis organizations; renal physician, nurse, and administrator organizations; and pharmaceutical companies, stated that it supported more consistent training and certification for patient care dialysis technicians. In the 109th Congress, they noted that S. 635 and H.R. 1298 introduced by Sens. Rick Santorum (R–PA) and Kent Conrad (D–ND) in the Senate and Reps. Dave Camp (R–MI) and William Jefferson (D–LA) in the House, would have required that patient care dialysis technicians receive uniform training and become certified, indicating at least a minimum level of competency to provide dialysis-related services. These technicians would have been required to repeat training or become recertified if 24 consecutive months had passed during which they had not performed dialysis-related services. Service providers and renal dialysis facilities would have been required to provide performance reviews and in-service education to assure ongoing competency. Although KCP recognized the importance of deferring to the States to regulate health care workers, they noted that the Medicare program had already established similar training requirements for unlicensed personnel in skilled nursing facilities. They urged us to incorporate these substantive requirements from the legislation (which expired without action at the end of the 109th Congress) into our final rule.

A commenter suggested that on-the-job training was only equal to an orientation and recommended national certification for PCTs. Another commenter advocating certification stated that dialysis patients have been asking for assurances of technician competency and certification would help assure such minimal competency.

One state surveyor opposed any language permitting the use of unlicensed personnel for the practice of nursing or medicine, and stated that our requirement should not conflict with State nursing and medicine practice acts. The commenter also argued that the use of unlicensed staff was dangerous.

One commenter opposed PCT certification, stating that it would not be prudent to add this requirement, pointing to the ''pro and con'' certification discussion in the proposed rule (70 FR 6223).

Response: PCTs perform a variety of clinical tasks (subject to the limitations of State law), that include preparing dialysis apparatus, performing equipment safety checks, initiating dialysis (including cannulation and venipucture with large gauge needles), intravenous administration of heparin and sodium chloride solutions, subcutaneous or topical administration of local anesthetics in conjunction with placement of dialysis needles, monitoring patients during dialysis, taking vital signs, documenting tasks and patient observations, and more. The proposed rule preamble discussed PCT certification, but recognized some barriers to national certification (70 FR 6223). The large majority of commenters did not agree that these potential barriers (state control, lack of renal community consensus at that time, burden and costs) outweighed the patient safety benefits of PCT certification.

Therefore, we have revised § 494.140(e) ''Patient care dialysis technicians'' by adding paragraph (e)(4), which requires that PCTs, ''Be certified under a State certification program or a national commercially available certification program as follows: (i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician, or (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date. We are allowing an 18-month time period for certification to ensure that a sufficient time period is available for PCTs to schedule a date to sit for the certification exam. Because we are allowing a lengthy time period to become certified, we are retaining the proposed rule's training program topics to ensure that non-certified PCTs have appropriate training before they begin to provide patient care as a PCT trainee.

National commercially available certification programs include those of the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners Nursing and Technology (BONENT), and the National Nephrology Certification Organization (NNCO). Dialysis facilities or dialysis corporations may conduct their own in-house certification programs and testing but it must be in addition to a certification program made available by an external body. The NNCC offers the Certified Clinical Hemodialysis Technician (CCHT) examination, which is offered as a valid measure of basic competency for hemodialysis PCTs. Technicians are eligible to take the CCHT examination with a suggested minimum of six months experience in nephrology technology. The CCHT examination measures performance in four dialysis practice areas: clinical (50 percent), technical (23 percent), environmental (15 percent), and role (12 percent). Information on the CCHT examination, a schedule of test sites and dates, and applications is available at *http://www.nncc-exam.org*. If the State has a certification and competency-testing program in place that is specific to dialysis PCTs, then State certification also satisfies this requirement.

We will be reviewing any new national commercially available certification programs that emerge in the future to determine whether a program meets the intent of these conditions for coverage. Based on these reviews, we will determine whether further rulemaking is necessary to ensure the competency of PCTs and to protect patient safety.

Comment: A small number of commenters did not agree that PCTs should have 3 months of experience following a training program under the ''direct'' supervision of an RN. While commenters agreed there should be PCT training, they did not agree that 3 months of experience should be under the ''direct'' supervision of an RN. Some of the commenters stated that the 3 months was too long a time period, and others said this would demand too much RN time. A few commenters stated the training program and 3 months of experience should be allowed to occur simultaneously. Some commenters sought clarification of the term ''direct supervision'', since RNs could supervise without constant one-on-one contact. Some commenters stated this was not good use of RN time and that other staff, for example, PCTs and LPNs, could mentor new PCTs. Two commenters agreed with the 3-month experience provision. One commenter stated that some State nurse practice acts delineate delegation of training by RNs.

Response: Since we are requiring that new PCTs complete an initial training

program and become certified within 18 months of beginning PCT employment, we are not finalizing the requirement that the PCT have at least 3 months of experience that was proposed at § 494.140(e)(3). In addition, this training program includes on-the-job training and experience that must be under the general supervision of a registered nurse. We agree with some commenters that PCT trainees may gain patient care experience during the up to 18-month period under the supervision of an RN with mentoring by LPNs, licensed vocational nurses (LVNs), and certified PCTs. Therefore, we have revised § 494.140(e)(3) to provide this clarification. This new wording allows new PCTs to be mentored by LPNs, LVNs, and certified PCTs under the guidance of an RN. Also, once certified, PCTs work ''under the direction of a registered nurse,'' instead of ''under the direct supervision of a registered nurse.''

We have moved the description of the PCT training program from proposed § 494.180(b)(5) to § 494.140(e)(3) in this final rule so that the PCT training requirements may be located in one section of the final rule.

Comment: One commenter suggested that we strengthen the training requirement so that training must be provided under the direct supervision of an ''RN with at least 6 months of experience of providing care in dialysis.''

Response: We do not agree with this comment. As stated in the previous response, PCT trainees may gain patient care experience during the up to 18-month period under the supervision of an RN with mentoring by LPNs, LVNs, and certified PCTs. We have revised § 494.140(e)(3) to provide this clarification. This new wording allows new PCTs to be mentored by LPNs, LVNs, and certified PCTs under the guidance of an RN. Once certified, PCTs work under a nurse's direction.

In addition, for nurse manager and charge nurse experience in this final rule we require all registered nurses to have 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis. We believe that this level of experience is sufficient for a nurse manager or charge nurse to be able to provide or oversee training to a PCT.

Comment: A commenter suggested that we revise proposed § 494.140(e)(3) and replace ''patient sensitivity training and care of difficult patients'' with ''conflict management and patient centered care.''

Response: We do not agree that the suggested more general wording adds clarification. Therefore, we have retained the proposed language.

Comment: Several commenters supported inclusion of § 494.140(f) ''Water treatment system technicians,'' as proposed. A few commenters suggested that we revise or expand § 494.140(f) to make the educational requirements the same as those proposed for PCTs. Another commenter recommended that water treatment training be required for all staff who work on the water treatment system.

Response: We have incorporated the AAMI RD52 2004 ''Dialysate for hemodialysis'' guidelines into this final rule at § 494.40(a). Section 9 of the guidelines entitled ''Personnel'' includes requirements for water treatment staff as follows:

Policies and procedures that are understandable and accessible are mandatory, along with a training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues. Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer. The training should be specific to the functions performed (that is, mixing, disinfection, maintenance, and repairs). Periodic audits of the operators' compliance with procedures should be performed. The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

Any staff who operate the water treatment system must complete a training program that has been approved by the medical director and the governing body as required at § 494.140(f).

Comment: A few commenters suggested that advanced practice nurses and physician assistants be recognized in the final rule as ''physician extenders'' (that is, NPs, CNs, PAs (Nurse Practitioners, Clinical Nurse Specialists, and Physician Assistants)). Some commenters were concerned that excluding these professionals from the final rule might affect reimbursement.

Response: We recognize the contributions of physician extenders in dialysis facilities in providing quality dialysis care and note that the Medicare payment system recognizes the role of physician extenders. While we will not require dialysis facilities to have NPs, CNs, or PAs, they are subject to our requirement at § 494.140, which requires that ''all dialysis facility staff meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.'' The provisions of this section will not affect reimbursement of physician extenders.

Comment: We received a very large number of comments regarding the proposed rule preamble discussion (70 FR 6224) regarding what role, if any, the pharmacist should play within a dialysis facility and what a dialysis facility's appropriate responsibility is for pharmaceutical services and the efficient use of medication.

More than 40 pharmacists recommended that we include a pharmacist on the facility interdisciplinary team, and submitted comments containing references and journal articles. According to the commenters, the DOPPS data showed that ESRD patients take 9–12 medications on average, per patient, and that there are complex interactions between many of these medications. Pharmacists receive specialized training for renal patient care; and pharmacists with such training should prepare facility protocols and policies to manage medications. Pharmacists believe they will be able to coordinate medication administered within facilities with medications administered outside the facility and over-the-counter drugs. The commenters stated that dialysis patients need comprehensive medication reviews at appropriate intervals, similar to the CMS-required monthly medication reviews in SNFs and ICFs. The pharmacists believed they could train other staff regarding various medications' relationships, which would improve quality of care and treatment plans. Pharmacist-consultants could work with patients and caregivers to coordinate medication use and dietary supplements. They observed that the Department of Veterans Affairs has assigned pharmacists to its dialysis clinics. They argued that comprehensive medication plans and reviews would increase patient safety and reduce overall program (Medicare) costs by preventing adverse ''medication events'' and reducing medication costs. They noted that expert knowledge of the new Part D formulary will be an important part of treating dialysis patients.

One commenter suggested dialysis patients should be recipients of dialysis-provided Medication Therapy Management Services for third-party payers that participate in Part D. In addition, the commenter indicated that Dialysis pharmacists would like to be able to bill for ESRD patient consultation using these codes.

Several commenters did not support including pharmacists on the dialysis facility interdisciplinary team. These

commenters suggested that pharmacist consultation should remain an option, not a requirement. One commenter stated there was no need for pharmacist participation. Other commenters stated that routine assessment of medications should not be required unless it was Medicare reimbursable. A commenter stated that this would be an unnecessary, burdensome requirement without benefit, since nephrologists have the necessary dosing and medication interaction knowledge; the average pharmacist salary is $73,000 annually, which was cost-prohibitive for his organization's 1,200 dialysis facilities. Another commenter said that RNs were the appropriate professionals to monitor patients' medications and to do patient teaching, and believes it could be confusing to the patient to further fragment care by introducing another discipline into the patient care scenario. This commenter did not believe there was a need for clinical pharmaceutical services beyond continuing staff education on new products for dialysis patients; the commenter stated that technology would improve medication management and safety. One commenter said that dialysis facilities lacked the expertise to manage a pharmacist properly. Another commenter suggested that since Medicare did not cover the cost of providing treatments and pharmaceuticals to patients, this suggestion was fiscally unrealistic.

Several commenters stated that pharmacist participation was desirable but not practical absent funding. A commenter stated that a routine pharmacist assessment for patient medications would be desirable and Medicare payment should be revised to allow direct reimbursement outside the composite rate. A few commenters suggested that we add a requirement for routine consultations with pharmacists to review policies on medication acquisitions, storage, administration, and medical record reviews.

Response: Pharmacists fully support a role for the pharmacist on the interdisciplinary team, while other commenters support an optional role for pharmacists in dialysis facilities.

The Medicare Part D reimbursement for pharmacists suggested by one commenter is limited, as pharmacist charges are paid on a case-by-case basis if an individual pharmacy plan has agreed to reimburse Medicare for this service under Part D.

Due to a lack of consensus among commenters, we are not requiring dialysis facilities to include pharmacists as members of the dialysis interdisciplinary team. We do, however, encourage dialysis facilities to use pharmacist expertise as appropriate. The facility policies and procedures referred to at § 494.150(c)(1) must include medication policies and procedures that adequately protect patient safety.

b. Responsibilities of the Medical Director (Proposed § 494.150)

We proposed to retain the condition addressing the facility's medical director (§ 405.2161) as a separate condition and strengthen the role of the medical director, at § 494.150. The medical director would be required to meet the qualifications for the position at proposed § 494.140(a) and would be responsible for the delivery of patient care and patient outcomes in the facility. The medical director would be responsible for operational responsibility for the facility's QAPI program. We proposed to retain the existing requirement at § 405.2161 for the medical director to ensure that staff in the facility are adequately trained. The existing requirement at § 405.2161 was modified in the proposed rule to require that the medical director participate in the development, periodic review, and approval of the patient care policies and procedures manual. We also proposed that the medical director be responsible to ensure these patient care policies and procedures are adhered to by staff who treat patients in the dialysis facility, including attending physicians and non-physician staff. The proposed rule also would require that the medical director be responsible for ensuring that the interdisciplinary team follows the facility's discharge and transfer policies and procedures.

Comment: Many commenters supported the proposed condition for the medical director, including the responsibilities laid out in the new condition. Commenters remarked that this condition assigned more accountability to the medical director for the overall care of patients.

Several other commenters suggested additional language in or revisions to the final rule. One commenter remarked that there should be a direct line of responsibility from the medical director to the care provided. One commenter suggested clearly delineating responsibilities by deleting the phrase ''but are not limited to'' in the last phrase of the proposed condition stem statement.

Another commenter recommended that we clarify that facilities should have only one medical director. The commenter went on to state that some facilities have multiple medical directors. Another commenter however, suggested it may be advantageous for the same individual to hold the medical director position for a defined number of facilities.

Response: We appreciate the comments regarding the proposed medical director condition for coverage. In response to comments, we have added language at § 494.150 to state explicitly that ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' In addition, the medical director has the responsibility of ensuring that all policies and procedures relative to patient care and safety are followed by all who treat the patient, as required at § 494.150(c)(2). This modification clearly holds the medical director responsible for the care that is furnished. Each facility must have a single medical director to carry out the responsibilities of this position.

We have retained the language in the final rule making the medical director responsible for matters that are related to health and safety standards for patient care. Individual dialysis centers may have individual needs that surpass these minimum requirements. Therefore, we are allowing facilities to have flexibility in their dealings with their medical directors. Regarding the number of facilities for which a physician may act as the medical director, this regulation requires that the medical director meet all conditions and responsibilities, regardless of whether he or she directs one facility or multiple facilities. However, each facility must have exactly one specific individual to be fully responsible for all matters under § 494.150.

Comment: Several commenters supported assigning responsibility for QAPI program to the medical director.

Response: We appreciate the supportive comments to retain the proposed language regarding responsibility for QAPI. Language at § 494.150(a) has been adopted in the final rule.

Comment: One commenter remarked that the wording at § 494.150 needs to be clarified. The commenter stated that ''the medical director is acting in an administrative leadership capacity'' and thus the final rule needs to take into account that responsibilities of the medical director should be performed in that context. One commenter suggested that the medical director undergo management training, as staff needs ''leadership from the top'' to effect necessary changes needed in quality control situations.

Response: The medical director is responsible for care provided by the facility. The governing body has the

flexibility to use the medical director in an administrative capacity as long as this does not prevent the medical director from performing the responsibilities required by this final rule. The final rule at § 494.180(b)(3) requires that the governing body ensure that all staff have appropriate orientation regarding their employment responsibilities, including medical directors employed by the facility. This requirement does not preclude the governing body from requiring that the medical director receive additional training deemed necessary to perform the duties of his or her position. The proposed language has been retained in the final rule.

Comment: One commenter suggested we add record-keeping to the list of responsibilities for which the medical director is ultimately held responsible.

Response: Record-keeping is a responsibility that falls under policies and procedures relative to patient care, and thus is covered under the purview of the medical director at § 494.150(c)(2)(i). In addition, there is a condition for Medical records, found at § 494.170, which stipulates what is required of the dialysis facility with respect to record-keeping. Therefore, we are not making the suggested additions to the final rule.

Comment: Another commenter suggested we add language to require the medical director to be present in the facility at least once a month.

Response: Dialysis facilities have the flexibility to address this issue in their agreement with their medical director. The medical director's presence must be frequent enough to perform his or her responsibilities as required by these conditions.

Comment: One commenter suggested that we add language stating that the medical director has the responsibility for assuring that pediatric patients have regular access to care from a nephrologist, dietitian, and a social worker with pediatric expertise.

Response: Dialysis facilities are required by this final rule to provide quality care and services that meet the needs of the patient, as identified during the comprehensive assessment and addressed in the plan of care. The patient assessment and patient plan of care required at § 494.80 and § 494.90 respectively, should accurately reflect the needs of all patients, including pediatric patients, and the proper resources should be obtained and used as necessary.

Comment: Some commenters remarked that the medical director should bear primary responsibility for infection control oversight in the dialysis unit, as opposed to a nurse.

Response: We determined that it would be practical to hold the medical director accountable for oversight of infection control as the leader of the quality improvement committee. We also proposed that the medical director be responsible for assessment and performance policies and procedures relative to patient care and safety at § 494.150(c)(2)(i). Upon consideration of comments, we have added infection control to the list of policies and procedures for which the medical director exercises oversight at § 494.150(c)(2)(i). In addition to this new requirement at § 494.150(c)(2)(i), we have also added ''patient admissions'' to the list of policies for which the medical director is responsible. This modification is in response to comments received on the ''Governance'' condition. Please see the ''Governance'' preamble discussion below for more information.

Comment: Some commenters expressed concern regarding oversight of the medical director's performance of his or her duties under § 494.150. The commenters remarked that the only mechanism to deal with a poorly performing medical director would be to dismiss him/her. Commenters went on to explain that it could be difficult to fill a vacant medical director position, which would be required to be done quickly in order to continue to be reimbursed by Medicare. It was recommended that CMS consider mechanisms by which medical directors who failed to fulfill their responsibilities as outlined in the conditions for coverage, could be disciplined by the facility. Commenters suggested perhaps there was a role for Network Medical Advisory Boards, State Licensing Boards or State Professional Boards to assist facilities in evaluating medical director performance and determining disciplinary action.

Response: The medical director is accountable to the governing body. The governing body is responsible for communicating expectations to the medical staff regarding their participation in improving the quality of medical care provided to facility patients, as required at § 494.180(c)(3). The governing body could develop a process to improve the medical director's performance. A facility's governing body could also contact the appropriate authorities, such as the Network Medical Advisory Boards, State Licensing Boards, State Professional Boards, and any other suitable agencies or organizations. We feel that this matter is best left to the governing body's discretion. We are making no changes based on this comment.

Comment: One commenter concurred with the language regarding the medical director's responsibility for managing problem nephrologists, but suggested that there be some reasonable basis for protecting the medical director from lawsuits related to this management activity. Another commenter asked for clarification regarding the legal liabilities for medical directors employed by large dialysis organizations (LDOs). The commenter questioned what recourse a medical director would have when he or she disagreed with the LDO.

Response: We do not have authority through this vehicle to provide legal protection for the medical director, moreover, these issues are generally matters of state law. Medical directors employed under a contract may negotiate the terms of that contract with business owners/center management within the state practice limitations, including issues such as legal liability, but such matters are not under the purview of this regulation.

Comment: Some commenters recommended that the medical director should have responsibility for ensuring that the ESRD facility supports the goals of the ESRD Network.

Response: The Medicare statute specifies that facilities must meet Network goals (section 1881 of the Act) in order to participate in Medicare. We do not agree it is necessary to add language to the medical director condition regarding responsibility for Network relationships. As stipulated at § 494.180(i), dialysis facilities must cooperate with the ESRD Network in fulfilling the terms of the Network's current statement of work. Section 494.180(a)(3) mandates that the chief executive officer or the administrator be responsible for the relationship with the ESRD Networks.

Comment: One commenter believed that the proposed new responsibilities for the medical director were overly burdensome with respect to very small dialysis units, where the medical director might be the only attending physician with an internal medicine practice. Another commenter disagreed with the proposed language, remarking that it was too restrictive and confusing for multi-facility organizations to have the medical director responsibilities assigned at the unit level. This commenter remarked further that policies were made at the corporate level and recommended that this requirement be removed entirely.

Response: As stated earlier, the majority of commenters supported the ''Medical director'' condition for coverage. No evidence was submitted to support removing the condition for coverage from the final rule. Several responsibilities addressed in the proposed condition are included in existing regulation at § 405.2161(b), and thus medical directors have previously been expected to ensure that the needs of the patient are properly addressed. We do not believe that the duties of the medical director are too burdensome, therefore, the proposed language will be retained in the final rule.

Comment: A commenter recommended that we add language in the final rule that would allow the medical director to have a major role in the appointment and selection process for hiring individuals who would have admitting privileges in the facility (specifically physicians, physician's assistants, and nurse practitioners).

Response: The medical staff appointments standard at § 494.180(c) places responsibility for medical staff appointments with the governing body. The governing body would address the question of whether medical directors would be included in medical staff appointment decisions. Regulatory language does not preclude the medical director from participating in the selection process; however, we are not going to require that medical directors participate in these decisions.

Comment: One commenter suggested changing the language of the final rule to reflect that most medical directors would normally not participate in developing policies and procedures for an ESRD facility. A commenter noted that policies and procedures are most often developed by the large dialysis organizations; however, medical directors may assist or be asked to assist in revisions. The commenter suggested we add ''participate in the development or refinement (of policies and procedures) * * *.'' in the final rule language. Another commenter suggested we change the language at § 494.150(c)(2) to indicate that the medical director would ''participate with the facility staff to ensure'' that the conditions of that paragraph were met. Another commenter remarked that the medical director could oversee and support the facility but could not ''ensure'' policies and procedures were adhered to by facility staff, as often the owner/chain refused to support their own policies and procedures.

Response: Regardless of whether policies and procedures are developed within the facility or via a corporate process, the medical director is responsible for ensuring that appropriate patient care polices are developed and implemented. The majority of commenters supported the proposed requirement without modification. The medical director is responsible for the clinical care provided in an ESRD facility and thus should be held accountable for that care. We expect the medical director would work with the governing body to ensure that appropriate patient care policies are developed and implemented within the facility.

Comment: We received many comments regarding the medical director's scope of authority within a facility. Some commenters recommended that the final rule mandate that medical directors be given the ability and the authority to monitor and improve the care provided by attending physicians, as well as the entire patient care team, including nurses, physician's assistants, dietitians, social workers and other staff; these commenters thought there ought to be more accountability for poor performers in the facility. Another commenter remarked that if attending physicians were uncooperative, then the medical director should assume responsibility for patient care. The commenter further remarked that the final rule language needs to be ''grounded in a realistic approach'' by which medical directors could influence attending physicians with competing goals. Some commenters suggested that § 494.150(c)(2)(i) be expanded to allow medical directors the ability and authority to monitor and improve care in the facility, including the care provided by attending nephrologists. Other commenters supported the idea that the unit's attending physicians be subject to peer review, under the direction of the medical director, and potentially subject to discipline (within the framework of due process procedures). One commenter remarked that governing bodies should be required, as part of their policies and procedures, to specify the extent of the medical director's authority to manage inadequately performing staff and attending physicians.

Response: The medical director is responsible for the delivery of patient care and outcomes in the facility, which includes responsibility for the QAPI program, staff education, training and performance as well as policies and procedures of the ESRD facility. To strengthen the ''Responsibilities of the medical director'' condition for coverage, we have added language to the first paragraph of § 494.150, reading ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' The role of the medical director is also strengthened in the final rule at § 494.150(c)(2)(i), to include patient admissions and infection control. Section 494.150(c)(2)(i) now requires the medical director to ensure that all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. We believe that the facility governing bodies will provide medical directors with adequate institutional authority to permit the medical directors to perform these duties effectively.

If the medical director is unsuccessful in achieving staff compliance or managing disciplinary issues involving attending physicians and has exhausted all options, we expect that the matter would be referred to the governing body, the ESRD Network or other appropriate authorities, such as the state agency and state licensing boards.

Comment: One commenter suggested the addition of a new § 494.150(c)(2)(iii) to require the medical director to ensure that ''staffing is sufficient to meet the acuity of patients treated in the facility.''

Response: We have not added the suggested language to the ''Responsibilities of the medical director'' condition. Staffing concerns are addressed under § 494.180(b), which pertains to adequate and trained staff in an ESRD facility. We also note that the medical director may not have the organizational authority to determine staffing levels within the facility.

Comment: One commenter suggested we add language in the final rule to read, ''the medical director will have direct communication with the patient's other physicians when new or existing co-morbid conditions arise during the course of dialysis treatment.''

Response: We have not added the suggested language in the final rule. We encourage communication and coordination of care among all parties involved in the patient's care and we expect this would be an effort of the attending physician in order to decrease fragmentation of patient care and to ensure proper care for each patient.

Comment: One commenter recommended increased cooperation between nephrologists and dialysis facilities, via the medical director, to assist patients with transplant eligibility.

Response: We have added language throughout the final rule, such as in § 494.70, § 494.80, and § 494.90, to

ensure that patients are aware of their modality choices, including transplant options. Additionally, the medical director is responsible to ensure that all policies and procedures affecting patient care are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers, as required at § 494.150(c)(2)(i).

c. Relationship With the ESRD Network (Proposed § 494.160)

Requirements found in existing § 405.2110 through § 405.2113, related to the designation of ESRD Networks, the functions of ESRD Networks, and the role of the medical review boards will remain unchanged in subpart U. These provisions focus primarily on the role and responsibilities of the Networks rather than dialysis facilities. We proposed to require that each facility cooperate with the ESRD Network serving its designated area in fulfilling the terms of the Network's scope of work contract with CMS, consistent with the requirement at § 405.2134.

Comment: Several commenters suggested we replace ''statement of work'' with ''goals and objectives.'' Another commenter suggested we expand the requirements beyond the contract scope of work to include explicit references to local projects. A couple commenters recommended we retain language from subpart U at § 405.2134 that states that facilities must ''participate in network activities.''

Response: We appreciate the positive comments. The final rule at § 494.180(i) requires that each facility cooperate with the ESRD Network serving its designated area in fulfilling the terms of the Network scope of work contract with CMS, which is similar to the requirement under existing § 405.2134 concerning participation in network activities. The ESRD Network scope of work includes goals, objectives, and local projects. Therefore, it is unnecessary to modify the requirements as suggested by the commenter. Facilities must continue to share information with the Networks as necessary to support Network goals and objectives.

Comment: One commenter recommended that we require random audits by the ESRD Networks to validate the accuracy of self-reported dialysis facility data.

Response: Random audits by ESRD Networks are outside the scope of this regulation. We are not revising our ESRD network regulations at this time.

Comment: One commenter agreed with the proposed language, remarking that roles and responsibilities of the Network should not be part of the conditions for coverage. Two commenters supported the requirement that mandates each ESRD facility to cooperate with its own Network to fulfill the terms of the Network contract scope of work. A commenter remarked that the scope of work should emphasize the coordination of Network activities across all Networks as well as a limited number of local and national initiatives. Another commenter recommended we require Networks to share more information with the State agency, especially during a state survey of ESRD facilities.

Response: As noted above, the ESRD Network Scope of Work (SOW) is outside the scope of this regulation.

Comment: One commenter recommended we expand the language in this regulation to include transplant centers, as well as dialysis centers, using the rationale that ESRD Networks provide oversight to both.

Response: A separate transplant center health and safety regulation was published on March 30, 2007 (72 FR 15198), which requires transplant centers to participate in Network activities. This requirement can be found at § 482.104(c). Therefore we are not modifying language at proposed § 494.160 to include the suggested language in the final rule. We note, that for reasons described in that section, we have moved the substance of proposed § 494.160 to § 494.180, and removed and reserved § 494.160.

d. Medical Records (Proposed § 494.170)

In keeping with our goals to eliminate unnecessary requirements and to reduce burden on dialysis facilities, we proposed a modified version of existing § 405.2139. The proposed rule emphasized that a facility must maintain complete medical records for all patients under its supervision, including home patients. We proposed not to prescribe the elements facilities would have to include in the patient medical record, as was required in subpart U. We proposed to retain with modifications a previous requirement at § 405.2139 that requires a facility to protect its patients' medical records against loss, destruction, or unauthorized use, and proposed to eliminate the requirement that the facility must have written policies and procedures for recordkeeping. We proposed an expansion of the existing requirements regarding medical record release. Medical records could be released when the patient transferred to another facility; under certain exceptions provided for in law; under a third party payment contract; subject to approval by the patient, or in the course of an inspection by authorized agents of the Secretary, and as required by the Medicare program. We proposed to retain with modifications the previous requirement at § 405.2139(d) that current medical records and those of discharged patients be completed promptly and that all clinical information pertaining to a patient be centralized. We proposed that the dialysis facility be responsible for completing, maintaining and monitoring medical records for its Method II home dialysis patients and its other home patients. Minor revisions were proposed to § 405.2139(e) regarding medical record retention. We proposed that medical records be retained for a period of time not less than that determined by the applicable State statutes governing records retention or the State's statute of limitations. In the absence of State statutes, records would be required to be retained for 5 years from the date of discharge for an adult; or for a minor, 3 years from date of discharge or until the patient becomes of age under State law, whichever was longer. We proposed the elimination of the prescriptive requirements in existing § 405.2139(f) regarding medical record accessibility. We proposed to retain the existing requirement at § 405.2139(g) to require the facility to provide prompt transfer of medical information between treatment facilities. We also proposed a modification of § 405.2137(b)(4) to require that the facility exchange all medical record information within one working day. Finally, we proposed the elimination of the existing requirement for the designation of a medical records supervisor.

Comment: One commenter fully supported the less prescriptive approach in the proposed condition, while another commenter remarked that the proposed reduction of regulatory requirements in this condition for coverage was too broad. Some commenters concurred with the deletion of the medical records supervisor, while others disagreed with the elimination of this position, citing that a designated staff member for this task is essential to ensure an adequate recordkeeping process.

Response: We appreciate the positive comments regarding the elimination of the medical records supervisor requirement in § 494.170. Eliminating process-type requirements is in keeping with our overall goals. Additionally, we believe that the deletion of the medical records supervisor requirement would result in a cost savings for facilities. There is no evidence that removing this requirement would result in poor

outcomes. Therefore, the medical records supervisor requirement has not been included in the final rule.

Comment: Several commenters disagreed with the proposed elimination of the requirement that facilities have written policies and procedures regarding record-keeping. One commenter argued that a facility must have written policies and procedures for record-keeping in order for required outcomes to be achieved. This commenter argued that allowing facilities the flexibility to decide what information to include in the medical record would not assure that outcomes were achieved.

Response: We have decided not to carry over the language from part 405, subpart U, in order to decrease prescriptive, non-outcome oriented requirements and to increase dialysis facility flexibility. As long as there is a system in place to achieve that outcome, we do not believe it is necessary to dictate prescriptive requirements. Facilities are still required to protect medical record information and keep all patient records confidential and demonstrate that all of these conditions for coverage have been met. We do not, however, preclude a facility from having record-keeping policies and procedures as they see fit.

Comment: Two commenters suggested that a reference be added to the final rule to state that a medical record could always be released to a patient, guardian or other legally appointed patient representative.

Response: Patients have the right to look at their own medical record. We proposed at § 494.170(a)(2) that all patient medical record information be kept confidential, except when released to an authorized person approved by the patient. Furthermore, patients have the right to be informed of their medical status as documented in the medical record unless the medical record contains a documented contraindication to do so, as required at § 494.70(a)(10). The proposed language will be retained in the final rule, as it protects the patient's medical record information, while allowing for the release of confidential information to the patient or the patient's representative. We also note that many of our protections correspond to more general protections under HIPAA, found at 45 CFR parts 160 and 164.

Comment: One commenter suggested proposed language at § 494.170(a)(2) and § 494.170(a)(3) was unnecessary because of HIPAA protections already in place. The commenter suggested we retain existing language at § 405.2139(b).

Response: The proposed language was carried through from part 405, subpart U, and we believe the language at § 494.170(a)(2) and § 494.170(a)(3) adds clarification regarding the circumstances under which a patient's medical record may be released and any appropriate authorizations that are needed for that release. As noted above, the proposed language was consistent with the HIPAA privacy regulations at 45 CFR parts 160 and 164 and remains in the final rule.

Comment: A commenter suggested adding language at § 494.170(b) to require that when records are stored electronically, the facility must have procedures to protect in-center and home dialysis patient information, and must back up data daily.

Response: The concern of this commenter is addressed at § 494.170(a)(1), which mandates patient records be safeguarded against loss, destruction or unauthorized use. This requirement must be followed regardless of whether a facility uses written or electronic medical records. Additionally, § 494.170(b)(3) charges dialysis facilities with responsibility for completing, maintaining and monitoring medical records for its home patients.

Comment: Many commenters made remarks regarding what information should be required in the patient's medical record. One commenter was concerned that the proposed condition was reduced too much, stating that medical records of ESRD patients were even now often incomplete, inaccurate and not in accordance with identified medical records standards. Two commenters suggested that the day-to-day events should be documented by the end of each shift in which they occurred, and another commenter suggested we retain existing language from § 405.2139, which specified the information that must be kept in the active patients' chart and readily available. Other commenters suggested a requirement specifying inclusion of treatment information, the treatment settings, safety checks, medical events, pre/post-patient assessments, medications, etc. Another commenter recommended that the final rule include a requirement for documentation of medical injuries and accidents, medication changes, as well as patient phone numbers and emergency contact numbers, which should be entered immediately in the patient's record and be updated if they changed. One commenter suggested a requirement that unusual events during treatment be documented.

Response: The existing part 405, subpart U language was removed from the proposed rule because we believe facilities should have the flexibility to decide what information would be included in the medical record, as long as the patient's medical needs were being addressed and these conditions for coverage were met. Medical professionals are expected to accurately record complete and pertinent information in their patients' medical records, including many of the issues identified by the commenters. Many of the topics identified by the commenters would have to be included in the patient's record in order to comply with the ''Patient assessment'' and ''Patient plan of care'' conditions at § 494.80 and § 494.90. All clinical information pertaining to a patient must be centralized in the medical record (§ 494.170(b)(2)). If a facility kept incomplete, inaccurate medical records, as suggested by the first commenter, this ''Medical records'' condition for coverage would not be met and would be cited during a facility survey.

Comment: One commenter suggested we add language to allow use of electronic medical records and recognize them as a satisfactory and secure system for keeping and protecting patient medical records.

Response: The proposed language at § 494.170(b) does not specify that medical records must be in ''hard-copy'' form only, and thus we see no need to make this suggested change in the final rule. We allow electronic health records, and in fact encourage them. In 2004, the President issued an executive order calling for the widespread adoption of interoperable health records within ten years, and the Department of Health and Human Services has been leading the nation's efforts in advancing the nationwide health IT agenda.

Comment: We received several comments regarding the timeframe for completion of medical records. One commenter supported a requirement that records be up-to-date and accurate. Some commenters suggested we specify a 30-day timeframe for completion of the medical record, while another remarked that the medical record should be updated within 2–4 days after any event so that the information would be available by the next dialysis treatment. One commenter remarked that the proposed language regarding prompt completion of medical records was sufficient. Another commenter suggested that we require all assessments to be placed in the front of the chart to improve availability.

Response: To ensure a comprehensive and accurate medical record, we feel that it is vital that charting be completed promptly. The language at proposed

§ 494.170(b) was retained from existing language in subpart U at § 405.2139(d), and we are codifying it in the final rule. Each member of the interdisciplinary team must have access to the most recent information on the patient's condition and prescribed treatment. It is a ''best practice'' to complete charting without delay to ensure patient health and safety during each treatment. Facilities may choose to establish policies regarding the method in which patient medical records are organized, but we will not mandate such a requirement in this regulation.

Comment: Some commenters pointed out that according to HIPAA regulation at 45 CFR § 164.530(j), documentation must be retained for 6 years.

Response: According to the HIPAA Privacy Rule at 45 CFR § 164.530(j)(2), certain written communications, policies and procedures must be retained for 6 years. Therefore, we agree with the commenters and we have modified standard (c) to stipulate that medical record documentation must be retained for 6 years for both adults and children. Standard (c) now reads as follows: ''In accordance with 45 CFR 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.'' Note, proposed § 494.170(c)(1) has been redesignated to standard (c) and § 494.170(c)(2) has been removed.

Comment: Several commenters argued that transferring all medical records within one day was unreasonable, burdensome, and unnecessary, while other commenters supported the requirement. Another commenter remarked that discharged patient records, including mortality reviews, should be completed within 30 days. This commenter also stated 30 days was plenty of time to collect necessary data and was within the timeframe of one cycle of required monthly patient blood work from which thresholds were evaluated. One commenter remarked that the transfer of medical records information should be defined clearly to include at least the care plan, the three most recent dialysis flow sheets, the patient's medication list, lab reports, the comprehensive assessment, and any physician order(s). Still another commenter suggested the addition of language in the final rule to require information such as nutritional status, psychosocial status, and rehabilitation status be transferred within one working day. Another commenter suggested that it would be helpful to have standard criteria and a form for patients to use when traveling to another unit, in order to ensure that appropriate and consistent information is transferred.

Response: The proposed language at § 494.170(d) required the transfer of all medical record and other necessary information within one working day. We maintain that the requirement should apply not only to the care plan, but also to all medical record information. However, we recognize the commenters' concerns that there may be a substantial amount of documentation that may require more time for transfer. We have therefore revised the language at § 494.170(d), which now reads, ''When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.'' Our goal is to minimize the potential for communication breakdown between facilities and ensure that patients continue to receive the necessary care and services. We are therefore requiring only that the minimum amount of medical information be forwarded as appropriate. Some information, such as recent lab results, may not be readily available within 1 day. This minimum information would likely include the physician orders, the patient assessment, and the patient plan of care, insurance information, the last three recent dialysis run sheets, and other pertinent information as necessary. Facilities may wish to create a standard medical record information transfer form as part of their policies and procedures regarding the transfer of patients, but we are not mandating it.

Comment: One commenter suggested we add the following language: ''Patients must have physician orders for all treatment parameters and these orders must be followed.''

Response: We expect that the facility is following physician orders for all of its patients, as required by State Practice Acts and in accordance with Federal, State and local laws and regulations, as required at § 494.20. Therefore, there is no need to add the suggested language in the medical records condition for coverage of this final rule.

Comment: Two commenters remarked that facilities need a centralized medication administration record in order to identify and track medication errors. Another commenter recommended that facilities be required to work towards a system to improve documentation of medication administration and decrease the incidence of potential medication errors. The commenter further suggested that the success or failure of these systems be followed by a quality assessment and performance improvement program within the facility.

Response: Under the final QAPI condition at § 494.110(a)(2)(vi), facilities must measure, analyze, and track medical injuries and medical errors. We believe this requirement addresses the commenters' concerns. Some facilities may choose to put into practice a specialized centralized medication administration record or some alternative process to assist in easier detection of medical errors.

e. Governance (Proposed § 494.180)

We proposed an updated version of § 405.2136 to modernize the requirements and delete unnecessary processes where possible. Consistent with § 405.2136, we proposed that the ESRD facility be under the control of an identifiable governing body, or designated person, with full legal authority and responsibility for the governance and operation of the facility. The proposed rule retained the requirement that a CEO or administrator be identified. Proposed administrator responsibilities would include management of staff appointments, fiscal operations, ESRD Network relationships, and allocation of staff and resources for the QAPI program. We proposed a standard similar to § 405.2162(b)(2) that would require that the governing body or designated person ensure that there was an adequate number of qualified and trained staff to provide a level of dialysis care to meet the needs of patients. The proposed licensed person on duty when patients were undergoing dialysis would be an RN who would be available in the event of a patient emergency. We proposed, consistent with part 405, subpart U, that dialysis facility employees have an opportunity for continuing education and related development activities. A new proposed provision specified a governing-body-approved, written patient care technician-training program that included eight mandatory topics. We proposed that the governing body be responsible for medical staff appointments and credentialing, and ensuring that all medical staff providing care in the facility were informed of facility policies and procedures and the QAPI program.

We proposed that the governing body ensure that the dialysis facility furnished directly services on its main premises or on other premises that were at least contiguous with the main premises. A new standard was proposed that would require the dialysis facility to implement an internal grievance process that included a procedure for the submission of grievances, facility timeframes for grievance review, and a description of how the patient (or

representative) would be informed of steps taken to resolve the grievance. The proposed rule also addressed a procedure that would have to be followed before a patient could be discharged involuntarily. We proposed to retain the § 405.2138(b)(2) provisions that allowed patient transfer or discharge because of non-payment, or because of facility inability to meet the patient's medical needs. We also proposed that a patient could be discharged or transferred because of disruptive patient behavior that seriously impaired the facility's ability to operate effectively. We proposed a process for involuntarily discharging or transferring a patient. These steps included reassessing the patient, documenting the problem and ongoing efforts to resolve the problem, obtaining a written discharge or transfer order signed by the attending physician and the medical director, documenting efforts to place the patient in another facility, and notifying the State survey agency and the ESRD Network.

The proposed rule included emergency coverage provisions at § 494.180(g) that were similar to those at § 405.2136(g)(2) and § 405.2160(a). This proposed standard would task the governing body with ensuring that patients and staff received written instructions for obtaining emergency medical care, that there was a roster with the names of physicians to be called for emergencies and their contact information, and that there was an agreement with a hospital capable of providing emergency medical care to dialysis patients at any time.

We specified in the February 4, 2005 proposed rule at § 494.180(h) that dialysis facilities would continue to be required to provide to CMS data and information for ESRD program administration, however, this data would be required to be sent electronically in a format and at a frequency specified by the Secretary. We added to the proposed requirements, a proposal that facilities submit data necessary for existing ESRD clinical performance measures, currently only collected on a sample of dialysis patients, and any future clinical performance standards developed in accordance with the National Technology Transfer and Advancement Act of 1995 process adopted by the Secretary. The final subsection of proposed § 494.180 would update § 405.2136(a)(1) to require the governing body to report ownership interests of 5 percent or more to the State survey agency, consistent with § 420.200 through § 420.206. We received more than 100 comments on § 494.180 ''Governance'' condition. Some commenters concurred with the condition as proposed, and many commenters suggested modifications.

Comment: Two commenters suggested that the final rule (at § 494.180(a)) limit the number of facilities a single CEO may serve, as it is not unusual for one CEO to cover 4 or more units.

Response: A facility CEO or administrator must have available sufficient time to carry out his or her responsibilities and requirements to allow the facility to fully comply with § 494.180. Although the CEO of a large facility may not have adequate availability to serve multiple dialysis facilities, it is possible that a CEO could adequately serve more than one small facility. We have not added a restriction to limit the number of dialysis facilities a CEO may serve, but require the CEO to satisfactorily fulfill the CEO responsibilities listed at § 494.180(a).

Comment: One commenter suggested that we not use the terms ''CEO'' and ''administrator'' interchangeably in the final rule. A second commenter recommended that we delete the term ''CEO'' from the final rule and use the term ''administrator.'' The rationale given by one commenter is that the terms imply different things; for example, an administrator manages a unit and a CEO has ultimate authority in the organization.

Response: The proposed rule specified that the CEO or administrator would exercise responsibility for the management of a specific facility and the provision of all dialysis services including, but not limited to, staff appointments, fiscal operations, the ESRD Network relationship, and allocation of resources. The term specifically does not refer to the CEO of a parent company or entity that owns or controls several facilities. We do not expect that there will be confusion about the use of the terms ''CEO'' or ''administrator,'' as the responsibilities are clearly specified in the final rule.

Comment: One commenter suggested that the CEO or administrator be responsible for addressing those financial collections issues with patients that affect the functioning of the facility or jeopardize the continuance of provision of dialysis services to the patient.

Response: As stated in the response above, the CEO or administrator is responsible for the fiscal operations of the facility. We are not detailing the tasks associated with this function in this regulation because financial issues are normally a component of the facility's business practices and are therefore not within the scope of this rule. Discharges of facility patients for non-payment are allowed as stated in § 494.180(f)(1), and we believe that facilities generally make every effort to collect payment for dialysis services.

Comment: We received more than 70 comments regarding our proposed requirement at § 494.180(b)(1), that the governing body ensures that there is an ''adequate number of trained and qualified staff.'' A few commenters concurred with standard (b) as proposed. One commenter stated that the term ''adequate staff'' is ''too open to interpretation'' and should be clearer.

More than 60 commenters recommended placing staffing ratios for various patient care staff in the final rule. Many commenters stated that huge case loads are affecting the quality of care, and that Medicare should designate at least an enforceable upper limit on the number of patients for each staff member. A commenter stated that ''California does not have any (staffing ratios) for dialysis facilities'' and she has ''seen as much as 1 RN for 21 patients in facilities by one corporate provider.'' This commenter stated that adequate staffing provisions are difficult to enforce and she has found facility staffing policies that allowed unsafe staffing levels. The commenter argued that to ensure the safety of the patients, minimum staffing ratios are necessary, and should be included in the CMS regulations. Commenters suggested staff-to-patient ratios for various dialysis staff; one commenter stated the RN-to-patient ratio should not exceed 1:10, and other commenters suggested PCT-to-patient ratios of 1:4.

Many commenters suggested a 1:75 MSW-to-patient ratio, and stated that it was impossible for MSWs to do case review and counseling with high patient ratios. Commenters stated that MSWs were assigned large caseloads of between 125 and 300 patients each, and cited a 2005 study (Bogatz, Colasanto, and Sweeney) in support of this contention. Some commenters recommended that we require use of a standardized acuity-based formula for adequate staff, such as the NKF Council of Nephrology Social Workers' ''Professional Advocacy for the Nephrology Social Worker, First Edition 2002'' (pages 9–11). One social worker stated she had 150 patients in 3 units and could therefore only triage and ''put out fires.''

The American Dietetic Association voiced concern that inadequate staffing would affect the quality of care and was aware of many situations where RD-to-patient staffing ratios was 1:200. The ADA further stated that if CMS did not at least reference an optimum RD

national staffing ratio, facilities ''will demonstrate a lack of restraint for large case loads'' and the positive expectations for the new conditions for coverage will not be seen and may even negatively impact patient-focused quality care. Some commenters suggested a RD-to-patient ratio of 1:100 to 125. Some commenters stated that K/DOQI recommends a RD-to-patient ratio of 1:100 and no more than 1:150. A commenter stated that Texas has implemented a RD to patient ratio of 1:125, and that RDs are increasingly directed to do non-RD work that reduces the time available for care of patients who are older and sicker. Some commenters pointed out that dietitians and social workers are often shared between multiple facilities.

Several commenters recommended adding a new requirement for use of an acuity-based staffing model. A commenter stated that software was available to help establish staff to patient ratios based on patient acuity. One commenter stated that acuity-based staffing would reduce facilities ''cherry picking'' patients that would likely occur if minimum facility-level standards were implemented. Some commenters would like to see staffing ratios included in acuity-based staffing plans. One commenter suggested convening an acuity-based staffing plan technical expert panel, and another, an acuity-based staffing plan demonstration. One commenter suggested that we require policies and procedures for staffing that identify numbers of patients, acuity levels, and patient-to-staff ratios.

Several commenters were opposed to both ratios and acuity-based staffing models, stating the current proposal provided necessary flexibility, and that facilities could assign adequate staff based on patient acuity. One commenter stated that CMS should not lock dialysis facilities into a ratio system in regulation, because regulations could take too long (as much as 20 years) to change. Another commenter stated there were no data to support mandated staff-to-patient ratios, and a case mix adjustment formula was needed to avoid facilities ''cherry picking'' patients. One commenter stated that acuity-based staffing ratios would foster confusion, ''up-coding,'' and additional paperwork burdens. The commenter further stated that if acuity-based ratios were adopted, then payment should be adjusted to allow providers to accommodate acuity-based staffing needs. A commenter stated that acuity-based staffing plans have been unsatisfactory and that the nursing shortage exacerbated problems. Another commenter stated that a federal acuity-based system was a bad idea, as there were too many variations from facility to facility, there would be conflicts with many State requirements, and this approach was very subjective.

Response: We solicited public comment in the proposed rule regarding whether we should include a requirement for an acuity-based staffing plan. The public comments were split on the acuity-based staffing plan issue. Clearly staffing is of concern to many commenters. While commenters agreed with the intent of the proposed adequate staff provision at § 494.180(b)(1), there was discontent related to how this provision would be interpreted and enforced. First, we would like to clarify that the adequate staff standard applies to all clinical patient care staff, including nurses, technicians, social workers, and dietitians who provide services to the dialysis patients. Appropriate staffing ratios are affected by a number of factors. These factors include patient acuity, level of staff expertise and skill mix, presence or absence of support staff/unlicensed personnel, available technology, distances between groups of patients served, efficiency of systems in place, scope of staff duties, degree of team work, State requirements, practice board-imposed limitations, number of meetings in which staff participation is required, paperwork demands, etc. We do not have a method available to identify and account for all of these types of characteristics in determining staff ratios that balance staff time to provide quality care and meet patient needs with the economic factors associated with dialysis facility labor costs. We are also concerned that any mandated minimum staffing ratios would be interpreted as the ''maximum ceiling'' that must be complied with which could lead to a decline in the number of patient care staff available.

''Adequate staff'' means staffing must be sufficient so that quality care is provided to dialysis patients that is consistent with the patient plan of care and professional practice standards. We are requiring under the ''Patient assessment'' and ''Patient plan of care'' conditions (§ 494.80 and § 494.90 respectively) that members of the interdisciplinary team complete a comprehensive assessment, followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. We are also requiring at § 494.110 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. The dialysis facility may need to evaluate staffing levels as part of their action plan for the QAPI program. In order to clarify that the adequate staffing standard applies to all clinical staff, we have added language to the requirement at § 494.180(b)(1), requiring that the RN, social worker and the dietitian be available to meet patient clinical needs.

Comment: Two commenters suggested that we hold the medical director accountable for adequate staffing.

Response: We proposed that the governing body or designated person responsible must ensure adequate staffing. The medical director would generally not be responsible for hiring and firing, and replacing vacant positions, or developing the work schedules for dialysis facility. The final rule will continue to hold the governing body or designated person responsible for ensuring an adequate number of trained and qualified staff.

Comment: More than 15 commenters supported the proposal that an RN be present in the facility during dialysis (§ 494.180(b)(2)). Two commenters requested that this provision be limited to hemodialysis because 24-hour RN coverage for peritoneal dialysis patients would be too burdensome. A few commenters recommended that the final rule prescribe more than one RN in large units. One commenter suggested that the final rule state that the RN must not be merely ''available'' but ''a directed patient care giver that provides direct supervision of care.''

A few providers opposed the proposal that requires the presence of an RN, stating that an LPN would be sufficient. They suggested that the nursing shortage would make this provision difficult to meet, especially in rural locations, and the LPN was capable of fulfilling this role. They further stated that this provision could force dialysis facilities to close.

Response: We do not agree with these commenters that the RN shortages would create an access to care problem. Therefore, we are retaining the requirement that an RN be present in the facility at all times that patients were being treated so that a nurse would be available who had the experience and training to react to patient care emergencies that could occur in this

increasingly older and medically-complex patient population. We believe that the RN has a key role in patient assessment and supervising LPNs, LVNs, and PCTs, and is the appropriate staff member to be responsible for the nursing care provided. An RN may also be needed to answer clinical questions from patients and caregivers. The rapidly changing demographics of the dialysis patient population has resulted in an older, sicker patient population with more serious co-morbid conditions and elevated potential for medical emergencies. An RN has the professional training and expertise to properly react to emergencies. Therefore, we believe that having an RN on the premises when treatment is being provided is a necessary health and safety measure for all patients.

We agree with commenters that large dialysis facilities caring for large numbers of dialysis patients simultaneously could require the presence of more than one RN; however, we are not mandating more than one RN. The presence of one RN is a minimum requirement and large dialysis facilities have the flexibility to schedule more than one RN if patient acuity and the number of patients dialyzing at one time necessitates it.

The provision at § 494.180(b)(2) regarding RN presence during dialysis is applicable to in-center dialysis and does not apply to times when peritoneal dialysis patients are self-dialyzing at home. While an RN may not be available at the dialysis center at all times that a patient is performing home dialysis, there must be an emergency plan for when home patients have an urgent situation, as required at § 494.180(g). We have clarified the RN presence requirement by modifying § 494.180(b)(2)(i), to require a registered nurse must be present in the facility at all times that ''in-center dialysis patients'' are being treated. We have also added the phrase ''responsible for the nursing care provided'' to further clarify the role of the RN on duty.

Comment: One commenter asked whether an ESRD facility within a larger facility needs to have an RN present during dialysis if other RNs are in the larger facility.

Response: This provision requires the RN to be present in the dialysis unit regardless of where the facility is located.

Comment: A few commenters suggested that we require medical director training so that the medical director is fully informed of the expectations associated with her/his role. One commenter suggested adding a requirement to properly orient, train, and inform the medical director.

Response: We agree that the proposed orientation requirement at § 494.180(b)(3) should apply not only to employees, but also to the medical director and all dialysis facility staff, regardless of employee or contractual status. In this final rule, we have modified this provision to read as follows: ''All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities.'' This requirement now applies to all dialysis facility staff.

Comment: We received several comments regarding the proposed requirement at § 494.180(b)(4), that ''All employees have an opportunity for continuing education and related development activities.''

One commenter suggested deletion of this requirement because facilities should not be ''obligated'' to provide developmental activities without funding.

Response: This continuing education provision was previously found at part 405, subpart U (§ 405.2136(c)(3)(viii)), and we are retaining it in the final rule. This requirement does not represent a new cost to dialysis facilities, since a normal cost of doing business is training and developing employees.

Comment: A commenter suggested that § 494.180(b)(4) be revised to read, ''all employees are provided continuing education and related developmental activities.'' Another commenter recommended the wording be modified to state that all employees ''must'' have opportunities for continuing education. A commenter suggested that we require mandatory training on quality improvement, quality standards, and the ESRD Network role. One commenter stated that § 494.180(b)(4) is vague and should include a requirement for mandatory continuing education for PCTs.

Response: We do not agree that inserting the word ''must'' after the word ''employees'' adds clarity. This provision requires the governing body or designated person responsible to ensure that employees have the opportunity for continuing education and development activities, which include education that is provided by the facility as well as education that is available outside the facility. We have not modified the wording to more narrowly define the continuing education opportunities as only those ''provided'' by the facility, nor have we added prescriptive language to define the areas in which the continuing education and development activities must occur. The facility has the flexibility to identify areas on which to focus educational efforts. Some areas might be identified via the QAPI program. Licensed, registered, or certified dialysis facility staff must meet certain ongoing educational requirements to maintain their licensures, registrations, and/or certifications, which are required under the ''Personnel qualifications'' condition.

Comment: Two commenters suggested that we require mandatory staff education on the patients' right to be free of verbal abuse by staff, as there have been ''numerous allegations'' of staff verbally abusing patients in the absence of such a requirement, and there was a need to maintain ''professionalism'' in facilities. The commenters stated that the line of professionalism was often crossed by staff in dialysis facilities.

Response: We are alarmed about allegations of dialysis patient abuse by facility staff. Any allegations of abuse should be immediately reported to the State survey agency and appropriate local authorities. We agree with the commenter regarding the need for staff to be knowledgeable about patient rights. A dialysis facility must inform patients of their rights and the facility must protect and provide for the exercise of those rights as required under the ''Patients' rights'' condition for coverage at § 494.70. These rights include the right to respect and dignity (§ 494.70(a)(1)). Dialysis facilities must ensure that patient rights are recognized and protected by all staff and would therefore need to educate staff regarding patient rights in order to achieve compliance with the conditions for coverage. Patient rights must be posted prominently in the facility. In addition, the medical director at § 494.150(c)(2)(i) must ensure all patient care staff adhere to all patient care policies. These policies would include protection of patient rights. We require, at § 494.180(b)(3), that all staff receive appropriate orientation to the facility and work responsibilities, which would include patients' rights training. However, we are not going to mandate that the facility provide training to staff on this matter because we do not want to prescribe or limit the orientation topics. Facilities must provide adequate staff training to ensure that they meet these conditions for coverage.

Comment: Several commenters concurred with the written PCT training program proposal at § 494.180(b)(5). One commenter was concerned that dialysis facilities would be allowed to ''police'' their own PCT training

programs, which could lead to a lack of consistency and validity.

Response: We appreciate the support for the PCT training requirements. We discussed PCT qualifications earlier in this preamble under ''Personnel qualifications.'' We have relocated the PCT training requirements from § 494.180(b)(5) and § 494.180(b)(6), to § 494.140(e)(3) and § 494.140(e)(4) so that all of the PCT qualifications may be found in one section of these conditions. We are requiring national PCT certification in this final rule. The certification exam would serve as a measure of PCT competency, and facilities would not be in the position of instituting their own certification programs.

Comment: We received many comments suggesting revisions to the content of the PCT training program. A large number of commenters recommended that we add a PCT training topic regarding patient psychosocial needs related to ESRD and its treatment regimens, and that this training be provided by the MSW. A commenter suggested adding ''communication and interpersonal skills, including patient sensitivity training and care of difficult patients.'' Another commenter suggested adding training on ethics and professionalism, and dealing with conflicts and challenging situations. A few commenters suggested PCT training on patient nutrition and psychosocial needs. One commenter recommended PCT training regarding possible symptoms and complications of dialysis, the potential for patients to live long and active lives on dialysis, and patient expectations.

Response: We do not agree that there is a need to expand the PCT training subject matter list. The proposed PCT training program (proposed at § 494.180(b)(5)) included the ''care of patients with kidney failure, including interpersonal skills'' and ''possible complications of dialysis.'' ''Care of patients with kidney failure'' (proposed § 494.180(b)(5)(ii)) would include psychosocial and nutritional aspects of care. The ''interpersonal skills'' training would include professional conduct and interactions during challenging situations. The ''complications of dialysis'' (proposed § 494.180(b)(5)(iv)) was already addressed in the proposed training topics list.

As discussed in the ''Personnel qualifications'' section of this preamble, we have moved the training list to § 494.140(e)(3). The training program must be approved by the medical director and the governing body. We are requiring certification of PCTs to ensure competency.

Comment: A commenter suggested that we retain all or part of existing § 405.2136(d) and § 405.2136(g).

Response: Standard 405.2136(d) required written personnel policies and procedures; and standard (g) addressed medical supervision and emergency coverage. Section 405.2136, standard (d) required that facility policies and procedures ensure the following: That all staff members are qualified to perform their duties; that a safe and sanitary environment exists for patients and staff; that trainees are directly supervised; that complete personnel records are maintained; that personnel policies including grievance policies are written and available; that all facility personnel are oriented and have continuing in-service training that is documented, and; that personnel manuals are maintained, updated, and available.

This final rule addresses staff qualifications at § 494.140, and a safe and sanitary facility environment is addressed throughout part 494, subpart B. Facility staff training and educational requirements are set out at § 494.180(b). In keeping with our goal of removing process requirements, we are not including personnel policy provisions in the final rule. Personnel policies and procedures are maintained as a usual business practice and do not need to be required by this regulation.

As for former § 405.2136(g), issues of emergency preparedness and emergency coverage are addressed in this final rule at § 494.60(d) and § 494.180(g), respectively. The substantive elements of medical supervision are encompassed within the ''Patient assessment'' (§ 494.80), ''Patient plan of care'' (§ 494.90), and ''Medical director'' (§ 494.150) conditions.

Comment: One commenter suggested adding a requirement for facilities to notify the State agency when there are changes in the governing body make-up, facility location, or medical staff.

Response: We do not believe that these specific procedural requirements should be included in the final rule. Communications of this type will be addressed via program instructions or interpretative guidelines as needed.

Comment: A commenter suggested that we require facilities to report all unusual incidents to the State agency.

Response: The condition at § 494.20 requires compliance with relevant Federal, State and local laws, some of which may include reporting requirements. We did not propose that facilities report unusual incidents to the state agency, although we are requiring that the State and ESRD Network complaint phone numbers be prominently posted (§ 494.70(c)). Dialysis facilities must report certain diseases to the state health department and must report certain incidents related to equipment failure to the FDA. We have not added any further reporting requirements to the ''Governance'' condition.

Comment: One commenter suggested that patients be able to nominate an individual to serve on the facility governing body.

Response: The governing body is an entity with full legal responsibility and accountability to operate the facility. Dialysis facilities have the option of having patient representation on their governing bodies if they choose. We support patient participation and encourage facilities to include patients in quality assessment and performance improvement efforts, and as representatives on facility committees and boards whenever appropriate.

Comment: Several commenters suggested that we add other staff (physician assistants, nurse practitioners, and clinical nurse specialists) to the § 494.180(c) list of medical staff that the dialysis facility would appoint and credential. One commenter stated that we should only refer to physician credentialing unless State law allows other professionals to be credentialed.

Response: The proposed rule addressed credentialing for physicians, physician assistants, and nurse practitioners. We have modified the language at § 494.180(c)(1) to include clinical nurse specialists since some dialysis facilities use these professionals. We agree with the commenter regarding congruency with State law. We have also added the phrase ''in accordance with State law'' at § 494.180(c)(1) to indicate that these credentialing requirements do not supersede State law regarding such ''physician extenders.''

Comment: A few commenters agreed that the governing body should support medical staff appointments. Two commenters stated the governing body should authorize and require the medical director to monitor and improve performance of attending nephrologists.

Response: The proposed language at § 494.180(c)(2) would require the governing body to ensure that all medical staff who provided care in the facility were informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program. The medical director is accountable to the

governing body for the quality of care provided. As discussed earlier in this preamble we have modified the language at § 494.150 to include, ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' In recognition of the role of medical staff in providing quality care we have also added language at § 494.180(c)(3) to require the governing body to communicate expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients. The governing body must ensure that adequate resources are available to provide quality care. The medical director is responsible for patient outcomes and must ensure adequate cooperation from anyone who treats patients in the facility (§ 494.150(c)(2)). If the medical director is unable to secure cooperation from individuals providing treatment, including attending physicians, the problem should be referred to the governing body. If the governing body is unable to remedy the problem, the medical director should notify the state medical board and/or the ESRD Network.

Comment: One commenter suggested that more physician accountability could be achieved through periodic re-credentialing. Another commenter stated that facilities had little control over physicians, and suggested use of hospital credentialing as required by the Medicare hospital conditions of participation, as a model. The commenter also stated that if physicians did not participate in QAPI, they should lose their credentialing.

Response: The hospital conditions of participation at § 482.22 require that the medical staff operate under bylaws approved by the governing body, be responsible for the quality of medical care provided to patients, be composed of doctors of medicine or osteopathy and in accordance with State law, may be composed of other practitioners appointed by the governing body, conduct periodic appraisals of its members, examine credentials of candidates and make recommendations to the governing body based on qualifications established in the medical staff bylaws, be well organized and accountable to the governing body for the quality of care.

We believe that the proposed rule has been strengthened via language in the final rule at § 494.150, ''Responsibilities of the medical director'' that states, ''The medical director is accountable to the governing body for the quality of the medical care provided to patients.'' This is consistent with the hospital conditions of participation. We have also added language to § 494.180(c) that states not only is medical staff informed of facility policies and procedures and the QAPI program, but that the governing body must communicate to all medical staff the expectations for the role of the medical staff and required participation in improving the quality of medical patient care. The governing body has the flexibility to perform annual credentialing or to choose another credentialing frequency. During initial credentialing, the governing body should review previous medical staff positions and whether a physician or physician extender has had privileges revoked in any other facilities.

Comment: We received two comments regarding § 494.180(d) ''Furnishing services.'' One commenter suggested that we define the phrase ''(the facility's) main premises'' so as to include home dialysis, while another commenter would like a loosening of the ''on-the-premises'' provision to allow ''across the street'' units.

Response: The provision at § 494.180(d) that the governing body ensure that services are furnished directly on its ''main premises'' or on other premises that are ''contiguous'' with (that is, not physically separate from) the main premises, facilitates dialysis facility accountability for the patient care provided. Therefore, an ''across the street'' dialysis facility is not considered to be part of another dialysis facility but an independent facility. As such, it must meet all these conditions for coverage and be certified to receive Medicare payment.

Home dialysis services must be provided in the certified dialysis facility or at the patient's home, unless the patient requests an alternate location. Home dialysis by definition includes the patient's home as an acceptable location for the performance of dialysis, and therefore is an acceptable site for the provision of support services.

Comment: One commenter suggested the final rule state (at § 494.180(e)) that the facility must accept a grievance in any form (oral or written) presented.

Response: We agree that facilities should not limit acceptance of grievances to written grievances, and therefore, we have added the words ''oral or written'' at § 494.180(e) to allow patients more flexibility in how they communicate a grievance. The sentence now reads, ''The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.''

Comment: Two commenters suggested we require the internal grievance process to be posted. Another commenter recommended patient involvement in the design and administration of internal grievance process.

Response: We are not prescribing the manner in which a facility must make its grievance process known. The facility has the flexibility to inform patients of the grievance process as required under the ''Patients' rights'' condition at § 494.70(a)(14), using the methods of its choice.

Comment: One commenter recommended that we require routine reporting to the ESRD Network on the number and topics of complaints. A second commenter supported the concept of an internal grievance process, but suggested the addition of an expectation of timely investigation, documentation, and resolution, along with a quality assurance requirement to prevent any recurrences.

Response: Grievances resolved at the facility level might not need to be escalated to the ESRD Network level. Grievances are to be addressed in a reasonable fashion in a reasonable period of time. The grievance process must include a clearly explained procedure for the submission of grievances, timeframes for reviewing the grievance, and a description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. Dialysis facilities must track grievances and patient satisfaction as part of the QAPI program in which trending and quality improvement efforts are expected (§ 494.110(a)(2)(viii)).

Comment: We received many comments supporting proposed § 494.180(f), ''Discharge and transfer policies and procedures.'' Several commenters endorsed the preamble language regarding the inappropriateness of patient discharges for non-compliance and recommended that we add language to the final rule stating that a patient cannot be discharged for non-compliance. A commenter stated that non-compliance could be due to lack of education on the effects of non-compliance. A few commenters suggested that recommendations from ''Decreasing Dialysis Patient-Provider Conflict National Task Force Position Statement on Involuntary Discharge'' developed by a national consensus conference held in October of 2003, be included. The report stated that patient non-adherence to the medical regimen was not an appropriate reason to discharge a patient, primarily because this type of behavior mainly

harmed the patient himself and not others, and because the patient could exercise his right to non-adhere to instructions. One commenter recommended that we include in the final rule the key elements from this report, which include the facility's right to refuse to treat violent, physically abusive patients; a physician right to terminate care only after taking ethical steps; and the recognition that both the unit and physician have legal obligations.

Some commenters stated that when an attending physician discharges a patient from care and another physician is not found to take over the patient's medical care, the dialysis facility has no choice but to discharge the patient. One commenter stated discharge should be allowed for patients whose behavior interferes with the plan of care, including non-compliance.

Response: The background section of the ''Decreasing Dialysis Patient-Provider Conflict National Task Force Position Statement on Involuntary Discharge'' (*http://www.esrdnetwork8.org/assets/pdf/DPCPositionStatement06.pdf*), adopted by the task force in January 2005, provides data on involuntary discharges. The number of involuntary discharges in 70 percent of dialysis facilities in 2002 was 458 (0.2 percent of 285,982 patients). ''Treatment non-adherence was the leading reason for discharge nationally at 25.5 percent (117 patients), followed by verbal threat at 8.5 percent (39 patients). Other reasons for discharge were lack of payment at 5.2 percent (35 patients), combinations of verbal abuse, verbal threat and physical threats at 5.2 percent (24 patients) and verbal abuse at 5 percent (23 patients).'' The report also stated that discharged patients were at high risk for morbidity and mortality and an unknown number of deaths have occurred due to lack of access to dialysis.

Patients may be involuntarily discharged for non-compliance by their physician because physicians have a right to end an established care relationship with a patient after providing the patient adequate notice (30 days) of the termination of the medical care and reasonable assistance in obtaining care elsewhere. If a physician discharges a patient from his or her personal care, the dialysis facility should locate another attending physician in the facility to provide ESRD care, or discharge the patient from the facility following the process required at § 494.180(f)(4).

The proposed rule preamble (70 FR 6202) stated, ''We would not expect a patient to be involuntarily discharged from a dialysis facility for failure to follow the instructions of a facility staff member.'' Facilities are expected to make ''good faith'' efforts to mitigate problems and prevent an involuntary discharge. The proposed circumstances under which involuntary discharge would be permissible, laid out at § 494.180(f)(1) through § 494.180(f)(4) were: Lack of payment; facility closes; the transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or the facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively has been seriously impaired.

The previous conditions for coverage at § 405.2138(b)(2), stated that patients could be transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Act) and that facilities would have to provide the patients with advance notice to ensure orderly transfer or discharge. Neither the proposed rule nor subpart U encouraged the involuntary discharge of patients because of patient non-compliance. Aside from a minor grammatical change we have not modified the proposed language regarding the permissible conditions for an involuntary patient discharge in this final rule. This final rule requires that if there is a problem with non-compliance, the problem must be addressed in the plan of care and facility staff must take appropriate actions. Patient education and social work interventions may be appropriate. The facility must weigh the ethical issues regarding the discharge of a patient from a life-saving therapy against the gravity and consequences of any non-adherence problem.

Immediate discharge is addressed under ''Patients' rights'' in this final rule at § 494.70(b)(2) and at § 494.180(f)(4) and § 494.180(f)(5). Under § 494.70(b)(2) the patient has the right to receive written notice 30 days in advance of the facility terminating care after following the procedure described in § 494.180(f). Moreover, in the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed. There may be situations where a patient's behavior is so egregious that a facility must discharge a patient with less than 30 days notice or even immediately. The facility must weigh the safety and care of other patients and staff against the consequences of continuing to provide dialysis care or conducting an expedited discharge of the patient from a lifesaving therapy. We proposed a process, which is retained in this final rule, that must be adhered to before a patient with disruptive or abusive behavior may be discharged.

We encourage facilities to use the materials and tool kit developed by the ''Decreasing Dialysis Patient-Provider Conflict National Task Force'' to proactively prevent conflicts and disruptive situations and to undertake appropriate actions when involuntary discharge is being considered. This kit is available from the ESRD Networks.

Comment: One commenter suggested revising proposed § 494.180(f)(3) to permit transfer under that paragraph when the transfer is necessary for the patient's welfare because the facility can no longer meet the patient's medical needs and goals as documented in the patient's plan of care as specified in § 494.90.

Response: The suggested additional phrase defines the medical needs as those specified in the plan of care and would therefore permit a facility to involuntarily discharge a patient if he/she did not meet care plan goals. We believe that the term ''medical needs'' is commonly understood and do not believe that failure to meet the plan of care goals should result in discharge of a patient. We are making no changes to this provision based on this comment.

Comment: A commenter recommended revising § 494.180(f)(4)(iii) to read, ''The governing body of facilities approached to accept the patient must ensure that the patient is not summarily declined a transfer without following the individual facility's policies and procedures for patient admission (including patient interview and medical records review, if applicable).''

Another commenter recommended the addition of a requirement for a facility admission policy that discourages discrimination. The commenter asked that our regulations address admission restrictions and discharges of patients who require a higher level of skilled care (ventilator, bed-bound, morbidly obese) since some current practices have caused access-to-care problems.

Response: Dialysis facilities should not deny admission to their facilities because they ''heard'' the patient was a ''problem'' without assessing the patient. Patient privacy rules must be observed and the admission review should include medical record information and not ''hearsay.''

Facilities should assess the medical needs of patients and the facility's ability to meet these medical needs. Facilities must comply with federal civil rights and anti-discrimination laws as required in § 494.20. Under our previous regulation, the facility was required to have admission criteria that insured equitable access to services, and to make such criteria readily available to the public (§ 405.2136(b)(3)). While we did not carry forward this provision in the proposed rule, in the final rule, we are holding the medical director responsible for the development, review, approval, and staff adherence to facility policies and procedures (§ 494.150(c)). Because facility admission policies would fall under the responsibilities of the medical director, we have added ''patient admissions'' to the list of policies and procedure categories for which the medical director is responsible (§ 494.150(c)(2)(i)). Dialysis facilities should offer equitable patient access to their facility and should have well defined ethical and legal admission policies. Facilities will be expected to adhere to their written admission policies.

Comment: One commenter agreed that both the governing body and the medical director should be responsible for ensuring that the facility complies with the involuntary patient discharge process. Another commenter suggested that only the governing body should be responsible.

Response: We believe that both the medical director and the governing body have an obligation to ensure that the facility appropriately conducts involuntary patient discharges.

Comment: Two commenters suggested adding ''patient choice'' to reasons for discharge so that when a dialysis patient voluntarily leaves, the facility does not have to implement the involuntary discharge procedure.

Response: We have renamed § 494.180(f) to include the word ''involuntary.'' The new title is ''Involuntary discharge and transfer policies and procedures.'' This clarifies that these provisions specifically apply to involuntary discharges, not all dialysis facility discharges.

Comment: A few commenters supported our proposal at § 494.180(f)(4)(ii), which would require both the attending physician and the medical director to sign an involuntary discharge order. One of the commenters stated that some patients have been involuntarily discharged from a dialysis facility without the attending physician's knowledge. A few other commenters suggested that one, not two physicians (attending physician and medical director), provide the discharge signature. Another commenter suggested that we only require the medical director's signature for involuntary discharges only.

Response: An involuntary discharge of a patient from dialysis, a life-saving therapy, is a last-resort action that can have grave consequences. We believe the responsibility for, and obligations to, the patient, are shared between the attending physician and the dialysis facility. In this situation, the medical director represents the dialysis facility. The medical director and the attending physician should concur that the last resort approach is needed before discharging the patient; otherwise, the involuntary discharge should not occur.

We agree that the medical director's discharge signature is only necessary when the discharge is involuntary. We have renamed standard (f) ''Involuntary discharge and transfer policies and procedures.'' This clarifies that these provisions apply to involuntary discharges, and not all dialysis facility discharges. The signature requirement has been redesignated in the final rule as § 494.180(f)(4)(ii).

Comment: Commenters offered varying interpretations of how facilities may satisfy the requirement at § 494.180(f)(4)(iii) regarding attempts to place the patient in another facility and documentation of that effort. One commenter stated that a ''good faith effort'' in finding a new facility should be enough, and the facility should not be held accountable for a patient's bad choices. Another commenter agreed, saying that facilities should document their attempt to place the patient in a new facility, and in some cases, difficult patients should make his or her own arrangements. Two commenters requested clarification of what would be required, and stated their belief that the responsibility for finding an alternate facility rested with the patient. Some commenters stated the facility should be required to provide a list of other nearby dialysis facilities and assistance with the transfer.

A few commenters suggested that the facility demonstrate its attempt to find an alternate placement ''by direct contact with the other facility.'' This suggestion is consistent with the ''Decreasing Dialysis Patient-Provider Conflict National Task Force'' recommendations. Another commenter recommended inclusion of a requirement for the discharging facility to make arrangements and pay for treatment at a hospital for the services they are refusing to provide, until a hearing is held.

Response: In response to comments, we have revised the provision to require that the facility must contact an alternate dialysis facility to attempt to place the patient who is involuntarily discharged and must document that effort.

Comment: We received several comments regarding the requirement at proposed § 494.180(f)(4)(iv) that the facility notify the State survey agency and the ESRD Network of an involuntary discharge. Several commenters suggested that we require ESRD Network involvement or a mandatory ESRD Network referral before an involuntary discharge. Two commenters said there should be Network notification 48 hours prior to an involuntary discharge. A commenter stated that notifying the State agency and the Network after the fact was too late; community human services agencies should be notified earlier in the process, in order to provide resource support to help prevent an involuntary discharge.

Response: We agree that the ESRD Network could be of more assistance in acting as a resource and resolving problems leading up to an involuntary discharge if notification were provided prior to the discharge. The proposed rule required notification of the State survey agency and the ESRD Network of the involuntary transfer or discharge without specifying when notice would be given. We have modified standard (f) to include a new requirement, now at § 494.180(f)(4)(ii) in this final rule, so that the facility must now notify its ESRD Network within the same time frame in which the patient is given written notice of the involuntary discharge (that is, 30 days). The proposed provisions at § 494.180(f)(4)(ii) through § 494.180(f)(4)(iv) have been renumbered in this final rule to reflect the insertion of the new paragraph (ii).

Comment: A few commenters suggested that the ESRD Network be involved in performing audits, patient placement, arbitration, and in finding alternate solutions related to dialysis facility grievances related to involuntary discharges.

Response: The extent of the role of the ESRD Network in involuntary discharges is defined by the ESRD Network scope of work. It would be inappropriate in these conditions for coverage to address Network authority or responsibilities.

Comment: One commenter stated the ESRD Network should be allowed to notify the State survey agency so the facility does not have to call both entities. Another commenter stated that notification of both State and Network

is too burdensome, and one (the ESRD Network) should be enough.

Response: We believe the burden of notifying both the ESRD Network and the State survey agency represents an acceptable level of burden. We have retained ESRD Network and State agency notification of an involuntary patient discharge in the final rule.

Comment: A commenter suggested facilities be encouraged to develop and share discharge criteria with patients to ensure they are fully informed of expectations, policies, and procedures.

Response: We refer the commenter to the ''Patients' rights'' condition. Patients have the right to be informed regarding the facility's discharge and transfer policies as required at § 494.70(b). Facilities must also inform patients of the rules and expectations of the facility regarding patient conduct and responsibilities (§ 494.70(a)(13)).

Comment: A few commenters recommended the addition of a final rule provision that would allow immediate patient discharge when an immediate serious physical threat to staff or patients exists. Two commenters noted that in these cases, there must be thorough documentation and a police report is normally filed.

Response: The proposed rule preamble (70 FR 6202) discussion recognized that there may be occasions when an immediate or an abbreviated patient discharge process may be appropriate in order to protect other patients and staff. We agree that it is reasonable to add language under the discharge standard in § 494.180. We also note that there may be instances when local law enforcement officials must be notified of questionable behavior. Therefore, in response to comments we have modified § 494.180(f) by adding, at (5) ''In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.'' This abbreviated procedure allows less than a 30-day time period for the discharge notice. The facility must still provide patient assessment, interventions, and an effort for resolution to the extent possible based on the unique situation. Documentation in the medical record of the events leading up to the involuntary discharge is required in every case.

Comment: Two commenters suggested the addition of language to § 494.180(f)(4)(i) that would require counseling and support from the team to resolve patient behavioral issues and also require that the team inform patients of behaviors that could lead staff to notify police or referral for evaluation of risk to self or others. Some commenters stated there should be social worker involvement before a patient is involuntarily discharged. Another commenter suggested that we add a condition that no patient be involuntarily discharged except in an emergency situation without documentation that a program was implemented to resolve inappropriate behavior.

Response: The involuntary patient discharge requirements at § 494.180(f)(4)(i) address reassessments, ongoing problems, efforts made to resolve the problem, and documentation in the patient's medical record. These ''efforts made to resolve the problem'' may include counseling and support from the team to resolve behavioral issues. We are not narrowly defining or specifying what the ''efforts made to resolve the problem'' must encompass, as patient needs vary. The team must assess the patient and use appropriate interventions that address the patient's individual issues.

As stated above, patients have the right to be informed regarding the facility's discharge and transfer policies as required at § 494.70(b), which include policies regarding notification and referrals.

Comment: We received a few comments regarding § 494.180(g)(3), ''Emergency coverage.'' Some commenters supported our proposed requirement that each ESRD facility have an agreement with a hospital. One commenter suggested including a provision requiring that the agreement address psychiatric emergencies. Two commenters recommended requiring the facility to make an agreement only with hospitals that had the ability to provide inpatient dialysis, which the commenter argued was especially important in rural areas. One commenter stated that patients needed to know about the nature of the relationship between the dialysis unit and the hospital under agreement to provide emergency services.

A commenter stated that this provision should require the dialysis facility and hospital to agree to provide mutual aid in the event of a large disaster and suggested that each unit have one or more ''mutual aid agreements'' with other facilities both near and far. The commenter stated that the issues facing ESRD patients in the event of a disaster are not often considered by emergency planners.

Another commenter questioned the need for an agreement with a hospital, stating that hospitals were reluctant to enter into such agreements and that such agreements were not required of hospitals in their conditions of participation.

Response: The proposed provision regarding the hospital agreement is less prescriptive than part 405, subpart U requirement formerly found at § 405.2160. Instead of including process-oriented requirements, we proposed a requirement that was aligned with our intent to ensure access to suitable inpatient care for dialysis patients. We agree with the commenter that dialysis care should be available in any hospital with which an agreement is made. We have revised the final rule to require that dialysis facilities must have an agreement with a hospital that can provide routine and emergency dialysis services, and to specify this in the agreement. The provision at § 494.180(g)(3) now reads, ''The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week * * *.''

One commenter (a state survey agency) noted that hospitals were often reluctant to enter into agreements with dialysis facilities, but no dialysis facilities related any difficulties in this regard in their comments. Therefore, we do not believe that this is a barrier to dialysis facility compliance with this provision.

Our final rule at § 494.60(d)(4)(iii) requires a dialysis facility to contact its local disaster management agency to make the agency aware of dialysis facility needs in the event of an emergency. This provision will ensure at least annual communication between the dialysis facility and the local disaster management program. We believe this addresses the commenter's concern about lack of contact with emergency planners.

Facilities also have the flexibility to include any of the additional commenter suggestions when writing their agreements and to communicate emergency services arrangements with patients as appropriate. We are not mandating these processes in this final rule.

Comment: We received many comments regarding proposed § 494.180(h), ''Furnishing data and information for ESRD program administration,'' which would require a dialysis facility participating in Medicare to furnish data and information electronically and in intervals specified by the Secretary. These data would include cost reports, administrative forms, patient survival data, ESRD clinical performance measures and any future standards developed in accordance with the

NTTAA process adopted by the Secretary.

Many commenters expressed support for the proposed electronic data collection. Some commenters recommended expansion of the ''Dialysis Facility Compare'' Web site at *http://www.cms.hhs.gov/dialysisfacilitycompare/* to include all data collected, home dialysis data, measurements of patient satisfaction, other relevant lab data, and facility aggregate functioning and/or well-being data.

Several commenters had concerns regarding the burden associated with electronic data collection. Two commenters stated that VISION (Vital Information System to Improve Outcomes in Nephrology) is not ready for full implementation and may not be universally applicable, and therefore a data collection requirement should be delayed.

One commenter stated that electronic reporting would duplicate the information collected by large dialysis organization information technology systems. A few commenters recommended that only one of electronic or paper data collection should be required, as both would be too burdensome. One commenter suggested that a timeline was needed to implement electronic reporting.

One commenter stated that providers should have the opportunity to provide input when CMS defines data collection efforts.

Response: The proposed rule would require the electronic submission of data necessary for CMS administration of the Medicare ESRD program. These electronic data specifically include administrative data (including, but not limited to the CMS–2728, Medical Evidence/Medicare entitlement form data and CMS–2746, ESRD death notification data, and the United States Renal Data System data) and the existing ESRD Clinical Performance Measures (CPM) data (CMS–820 and CMS–821), and any data necessary for future performance measures developed in accordance with a voluntary consensus standards process identified by the Secretary.

This final regulation requires facilities to provide data and other information that are necessary to support administration of the ESRD program. In order to increase efficiencies and improve the usefulness of these data, we are requiring electronic submission of necessary administrative data as well as specified data for calculation of ESRD CPMs.

This electronic data collection is consistent with the IOM's recommendation that ''* * * the Department of Health and Human Services should move forward expeditiously with the establishment of monitoring and tracking processes for use in evaluating the progress of the health system in pursuit of the above-cited aims'' (IOM 2001). It is also consistent with White House Executive Order 13410, *Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs,* issued on August 22, 2006, which states:

> ''Each agency shall implement programs measuring the quality of services supplied by health care providers to the beneficiaries or enrollees of a Federal health care program. Such programs shall be based upon standards established by multi-stakeholder entities identified by the Secretary or by another agency subject to this order. Each agency shall develop its quality measurements in collaboration with similar initiatives in the private and non-Federal public sectors.''

(*http://www.whitehouse.gov/news/releases/2006/08/print/20060822-2.html*) (71 FR 51089.)

Finally, it is consistent with recommendations from various governmental bodies that provide oversight of the Medicare program. For example, in a recent report (OEI–05–05–00300) titled ''Availability of Quality of Care Data in the Medicare End-Stage Renal Disease Program,'' the Department of Health and Human Services' Office of the Inspector General (OIG) recommended that CMS ''increase its efforts towards regularly collecting data from all patients and all facilities on all clinical performance measures identified by CMS to address quality of care issues in the ESRD program'' (HHS/OIG 2006). We have received recommendations to require facilities participating in Medicare to report on performance measures to stimulate improvements in the quality of care and to achieve a greater degree of accountability for performance. These recommendations come from the OIG in its reports ''External Quality Review of Dialysis Facilities/A Call For Greater Accountability'' and ''Availability of Quality of Care Data in the Medicare End-Stage Renal Disease Program'' (DHHS/OIG, 1999, 2006); from the IOM in its report ''Crossing the Quality Chasm, 2001'' (IOM, 2001); from the Medicare Payment Advisory Commission (MedPAC) in its report ''Improving Quality Assurance for Institutional Providers'' (MedPAC, 2000); and from the Government Accountability Office (GAO) in its report ''Dialysis Facilities: Problems Remain in Ensuring Compliance with Medicare Quality Standards'' (GAO, 2004). The requirement to submit data necessary to calculate specified CPMs is an important step in moving in this direction.

The electronic data provided to CMS will be used to monitor the performance of the public health system and dialysis facilities certified to care for Medicare beneficiaries with ESRD. The data will also be used to provide information to individuals who have or may develop ESRD and their caregivers to assist them in making health care decisions; to allow the identification of opportunities for quality improvement at a national, regional, or dialysis-facility level; and to help align our payment system with high-quality care through improvements in case-mix adjustment and the potential future use of payment for performance.

CMS, the ESRD Networks, dialysis facilities, and other interested stakeholders have used the ESRD CPMs to assess the care of a representative sample of individuals with ESRD in the areas of adequacy of dialysis, anemia management, nutrition (serum albumin), and more recently, vascular access (Centers for Medicare & Medicaid Services. 2005 Annual Report, End-Stage Renal Disease Clinical Performance Measures Project. Am J Kidney Dis 48:S1–106, 2006 (supp. 2)). CMS developed the ESRD CPMs to implement section 4558(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33), which required the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare no later than January 1, 2000. These measures were developed based on widely accepted, evidence-based clinical practice guidelines and were subsequently used to guide national, regional, and facility based quality improvement efforts.

Beginning in the mid-1990s, the National Kidney Foundation's (NKF's) Dialysis Outcomes Quality Initiative (DOQI) development process released guidelines to help shape the development of clinical measures based on strength of evidence, clinical importance and feasibility. The NKF has since expanded and updated their early efforts and their Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines are widely accepted among the renal community. These may be a source of potential future CPMs that can be developed and supported by a broad cross-section of stakeholders, including clinical practitioners, industry representatives, professional associations, and others interested in assessment and improvement of the care provided to individuals with ESRD.

We proposed using the VISION application for the provision of electronic data but based on technological advances and public comments, we are implementing a new Web-based system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), for this purpose. VISION was a patient-specific, stand-alone, facility-based information system with software that resides on facility computers, which presents challenges for updating the software. We agree with commenters that VISION did not represent the best technology for widespread collection of data from dialysis facilities and large dialysis organizations.

Use of the CROWNWeb system will increase the efficiency of data collection both for CMS and for facilities, improve data quality, and provide a more stable and accessible platform for continual improvements in functionality. It will also complement the advanced information infrastructure used by many dialysis facilities.[1] We believe that CROWNWeb will not duplicate information technology systems in large dialysis organizations, but will facilitate data reporting and provide efficiencies.

We believe that the collection and reporting of ESRD CPMs has been an effective tool to facilitate ESRD quality improvement, and has allowed us to track positive improvements in several intermediate outcomes for individuals with ESRD. Therefore, we are requiring under the ''Governance'' condition for coverage (§ 494.180(h)), that the ESRD CPMs in effect on the date of the Final Rule's publication be included as the initial set of CPMs that all ESRD facilities are required to collect for all individuals with ESRD and submit to us electronically. We will carefully evaluate any revisions to current CPMs as well as any future CPMs developed in accordance with a voluntary consensus standards process for possible inclusion in these electronic reporting requirements. The Secretary will provide notice and an opportunity for comment in the **Federal Register** before any changes to the electronic reporting requirements based on the CPMs are enacted.

We recognize that electronic data reporting may result in some additional facility burden. However, the availability of batch data reporting will reduce the level of burden. We believe that there is a return on this investment for all primary stakeholders, including patients, dialysis facilities, and the public. CROWNWeb will allow for the more timely, accurate, and efficient use of data to support administration of the ESRD program by replacing the current predominately paper process with an electronic process that considers the capabilities of providers, which has tangible benefits for dialysis facilities, individuals who have or may develop ESRD, and other stakeholders. CROWNWeb provides facilities with the ability to submit the required data directly from their electronic health records, thus reducing burden and freeing facility personnel to concentrate on patient care. Another expectation is that claims payment will be improved due to improved quality and timeliness of patient eligibility and enrollment information. Finally, we expect that the new system will provide reports that will allow facilities to compare themselves with their peers.

CROWNWeb will also increase the transparency of the health care system for patients and thus, help empower patients to find better health care value and better health care quality as well as help assure appropriate patient access to care. For ESRD Networks, CROWNWeb will provide more timely, accurate, and complete information to inform quality improvement, and it would reduce Network resource use for data collection activities. For example, CROWNWeb will be able to recreate the data included on the current CMS 2744 Annual Facility Survey more timely as opposed to on the last day of the year and it would free up Network resources that currently perform a four-month manual reconciliation process. In addition, for all primary stakeholders, we expect that the new system will provide more timely report capabilities that will allow them to compare individual facilities and facility groups with various peer groups, national, and local benchmarks.

In February 2007, CMS' Quality Infrastructure Support (QIS) contractor held its first CROWNWeb CPM technical expert panel, which represented initial CROWNWeb users, including large and small dialysis organizations, dialysis professional societies, ESRD Networks, CMS, and associated Federal contractors, to survey primary stakeholders about desired/expected performance attributes of CROWNWeb relative to the CPMs, including feedback reporting. Based on the input received from members of the panel as well as ongoing input from the community at large through either publicized monthly calls and/or e-mail (*craft@nw7.esrd.net*), CMS' QIS contractor developed draft business requirements, which CMS evaluated, approved, and forwarded to its IT contractor for incorporation into CROWNWeb.

CROWNWeb will also facilitate greater transparency for patients through more timely, accurate, and complete reporting. In September 2002, CMS contracted with the Research Triangle Institute to conduct an evaluation of the content of DFC. The Final Report of the Evaluation of the Content Dialysis Facility Compare as submitted to CMS in March of 2004 (*http://www.cms.hhs.gov/DialysisFacilityCompare/03_Evaluation%20of%20DFC.asp.*) A revised version of the Web site, based on findings from the evaluation and integrating more user-friendly ''next generation compare'' software, was posted in June 2004 and CROWNWeb will provide the infrastructure so that DFC can provide additional value for persons who have or may develop ESRD and the caregivers who assist them in making health care decisions.

The electronic collection and reporting of CPM data via CROWNWeb for all individuals with ESRD will add significant value for facilities and individuals who have or may develop ESRD in three ways:

1. Validation and comparative reports can be viewed more timely once the data submission is complete since the CPM data are electronically available.
2. There is no claims time lag because the CPM measures are computed using clinical as opposed to administrative and claims information.
3. Facilities can see facility-specific information that compares themselves to various peer groups because the CPM data cover all Medicare-certified dialysis facilities and will include all patients.

While submission of data and information is an existing requirement in § 405.2133 and electronic submission of cost report data and information is an existing requirement in § 413.24, the requirement to provide CPM data is new. Additionally, the requirement to provide necessary administrative data in electronic format is a change from the paper-based process that has historically been used to support the ESRD program.

Initially, the data will consist of information necessary to calculate the ESRD CPMs and administrative data elements from existing data collections in effect as of publication of this final rule. In response to community input requesting time to get their information systems aligned with this new requirement as well as train necessary resources, we will delay the requirement for reporting the data

[1] This advanced information capability is detailed in the 2002 OIG series, ''Clinical Performance Measures for Dialysis Facilities,'' OEI–01–99–00052.

necessary to calculate the specified CPMs and other administrative data using the CROWNWeb system until February 1, 2009. Thereafter, all facilities must collect and report on an ongoing basis the necessary administrative data, and the CPM data at least annually for all eligible ESRD patients via CROWNWeb as specified by CMS. In the interim, dialysis facilities will use existing processes to collect and report necessary administrative data and data necessary to calculate ESRD CPMs for individuals with ESRD that are included in the national ESRD CPM sample. Thus, 2008 will be the last year we will collect data to calculate the existing ESRD CPMs on a 5 percent representative sample to fulfill section 4558(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33). In 2009, we will be requiring facilities to collect and report CPM data on all ESRD patients in their facilities.

In order to provide support for facility-based quality assurance and performance improvement as specified in § 494.110, facilities may voluntarily submit specified CPM data via CROWNWeb more frequently than annually. In order to support national quality improvement efforts (for example, the Fistula First Breakthrough Initiative) as specified in the Relationship with the ESRD Network condition at § 494.180(i), facilities may be required to submit data for a subset of specified CPMs more frequently than on an annual basis. Thus, facilities may provide a more frequent subset of data either voluntarily or as required as part of a national quality initiative, but we will only require the submission of the complete set of data necessary to calculate specified CPMs on an annual basis in this final rule.

In response to the comment regarding including providers' input as we define data collection efforts, CMS and the ESRD Networks have a history of collaboratively working with the ESRD community on improving data quality. Between 2003 and 2005, CMS and the ESRD Networks partnered with the ESRD community to develop the Core Data Set, which created a common ''kidney data dictionary'' complete with standardized data elements, data definitions, and integrity constraints necessary for ESRD Networks to conduct quality improvement oversight activities and for CMS to conduct ESRD Program oversight activities.

In 2006, CMS funded a Quality Infrastructure Support (QIS) contractor to solidify the early work of the Core Data Set by soliciting ongoing input from the ESRD Networks and other stakeholders and summarizing it in recommended business requirements to CMS for the new information system. The process the QIS contractor used for incorporation of community input is referred to as CRAFT (CROWN Responsiveness and Feedback Tree) and includes public presentations (available at *http://www.esrdnetworks.org/2007CMSForumAMpresentations.htm*), monthly calls, technical expert panels, an e-mail suggestion box, focus groups, and site visits.

CROWNWeb supports the following existing systems, all of which will be integrated by CROWN, thus reducing the federal cost of administering the ESRD program.

- The ESRD Standard Information Management System (SIMS). SIMS supports the business processes of the ESRD Network Organizations and allows data exchange among the Networks, the facilities and CMS via a secure, web-enabled environment called the ''QualityNet Exchange.''
- The Renal Management Information System (REMIS). REMIS determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access information in the ESRD program Management and Medical Information System Database. REMIS includes an operational interface to the SIMS Central Repository. (REMIS replaces REBUS, the mainframe Renal Beneficiary and Utilization System.)

CROWNWeb uses an encryption technology that assures privacy, confidentiality, and security for electronic communications and is consistent with applicable HIPAA and Privacy Act statutes and related regulations and would be available free-of-charge to all dialysis facilities with Internet access. CROWNWeb also meets applicable security criteria included in the CMS Information Security Acceptable Risk Safeguards (ARS) policy (*http://www.cms.hhs.gov/InformationSecurity/14standards.asp#TopOfPage*) which contains a broad set of CMS security controls based upon National Institute of Standards and Technology (NIST) requirements. We have further improved CROWNWeb's efficiency, functionality, and timeliness by working with dialysis organizations to develop a mechanism for accepting batch data submittals.

Comment: Two commenters stated that large dialysis organizations should not have to subsidize the small independent dialysis facility electronic data collections.

Response: We assume the commenters are referring to the proposed rule preamble discussion (70 FR 6231 and 70 FR 6241). The VISION software was intended to be available to all dialysis facilities. If an LDO opted not to use VISION, then file specifications would be developed and this approach might result in costs to those dialysis facilities. We are no longer planning to use the VISION software and our approach does not call for LDOs to ''subsidize'' small independent facilities.

Comment: We received several comments regarding the content of the clinical performance measures. One commenter stated support for using the same CPMs for home patients and in-center patients. Another commenter suggested that special consideration be given to small rural units and that we consider case-mix when developing new measures.

Some commenters suggested the addition of one of the following indicators for use as CPMs: Depression scale scores, infection control measures, K/DOQI Bone metabolism and renal bone disease, patient functioning and well being, and ESRD Network 9/10 technical expert panel recommended transplant referral measures.

Response: The development of new CPMs is not carried out via the conditions for coverage. Historically, we have funded the development of measures by contracting with an organization that possesses the technical knowledge and skills and who convenes a TEP to assist them in the development of the measures or in the review of the science or guidelines to determine when existing measures need to be updated. Facility-level measures that would be enforced under the conditions for coverage would be developed in compliance with the National Technology Transfer and Advancement Act of 1995 (NTTAA) by a voluntary consensus standards body (§ 494.180(h)(3)(iv)). This process allows transparency as the facility-level measures and thresholds are developed. The implementation of new facility-level measures adopted by the Secretary will be done via a future rulemaking process, which will allow for public comment.

Comment: One commenter stated that an outcomes approach requires measures and standards. Several commenters supported the proposal to develop federal standards using a voluntary consensus standards body as described by the NTTAA. Another commenter suggested that any changes in the CPMs should be done in partnership with nephrologists and key stakeholders in the renal community. One commenter stated voluntary consensus standards and quality thresholds should be defined by actual

data distributions of outcomes of each parameter, denoting thresholds at one and two standard deviations. The commenter stated clinicians would support this approach.

Response: We agree that an outcomes approach requires measures and standards. The proposed process of using a voluntary consensus standards body to arrive at facility-level standards has been retained in the final rule. Nephrology experts and stakeholders should participate in the voluntary consensus standards process in which the development of facility-level thresholds would occur. Public comment will also be invited during the rulemaking process that implements the facility-level measures that are adopted by the Secretary.

Comment: One commenter suggested that ownership information be available to any member of the public upon request.

Response: The proposed requirement at § 494.180(i) has been moved to now § 494.180(j), regarding disclosure of ownership, which is consistent with § 420.200 through § 420.206. Information subject to public disclosure is addressed at § 420.206(a). The public may request current dialysis facility ownership information from the State survey agency. We also refer the commenter to 42 CFR 431.115(e)(4) and § 455.104 which describe Medicaid and State Children's Health Insurance Program ownership disclosure provisions, respectively.

As stated previously in this section, we will delay the requirement for reporting the data necessary to calculate the specified CPMs and other administrative data using the CROWNWeb system until February 1, 2009. The delay affects the specific standard found at § 494.180(h). We are delaying this requirement in response to dialysis facility community input requesting time to align their information systems with this new requirement, as well as train necessary staff.

D. Other Proposed Changes and Issues

1. Proposed Cross-Reference Changes

We proposed to make technical changes in the following sections of the regulations to correct cross-references to the sections in part 405, subpart U that have been relocated or deleted: § 410.5, § 410.50, § 410.52, § 410.152, § 410.170, § 413.170, § 413.172, § 413.198, and § 414.330.

2. Proposed Additions to Part 488

We proposed to add a new subpart H to part 488. Proposed subpart H would consist of the existing sanction provisions in part 405 subpart U. The existing sanction provisions are in § 405.2180, § 405.2181, § 405.2182, and § 405.2184 and are summarized as follows:

- Section 405.2180 specifies the basic sanction, which is termination of Medicare coverage, and the basis for reinstatement of coverage after termination.
- Section 405.2181 specifies the alternative sanctions denial of payment of any patients accepted for care after the effective date of the sanction, and gradual reduction of payments for all patients) and the circumstances under which they might be imposed.
- Section 405.2182 specifies the notice procedures that we will follow and the appeal rights of sanctioned suppliers.
- Section 405.2184 specifies (in greater detail) the rights of suppliers that appeal proposed imposition of an alternative sanction.

We proposed to redesignate these provisions (with technical and cross-reference changes) as § 488.604, § 488.606, § 488.608, and § 488.610 respectively.

We did not receive any comments on these proposed changes. Therefore, we are finalizing these proposals without change.

E. Survey & Certification Comments

Comment: There were several comments, including comments from many national organizations, which recommended that CMS convene a panel of experts, with a broad representation of dialysis providers including nephrology health care professionals and patients, to contribute to the development of the Interpretive Guidelines for the ESRD conditions for coverage. Commenters remarked that there is a wealth of expertise available in the renal community, which would be of great value to CMS. Commenters also strongly recommended that CMS ensure ''consistency in enforcement through the state survey process,'' stating that there is a need for clear, specific interpretations so that national consistency can be achieved.

Response: We have used and will continue to solicit input from experts from the renal community as well as the general public in developing the Interpretive Guidelines.

Comment: Two commenters stated that ESRD surveys are not completed frequently enough to ensure ongoing compliance with the ESRD Conditions for Coverage. One national organization expressed concern about having effective surveillance and enforcement of the conditions for coverage. Two State health departments suggested CMS mandate ESRD facilities be surveyed at least every 3 years with follow-up surveys for 2 years when a facility has been noncompliant with one or more conditions. Commenters also recommended funding be increased for this activity.

Response: We issue a Mission and Priority Document (MPD) each year, which prioritizes the survey goals for the upcoming fiscal year. Budget restrictions, statutorily mandated surveys, and CMS initiatives influence the survey priorities of the MPD. In Fiscal Year 2006, ESRD surveys were moved up in priority because safety and health can be positively influenced by compliance with the conditions for coverage. Changes in funding for surveys and/or survey mandates would likely require Congressional action.

Comment: Two commenters remarked on the redundancies in the format of the CMS survey report, Statement of Deficiencies. It was pointed out that the report is difficult to read and one commenter urged that state surveyors be instructed to list deficiencies only once in the Statement of Deficiencies report for corrective action.

Response: We are working on limiting the repetitive citing of a deficient practice to egregious cases where serious problems must be cited under several survey tags. We are aware that the format of the survey report, Statement of Deficiencies, could be improved and are considering the best ways to improve it.

Comment: One commenter asked if State laws could only be cited during a Federal survey after the law has been cited by the appropriate State authority.

Response: In the CMS Federal survey process, citations for a lack of compliance with State laws occur after the State authority has made a final determination regarding compliance with State law.

F. Impact Analysis Comments

Comment: Many commenters stated that the new conditions for coverage need to be consistent with payment rules.

Response: Specific commenter concerns about proposed rule requirements that were perceived to be inconsistent with Medicare payment policy were addressed in earlier sections of this preamble as each provision was discussed. We have modified requirements to more accurately reflect the dialysis facility's role in cases where the proposed requirement arguably exceeded the scope of services that dialysis facilities

provide. For example, in response to comments, we revised the patient rehabilitation services requirement (§ 494.90(a)(8)) so that dialysis facilities would provide rehabilitation assistance and referral as appropriate, but would not be required to provide the actual rehabilitation services. Payment concerns regarding erythropoietin were addressed under the Patient plan of care preamble discussion (proposed § 494.90(a)(3)). Physician visit payment comments were addressed under the proposed § 494.90(b)(4) preamble discussion, and the monthly physician visit provision was deleted. We provided clarification of vascular access ''monitoring'' in our earlier preamble discussion (proposed § 494.90(a)(4)) so that our requirement is clearly aligned with payment policy. Concerns regarding the costs of LSC compliance were addressed under the ''Physical environment'' condition at (§ 494.60) and the small number of existing dialysis facilities that would have been required to retrofit sprinkler systems are now exempted from this provision if such retrofitting is not required by the facility's State law and CMS finds that State law adequately protects facility patients.

Comment: Some commenters recommended that Medicare payment be adjusted to provide reimbursement for dialysis facility costs resulting from implementation of the final rule.

Response: The Medicare reimbursement rates for dialysis facilities are divided into distinct categories. The first category is the composite rate that covers the provision of dialysis and associated services that are enumerated in the Medicare renal dialysis facility payment manual. The composite rate is set by the Congress, and may be influenced by the recommendations of MedPAC, which performs cost analysis and provides annual reports to the Congress. The MedPAC analysis includes a review of the dialysis facility cost report data, which will encompass any new costs facilities bear due to compliance with the new conditions for coverage, including some categories of overhead costs. We expect that the MedPAC analysis and recommendations will reflect any new across-the-board dialysis facility costs that are associated with this final rule. The second reimbursement category focuses on separately billable drugs and biologicals. The Medicare Modernization Act of 2003 (amending sections 1842(o) and 1847A of the Act) included provisions regarding medication and biologicals reimbursement rates. The new provisions call for the calculation of the drug average sales price plus an add-on payment that is adjusted on a quarterly basis. Dialysis payment adjustments for 2007 implemented by Medicare were published on December 1, 2006 in the Physician Fee Schedule rule (71 FR 69623) and established calendar year 2007 reimbursement rates. We are not making any changes to our payment methodologies based on the issuance of these conditions for coverage.

Comment: One commenter requested a reimbursement change to allow advanced practice nurses to be identified and Medicare reimbursed in the final rule.

Response: Services that would be provided by advanced practice nurses would be included either in the physician monthly charges or under the dialysis facility composite payment rate, depending on the role of the individual. Insofar as the commenter is advocating a pass-through for APNs, this is not being considered in this rule; however, we will take the commenter's suggestion under advisement.

Comment: A few commenters suggested that Medicare provide funding for the purchase of automated external defibrillators (AEDs) if they are required in the final rule.

Response: AEDs would be included under ''capital costs'' in the dialysis facility cost report. MedPAC reviews all costs and makes recommendations to the Congress regarding the appropriate dialysis facility payment update. Medicare does not pay separately for specific dialysis facility capital expenditures.

Comment: Several commenters included general remarks regarding the overall Medicare payment system. Commenters stated that Medicare does not appropriately fund the ESRD program and that dialysis facilities must ''subsidize'' the cost of care provided to Medicare beneficiaries. They also referred to the ESRD composite rate as the only Medicare prospective payment system without an annual update mechanism to adjust for changes in input prices and inflation. Commenters discouraged CMS from implementing new conditions for coverage that would add significant costs to providing care without directly providing benefits to patients, unless an annual update mechanism is established for the ESRD composite rate.

Response: Although an annual composite rate update mechanism has not been established by Congress, we note that the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432, Division B, Title I, section 103(a)) provided an update of 1.6 percent to the composite rate component of the basic case-mix adjusted prospective payment system for dialysis services effective April 1, 2007. However, the issue of payment updates to dialysis facilities is determined by Congress and is outside the scope of these conditions for coverage. We have addressed specific concerns of commenters earlier in this preamble and have modified proposed requirements in several instances so that the provisions of this final rule do not exceed the scope of services that we could expect from Medicare-certified dialysis facilities.

III. Provisions of the Final Rule

In this final rule we are adopting the proposed provisions as set forth in the February 4, 2005, proposed rule, subject to the following revisions:

- Amend § 405.2102 ''Definitions'' by removing the definitions for ''Histocompatibility testing,'' ''Organ procurement,'' ''Renal transplantation center,'' ''Transplantation service,'' and ''Transplantation surgeon,'' leaving ''Network requirements'' the only remaining substantive component of the subpart.
- Amend § 405.2180 through § 405.2184 ''Termination of Medicare coverage'' and ''Alternative sanctions'' by recodifying these sections at § 488.604 through § 488.610 under Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities.
- Amend § 414.330 ''Payment for home dialysis equipment, suppliers, and support services'' by revising paragraph (a)(2)(iii)(C) to change the reporting timeframe from every 30 days to at least every 45 days.
- Amend § 494.1 ''Basis and scope'' by—
  + Removing paragraph (a)(2).
  + Redesignating paragraphs (a)(3) through (a)(7) as (a)(2) through (a)(6), respectively.
  + Replacing the phrase ''recombinant epoetin alpha (EPO)'' with ''erythropoiesis-stimulating agent(s)'', in paragraph (a)(5).
  + Revising paragraph (a)(6) to read ''Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.''
- Amend § 494.10 ''Definitions'' by—
  + Revising the definition for ''discharge'' to read ''means the termination of patient care services by a

dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.''

+ Removing the definition for the term ''interdisciplinary team.''

• Amend § 494.20 ''Compliance with Federal, State, and local laws and regulations'' by removing the phrase ''staff licensure and other personnel staff qualifications, fire safety, equipment, building codes, drugs and medical device usage.''

• Amend § 494.30 ''Infection Control'' by—

+ Expanding our incorporation by reference section (pages 20–21) of the CDC ''Recommended Infection Control Practices for Hemodialysis Units at a Glance,'' to include the corresponding narrative section (pages 18–28) with the exception of the hepatitis C screening found in ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001. The recommendation found on pages 27 and 28 under the ''HBV-Infected Patient'' header section of RR05 requires a separate isolation room. Therefore, we are allowing dialysis facilities 300 days after the publication of the final rule in the **Federal Register** to comply with the requirements of this provision at (a)(1)(i). Specifically, this provision must be complied with by February 9, 2009.

+ Adding a dialysis isolation room waiver provision at (a)(1)(ii), which allows a new dialysis facility to request a waiver of the isolation room requirement, subject to the Secretary's approval, when dialysis isolation rooms are available locally that sufficiently serve the needs of patients in the geographic area.

+ Redesignating proposed paragraph (a)(2) as paragraph (a)(3).

+ Redesignating proposed paragraph (a)(3) as paragraph (a)(4).

+ Adding a new paragraph (a)(2) incorporation by reference for the ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' sections entitled ''Recommendations for Placement of Intravascular Catheters in Adults and Children'' parts I–IV; and ''Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients'' (Morbidity and Mortality Weekly Report, volume 51 number RR–10, pages 16 through 18, August 9, 2002, developed by the HICPAC).

+ Removing the requirement in paragraph (b)(2) that an infection control officer that is a registered nurse be designated as the infection control or safety officer, and adding infection control as a component of the quality assessment and performance improvement program required at § 494.110(a)(2)(ix).

+ Revising the proposed requirement at paragraph (b)(2) to clarify that clinical staff in a dialysis facility must demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules.

+ Redesignating paragraph (b)(2)(ii) as paragraph (b)(3) and revising to read as follows: ''Require all clinical staff to report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee.''

+ Removing and moving the monitoring standard paragraph (c) to the QAPI condition for coverage at § 494.110(a)(2)(ix).

+ Redesignating paragraph (d) as paragraph (c).

• Amend § 494.40 ''Water quality'' by—

+ Revising the title to read ''Water and dialysate quality.''

+ Revising paragraph (a) to read, Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ''Dialysate for hemodialysis,'' ANSI/AAMI RD52:2004, which are incorporated by reference. Incorporation by reference of the AAMI ''Dialysate for hemodialysis'' has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.''

+ Removing from paragraph (a)(2) the requirements for frequency of water purity testing.

+ Removing the proposed requirement at paragraph (b).

+ Redesignating paragraphs (c) through (e) as paragraphs (b) through (d), respectively.

+ Removing the stem statement from proposed paragraph (c), now paragraph (b), chlorine/chloramines.

+ Removing language from proposed paragraph (a)(2)(i)(B).

+ Removing redundant language at proposed paragraphs (a)(2)(ii)(C) and (a)(2)(ii)(D).

+ Clarifying the carbon tank requirement at proposed paragraph (c)(1), now paragraph (b)(1), so that the water treatment system must include a component or carbon tank which removes chlorine/chloramine, and that the backup component or second carbon tank must be ''in series'' with the first component.

+ Adding at redesignated paragraph (b)(2)(i) (proposed paragraph (c)(2)(i)) an alternative to permit the facility to test total chlorine for acceptable levels of less than 0.1mg/L as an alternative to testing free chlorine and chloramines levels, and adding a reference to the frequency of water testing specified in our incorporation by reference of ANSI/AAM RD52:2004.

+ Revising redesignated paragraph (b)(2)(ii)(A) (proposed paragraph (c)(2)(ii)(A)) to allow an alternate action to terminating dialysis treatments when chlorine/chloramines testing reveals high levels. We have added, ''Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective * * *.''

+ Redesignating proposed paragraph (c)(2)(ii)(B) as paragraph (b)(2)(ii)(C).

+ Revising redesignated paragraph (b)(2)(ii) (proposed paragraph (c)(2)(ii)) with new language. The provision reads ''Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section above * * *.''

+ Clarifying at redesignated paragraph (b)(2)(ii)(D) that corrective action taken must ensure ongoing compliance with acceptable chlorine and chloramines levels.

+ Adding ''endotoxin levels'' to the testing that must be done (when clinically indicated) at redesignated paragraph (d)(1), (proposed paragraph (e)(1)).

+ Adding a new standard at paragraph (e) that addresses in-center use of preconfigured hemodialysis systems. The standard requires that when facilities use a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

+ Removing proposed standard at paragraph (f) regarding unused mixed bicarbonate; use of mixed bicarbonate is

addressed in the ANSI/AAM RD52:2004 document, which is incorporated by reference.

• Amend § 494.50 ''Condition: Reuse of hemodialyzers and bloodlines'' by—

+ Removing the undesignated paragraph that states, ''The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.''

+ Incorporating by reference the AAMI reuse guidelines, ''Reuse of hemodialyzers,'' ANSI/AAMI RD47:2002/AL:2003 at paragraph (b)(1).

+ Clarifying at paragraph (b)(3) that bleach used on hemodialyzers is considered to be a ''cleaner'' in this application.

+ Adding endotoxin levels to the blood and dialysate culture testing that must be done when clinically indicated at paragraph(c)(2)(i).

• Amend § 494.60 ''Physical environment'' by—

+ Modifying the room temperature requirement at paragraph (c)(2) by removing the phrase ''that is comfortable for the majority of its patients'', so that the facility must ''Maintain a comfortable temperature within the facility and make reasonable accommodations for the patients who are not comfortable at this temperature.''

+ Adding a privacy provision at paragraph (c)(3), which reads, ''The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.''

+ Adding a new monitoring requirement at paragraph (c)(4) that states, ''Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).''

+ Revising paragraph (d)(1)(i)(B) to read, ''Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated.''

+ Revising the requirement at paragraph (d)(1)(i)(C) that the dialysis facility contact information must include an alternate emergency phone number for instances when the dialysis facility is unable to receive phone calls due to emergency, unless the facility has the ability to forward calls to a working phone number under such emergency conditions.

+ Revising paragraph (d)(3) by adding an automated external defibrillator as an alternative to the defibrillator.

+ Redesignating proposed paragraphs (d)(3)(i) and (d)(3)(ii) as paragraphs (d)(4)(i) and (d)(4)(ii).

+ Adding a new requirement at paragraph (d)(4)(iii) that the facility must, ''Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.''

+ Revising paragraph (e)(1) to indicate that it is effective February 9, 2009.

+ Removing proposed paragraph (e)(2).

+ Adding a new paragraph (e)(2), to state that sprinkler systems are not required for dialysis providers using facilities built before 2008 on the rule's effective date, if their State law so permits.

+ Adding a clarifying phrase ''for individual dialysis facilities'' at paragraph (e)(4).

• Amend § 494.70 ''Patients' rights'' by—

+ Revising proposed paragraph (a)(5) to add the patients ''right to discontinue treatment'' as an option.

+ Revising proposed paragraph (a)(5) by redesignating the ''advance directive'' policy as paragraph (a)(6), and adding the phrase ''and the facility's policy regarding advance directives.''

+ Redesignating proposed paragraphs (a)(6) through (a)(16) as paragraphs (a)(7) through (a)(17), respectively.

+ Revising newly redesignated paragraph (a)(7), (formerly paragraph (a)(6)) to specify that patients have the right to receive resource information about dialysis modalities and options not offered by the facility, including alternative scheduling options for working patients.

+ Revising newly redesignated (a)(10) (formerly (a)(9)) to clarify that the patient has the right to be informed of his or her medical status by not only the physician, but the ''nurse practitioner, clinical nurse specialist or physician's assistant treating the patient for ESRD.''

+ Adding at paragraph (b)(1) a phrase, ''routine or involuntary'' to clarify that patients must be informed of both routine and involuntary discharge policies.

+ Removing the words ''reducing or'' and ''ongoing'' at paragraph (b)(2), and changing the word ''shortened'' to ''abbreviated.''

+ Adding ESRD Network ''mailing addresses'' to the list of information that must be posted in the dialysis facility at subsection (c).

• Amend § 494.80 ''Patient Assessment'' by—

+ Clarifying in the introductory paragraph that the patient may choose whether he or she wants to identify a designee to participate in the interdisciplinary team.

+ Clarifying the introductory paragraph to include ''a physician treating the patient for ESRD'' and removing our reference to the nephrologists.

+ Adding immunization history to the assessment criteria at paragraph (a)(3).

+ Modifying our reference to erythropoietin at paragraph (a)(4), by using the term ''erythropoiesis-stimulating agent(s).''

+ Clarifying at paragraph (a)(6) that the evaluation of patient nutritional status must be performed by a dietitian.

+ Clarifying at paragraph (a)(7) that the evaluation of patient psychosocial needs must be performed by a social worker.

+ Modifying the requirement in paragraph (a)(13) for evaluation of vocational and physical rehabilitation status and potential, so that the interdisciplinary team need only evaluate the patient for referral to vocational and rehabilitation services.

+ Modifying the title of paragraph (b), to clarify the meaning of ''new patient.'' It now reads ''Frequency of assessment for patients admitted to the dialysis facility.''

+ Modifying the time allowed to complete the initial patient assessment at paragraph (b)(1) from 20 days to 30 days, which corresponds to the implementation time for the plan of care. An alternate method of determining when the assessment must be completed (and plan of care implemented) was added; 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session to allow for occasions (such as hospitalizations) when the patient may be away from the unit. The assessment now must be completed within the latter of 30 days or 13 dialysis sessions.

+ Adding at paragraph (d)(2)(iv) the word ''concurrent'' and deleting ''with''.

• Amend § 494.90 ''Patient plan of care'' by—

+ Adding to the introductory text, ''The interdisciplinary team as defined at § 494.80 must develop and implement * * *.''

+ Removing the term ''community accepted'', from the introductory statement, and substituting ''professionally-accepted clinical practice,'' so that the ''outcomes'' specified in the patient plan of care may be ''consistent with current evidence-based professionally-accepted clinical practice standards.''

+ Adding ''manage the patient's volume status'' at paragraph (a)(1). We

are also adding the current NKF–KDOQI clinical practice guideline targets for dialysis adequacy (Kt/V of 1.2 for hemodialysis, and a weekly Kt/V of 1.7 for peritoneal dialysis), as well as an alternative equivalent of professionally-accepted clinical practice standards for adequacy of dialysis.

+ Revising paragraph (a)(2) to read, ''The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.''

+ Adding new paragraph (a)(3), requiring the interdisciplinary team to provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. The remaining plan of care components are renumbered to reflect the addition of a new paragraph (a)(3).

+ Revising proposed paragraph (a)(3) (now paragraph (a)(4)), to read in part, ''The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.''

+ Modifying the vascular access plan of care component at proposed paragraph (a)(4), now paragraph (a)(5), so that instead of providing the necessary care and services to achieve and sustain the vascular access, the interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The interdisciplinary team must also evaluate whether the patient is a potential candidate for arteriovenous fistula placement.

+ Adding a new psychosocial status requirement at paragraph (a)(6), requiring the interdisciplinary team to provide the necessary monitoring and social work interventions, including counseling and referrals for social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

+ Revising and redesignating proposed paragraph (a)(5) (now located at paragraph (a)(7)(i)), to require the interdisciplinary team to plan for home dialysis or explain why the patient is not a candidate for home dialysis.

+ Modifying the rehabilitation plan of care requirement, now at paragraph (a)(8), to require that the interdisciplinary team assist the patient in achieving and sustaining an appropriate level of productive activity, and make rehabilitation and vocational rehabilitation referrals as appropriate.

+ Clarifying at paragraph (b)(i) that the patient is to be included (if he or she desires) when the interdisciplinary team is completing the plan of care.

+ Clarifying the patient plan of care signature requirement (paragraph (b)(1)(ii)) to indicate that team members must sign the plan of care and, if applicable, the facility must document a patient's refusal to sign the plan of care, along with the reason the signature was not provided.

+ Modifying the plan of care implementation requirements (paragraph (b)(2)) so that the implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80 of this part.

+ Adding language to paragraph (b)(3) that requires the plan of care to be adjusted when the plan of care outcome targets are not met to reflect the patient's condition along with an explanation, and that the team must identify opportunities for improvement.

+ Adding ''nurse practitioner, clinical nurse specialist, or physician's assistant'' as the types of professionals who can meet the monthly visit requirement at paragraph (b)(4).

+ Modifying the transplantation referral-tracking standard at paragraph (c)(3), by requiring that the interdisciplinary team communicate with the transplant center regarding patient transplant status ''at least annually, and when there is a change in transplant candidate status.''

+ Revising the standard at subsection (d), ''Patient education and training,'' to require that the care plan include training in infection prevention and personal care, home dialysis and self-care, and benefits and risks of various vascular access types.

• Amend § 494.100 ''Care at home'' by—

+ Clarifying in the introductory text that care at home services must meet all applicable conditions of this part.

+ Replacing the word ''provide'' with ''oversee'' at paragraph (a).

+ Replacing ''hematocrit level of at least 33 percent or a hemoglobin of at least 11 gm/dL'' at paragraph (a)(3)(ii) with the phrase ''target level hemoglobin or hematocrit as written in the patient's plan of care.'' We are also replacing ''erythropoietin administration'' with ''administration of erythropoiesis-stimulating agent(s).''

+ Deleting ''implementation of a nutritional care plan'' at proposed paragraph (a)(3)(iii). We are also deleting ''how to achieve and maintain emotional and social well being'' from paragraph (a)(3)(iv). The remaining paragraphs have been renumbered to reflect these revisions.

+ Adding that potential dialysis complication training includes addressing ''water treatment problems'' (new paragraph (a)(3)(iii)).

+ Clarifying at paragraph (c)(1) that a home dialysis training facility must furnish home dialysis support services either directly, under agreement, or by arrangement with another ESRD facility.

+ Modifying paragraph (c)(1)(v) to specify that the facility must monitor the quality of water and dialysate used by home hemodialysis patients and conduct onsite evaluations and testing of the water and dialysate system in accordance with (A) the recommendations specified in the manufacturer's instructions; and (B) the system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

+ Revising paragraph (c)(1)(v) (revised as paragraph (c)(1)(v)(C)) to change ''the water quality'' to ''any water and dialysate quality problem.''

+ Adding ''and dialysate'' at paragraphs (c)(1) and (c)(2).

+ Clarifying at paragraph (c)(2)(vi) that the dialysis facility may not only purchase, but may also lease or rent medically necessary home dialysis supplies and equipment.

• Amend § 494.110 ''Quality assessment and performance improvement'' by—

+ Clarifying in the introductory paragraph, that the QAPI program requires participation by the professional members of the

interdisciplinary team to meet these conditions for coverage.

+ Adding mineral metabolism and renal bone disease to the list of QAPI program components at paragraph (a)(2)(iii). The subsequent QAPI program components have been renumbered accordingly.

+ Adding infection control to the list of QAPI program components at paragraph (a)(2)(ix).

• Amend § 494.120 ''Special purpose renal dialysis facilities'' by—

+ Revising standard (d), to require the special purpose facility to contact the patient's physician ''if possible'' prior to initiating dialysis.

+ Revising standard (e), to require the special purpose facility patient documentation to be forwarded to the patient's usual dialysis facility, if possible within 30 days of the last scheduled treatment.

• Amend § 494.140 ''Personnel qualifications'' by—

+ Adding a requirement to the introductory text to read, ''All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.'' References to State licensure and board of practice compliance for dialysis facility staff have been removed, where appropriate, in the later sections of § 494.140.

+ Revising paragraph (a)(1), to require the medical director be a board-certified physician in internal medicine or pediatrics by a professional board.

+ Revising the title of paragraph (b)(2) to read, ''Self-care and home dialysis training nurse.''

+ Adding a new provision at paragraph (b)(3)(iii) so that a charge nurse who is a licensed practical nurse or licensed vocational nurse, must work under the supervision of a registered nurse in accordance with State nursing practice act provisions.

+ Deleting proposed paragraph (c)(2).

+ Redesignating proposed § 494.140(c)(3) as § 494.140(c)(2).

+ Adding a ''specialization in clinical practice'' requirement to the social worker's master's degree provisions at paragraph (d)(1).

+ Adding the grandfather provision from part 405, subpart U for non-master's prepared social workers to paragraph (d)(2), to allow a dialysis social worker to qualify for this position if he or she has ''served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(2) of this part.''

+ Revising the patient care technician (PCT) qualifications at paragraph (e)(3), to remove the proposed requirement that the PCT have at least 3 months experience, and to require that the training program be only ''under the direction'' of a registered nurse, rather than ''under the direct supervision of a registered nurse.''

+ Revising paragraph (e)(3), to include the training program requirements from proposed § 494.180((b)(5).

+ Adding ''proper cannulation techniques'' to the training program subjects redesignated at paragraph (e)(3)(iii).

+ Adding ''and dialysate preparation'' to redesignated paragraph (e)(3)(v).

+ Adding a new requirement at paragraph (e)(4) that patient care dialysis technicians be certified under a State certification program or a national commercially available certification program. At paragraphs (e)(4)(i) and (e)(4)(ii), we are adding that newly employed patient care dialysis technicians must be certified within 18 months of being hired as a dialysis patient care technician and for dialysis patient care technician employed on the effective date of this rule within 18 months of such date.

• Amend § 494.150 ''Responsibilities of the medical director'' by—

+ Adding to the introductory paragraph, ''The medical director is accountable to the governing body for the quality of medical care provided to patients.''

+ Revising the requirement at paragraph (c)(2)(i) to read, ''All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers.''

• Amend § 494.160 ''Condition: Relationship with the ESRD Network'' by—

+ Redesignating the ''Relationship with the ERSD Network'' condition (at § 494.160) as § 494.180(i). The language for the ESRD Network requirements has been retained from the proposed rule.

+ Reserving section 494.160 without requirements.

• Amend § 494.170 ''Medical records'' by—

+ Adding at paragraph (b)(2) that the patient's record must indicate ''whether the patient has executed an advance directive.''

+ Revising language in standard (c) to read, ''In accordance with 45 CFR 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.''

+ Revising language at paragraph (d), to require the dialysis transferring a patient to send to the receiving facility only ''all requested medical record information.''

• Amend § 494.180 ''Governance'' by—

+ Removing the sentence, ''The governing body receives and acts upon recommendations from the ESRD Network'' from the introductory paragraph.

+ Adding language at paragraph (b)(1), to require that the RN, social worker and dietitian members of the interdisciplinary team must be available to meet patient clinical needs.

+ Revising paragraph (b)(2) to read, ''A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated.''

+ Revising paragraph (b)(3) to read, ''All staff, including the medical director, have appropriate orientation to the facility and work responsibilities.''

+ Removing the written training program requirements specific to dialysis patient care technicians from paragraphs (b)(5) and (b)(6) and adding them to paragraphs (e)(3) and (e)(4).

+ Revising paragraph (c), to indicate that the governing body is responsible for all medical staff appointments and credentialing in accordance with State law, including clinical nurse specialists.

+ Adding a new paragraph (c)(3), which requires the governing body to communicate ''expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.''

+ Clarifying the standard at subsection (e) that patients may file ''an oral or written'' grievance with the facility.

+ Revising the title of standard (f), to read ''Involuntary discharge and transfer policies and procedures.''

+ Modifying paragraph (f)(4), to clarify the sequence of procedures when a patient is involuntarily discharged, and to require ESRD Network notification at the time the patient is provided 30 days advance notice of the discharge, instead of at the time of discharge or later. New paragraph (f)(4)(ii) now requires that the interdisciplinary team provides the patient with a 30 day notice of the planned discharge, and also notifies the ESRD Network of the planned discharge. The proposed provisions at proposed paragraphs (f)(4)(ii) through (f)(4)(iv) are renumbered to reflect insertion of a new paragraph (ii).

+ Revising new paragraph (f)(4)(iv), to require a facility contemplating an involuntary discharge to contact and attempt to place the patient in another facility, and to document that effort.

+ Adding a new provision at paragraph (f)(5), which reads, ''In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.''

+ Adding ''routine and emergency dialysis'' to the services a hospital agrees to provide in an agreement with a dialysis facility at paragraph (g)(3).

+ Revising the proposed paragraph (h) introductory text to reflect an effective date of February 1, 2009 in the **Federal Register**.

+ Redesignating proposed paragraph (i) as paragraph (j).

+ Relocating the proposed ESRD Network-related requirements (proposed § 494.160) for dialysis facilities at new paragraph (i).

IV. Effective Dates for the Final Rule

The Administrative Procedure Act (APA) does not require that a final rule become effective within a certain maximum timeframe after publication in the **Federal Register**. However, under the APA, the effective date of a substantive rule must be no less than 30 days after its publication date, unless there is good cause for an earlier effective date (5 U.S.C. 553(b)). This final rule will be effective 180 days after its publication in the **Federal Register**. We are allowing dialysis facilities additional time beyond 180 days to come into compliance with three specific provisions of this final rule.

This final rule modernizes the existing ESRD dialysis facility conditions for coverage originally promulgated in 1976, which have not been revised in their entirety in 31 years. The ESRD conditions for coverage proposed rule (published on February 5, 2005 (70 FR 6184)) emphasized a patient-centered approach to care, thereby decreasing dialysis facility structure and process requirements while moving to an outcome-based orientation. This final rule will implement those proposed changes, while reflecting current professional standards of practice. In addition, they will update patient safety standards, provide a structure for internal facility quality improvement, and add a framework for external oversight. Because we are changing from a process-oriented to patient-centered approach, we believe that ESRD facility providers will need additional time to come into full compliance with the requirements of this final rule.

Under section 494.30(a)(1)(i), ''Infection control,'' certain facilities could be required to build isolation rooms as set out in ''HBV-Infected Patients'' found on pages 27 and 28 of RR05 (''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'') which has been incorporated by reference into our regulations. Some facilities would need additional time to implement this requirement, since construction of isolation rooms would require time for project development, construction approvals, architectural design, contractor bids and obtaining building permits. Therefore, we are allowing dialysis facilities 300 days after publication of this final rule to comply with the requirements found at § 494.30(a)(1)(i).

Under section 494.60(e)(1), ''Physical environment,'' facilities will be required to be in compliance with the 2000 edition of the Life Safety Code. If changes are required in the building structure, facilities will need time to make the appropriate changes. Therefore, we are allowing dialysis facilities 300 days after publication of this final rule time to comply with the requirements found at § 494.60(e)(1).

Under section 494.180(h), ''Governance,'' we are requiring facilities to submit certain data to CMS in an electronic format. Facilities may have to develop programs or obtain software that can be used to provide the data to CMS. This requirement may have a financial impact on some facilities and may also require them to make changes to their data systems to capture the data that they will be required to submit. We are allowing dialysis facilities until February 1, 2009 to comply with the requirements at § 494.180(h).

V. Reference Materials

A. Provisions of Part 494

This final rule contains a number of requirements that are not included in the existing regulations. For information and ease of reference, outlined below is a list of the new provisions, grouped by condition:

Condition	New provisions
Infection control (§ 494.30)	Infection control procedures (including the Recommended Infection Control Practices for Hemodialysis Units At A Glance CDC guidelines). § 494.30(a)(1)(i)—Patient isolation procedures.
Water quality (§ 494.40)	Incorporates by reference the updated 2001 American National Standard/Association for the Advancement of Medical Instrumentation guidelines for water purity.
Physical environment (§ 494.60)	§ 494.60(e)—Fire safety.
Patient rights (§ 494.70)	§ 494.70(a)(6)—Advance directives. § 494.70(a)(14)—Complaint systems. § 494.70(a)(15)—Complaint systems. § 494.70(b)—Discharge and transfer policies. § 494.70(c)—Posting of rights.
Patient assessment (§ 494.80)	§ 494.80(a)(2)—Appropriateness of dialysis prescription. § 494.80(a)(5)—Renal bone disease. § 494.80(a)(8)—Dialysis access type and maintenance. —Suitability for transplantation referral, including basis for referral or nonreferral. § 494.80(b)—Frequency of assessment. § 494.80(c)—Assessment of treatment prescription. § 494.80(d)—Patient reassessment.

Condition	New provisions
Patient plan of care (§ 494.90)	§ 494.90(a)(1)—Dose of dialysis.
	§ 494.90(a)(2)—Nutritional status.
	§ 494.90(a)(4)—Anemia.
	§ 494.90(a)(5)—Vascular access.
	§ 494.90(a)(7)—Home dialysis and transplantation status.
	§ 494.90(a)(8)—Rehabilitation status.
	§ 494.90(b)—Implementation of patient plan of care.
	§ 494.90(b)(4)—Direct physician/patient interaction.
	§ 494.90(c)—Transplantation referral tracking.
Care at home (§ 494.100)	§ 494.100(a)—Training.
	§ 494.100(b)—Home dialysis monitoring.
	§ 494.100(c)—Support services.
Quality assessment and performance improvement (§ 494.110).	§ 494.110(a)—Program scope.
	§ 494.110(a)(2)(i)—Adequacy of dialysis.
	§ 494.110(a)(2)(ii)—Nutritional status.
	§ 494.110(a)(2)(iii)—Mineral metabolism and renal bone disease.
	§ 494.110(a)(2)(iv)—Anemia management.
	§ 494.110(a)(2)(v)—Vascular access.
	§ 494.110(a)(2)(vi)—Medical injuries and medical error identification.
	§ 494.110(a)(2)(vii)—Hemodialyzer reuse.
	§ 494.110(a)(viii)—Patient satisfaction.
	§ 494.110(a)(ix)—Infection control.
	§ 494.110(b)—Monitoring performance improvement.
	§ 494.110(c)—Prioritizing improvement activities.
Special purpose renal dialysis facilities (§ 494.120)	§ 494.120—Definition.
Personnel qualifications (§ 494.140)	§ 494.140(b)—Nursing services.
	§ 494.140(e)—Dialysis technicians.
Responsibilities of the medical director (§ 494.150)	Quality assessment and performance improvement program.
	§ 494.150(b)—Staff education, training, and performance.
	§ 494.150(c)—Patient care policies and procedures.
Governance (§ 494.180)	§ 494.180(c)—Medical staff appointments.
	§ 494.180(d)—Furnishing services.
	§ 494.180(e)—Internal grievance process.
	§ 494.180(f)—Involuntary discharge and transfer policies and procedures.
	Emergency coverage.
	Furnishing data and information for ESRD program administration.
	Relationship with the ESRD Network.

B. ESRD Crosswalk (Cross Refers Existing Requirements to Final Requirements)

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
Scope of subpart	405.2100(a)	Statutory basis	494.1(a).
	405.2100(b)	Scope	494.1(b).
Objectives of ESRD program	405.2101	Deleted.	
Definitions	405.2102	Definitions	494.10.
Agreement		Deleted.	
Arrangement		Deleted.	
Dialysis		Deleted.	
End-stage renal disease		Deleted.	406.13(b).
ESRD facility (introductory text)		Deleted.	
(a) Renal dialysis center		Deleted.	
(b) Renal dialysis facility		Definitions	494.10.
(c) Self-dialysis unit		Deleted.	
(d) Special purpose renal dialysis facility		Special purpose renal dialysis facilities.	494.120.
ESRD service (introductory text)		Deleted.	
(a) Dialysis service		Deleted.	
(1) Inpatient dialysis		Deleted.	
(2) Outpatient dialysis		Deleted.	
(i) Staff-assisted dialysis		Deleted.	
(ii) Self-dialysis		Definitions	494.10.
(3) Home dialysis		Definitions	494.10.
(b) Self-dialysis and home dialysis		Deleted.	
Furnishes directly		Definitions	494.10.
Furnishes on the premises		Deleted.	494.180(d).
Medical care criteria		Deleted.	
Medical care norms		Deleted.	
Medical care standards		Deleted.	
Medical care evaluation study		Deleted.	

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
Network, ESRD		Retained in 405, Subpart U.	405.2102.
Network, organization		ESRD Network organization	405.2102.
(a) Chief executive officer		Deleted.	
(b) Dietitian		Personnel qualifications	494.140(c).
(c) Medical record practitioner		Deleted.	
(d) Nurse responsible for nursing services		Personnel qualifications	494.140(b).
(e) Physician-director		Personnel qualifications	494.140(a).
(f) Social worker		Personnel qualifications	494.140(d).
Designation of ESRD networks	405.2110	Retained in 405, Subpart U.	
[Reserved]	405.2111	Reserved in Part 405 Subpart U.	
ESRD network organizations	405.2112	Retained in 405, Subpart U.	
Medical review board	405.2113	Retained in 405, Subpart U.	
[Reserved]	405.2114	Reserved in Part 405 Subpart U.	
Provider status: renal transplantation center or renal dialysis center.	405.2131	Deleted.	
[Reserved]	405.2132	Deleted.	
Furnishing data and information for ESRD program administration.	405.2133	Furnishing data and information for ESRD program administration.	494.180(h).
Participation in network activities	405.2134	Relationship with ESRD network	494.180(i).
Compliance with Federal, State, and local laws and regulations.	405.2135	Compliance with Federal, State, and local laws and regulations.	494.20.
Governing body and management (introductory text).	405.2136	Governance (introductory text)	494.180 (introductory text).
(a) Disclosure of ownership	405.2136(a)	Governance	494.180(j).
(b) Operational objectives	405.2136(b)	Deleted.	
(c) Chief executive officer	405.2136(c)	Designating a chief executive office or administrator.	494.180(a).
(d) Personnel policies and procedures	405.2136(d)(1)	Governance	494.180(b)(3) and (b)(4).
	405.2136(d)(3–5, 7)	Deleted.	
(d)(2) Infection control/Incident reports	405.2136(d)(2)	Infection control and Quality assessment and performance improvement.	494.30(a) and 494.110(a)(ix).
(d)(6) Facility personnel educational programs.	405.2136(d)(6)	Personnel qualifications	494.140(e).
		Governance	494.180(b)(3) and (b)(4).
		Infection Control	494.30(a).
(e) Use of outside resources	405.2136(e)	Deleted.	
(f) Patient care policies	405.2136(f)	Policies and procedures	494.150(c).
(g) Medical supervision and emergency coverage.	405.2136(g)	Furnishing services	494.180(d).
	405.2136(g)(1)	Patient plan of care	494.90 (introductory text).
	405.2136(g)(2)	Emergency Coverage	494.180(g).
(h) Medical staff	405.2136(h)	Medical staff appointments	494.180(c).
Patient long-term program and patient care plan	405.2137 (introductory text)	Patient plan of care	494.90 (introductory text).
(a) Patient long-term program	405.2137(a)	Deleted.	
(b) Patient care plan	405.2137(b)	Patient plan of care	494.90 (introductory text).
(b)(1) Personalized care plan	405.2137(b)(1)	Patient plan of care	494.90 (introductory text).
(b)(2) Developed by a professional team	405.2137(b)(2)	Patient plan of care	494.90 (introductory text).
(b)(3) The patient is involved	405.2137(b)(3)	Patient plan of care	494.90(b)(1).
		Patient's rights	494.70(a)(5).
(b)(4) Frequency of care plan review	405.2137(b)(4)	Patient plan of care	494.90(b)(2).
		Patient reassessment	494.80(d).
(b)(5) Transfer of care plan	405.2137(b)(5)	Medical records	494.170(d).
(b)(6) Care plan for the home dialysis patient	405.2137(b)(6)	Development of patient plan of care.	494.90(a)(4). 494.100(c)(1).
		Care at home	
(b)(7) Erythropoietin for the home dialysis patient.	405.2137(b)(7)	Patient plan of care	494.90(a)(4).
Patients' rights and responsibilities	405.2138(a)–(d)	Patients' rights	494.70(a).
		Medical records	494.170(a).
		Posting of rights	494.70(c).
	405.2138(e).	Internal grievance process	494.180(e).
		Patients' rights	494.70(a)(14) and (a)(15).
		Posting of rights	494.70(c).
Medical records	405.2139	Medical records	494.170 (introductory text).
(a) Medical record contents	405.2139(a)	Medical records	494.170(b).
(b) Protection of medical record information	405.2139(b)	Protection of patient's record	494.170(a).
(c) Medical record supervisor	405.2139(c)	Deleted.	
(d) Completion and centralization	405.2139(d)	Completion of patient records and centralization of clinical information.	494.170(b).

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
(e) Retention and preservation	405.2139(e)	Record retention and preservation.	494.170(c).
(f) Location and facilities	405.2139(f)	Deleted.	
(g) Transfer of medical information	405.2139(g)	Transfer of patient record information.	494.170(d).
Physical environment	405.2140(a) (introductory text).	Physical environment	494.60 (introductory text).
(a) Building and equipment	405.2140(a)(1)	Building	494.60(a) and (b).
(a)(1) Fire	405.2140(a)(2), (3)	Fire Safety	494.60(e).
(a)(2), (3) Equipment and areas are hazard free.	405.2140(a)(2), (3)	Equipment maintenance	494.60(b).
(a)(5) Water quality requirements	405.2140(a)(5)	Water and dialysate quality	494.40(a).
(b) Favorable environment for patients	405.2140(b) (introductory text).	Patient care environment	494.60(c).
(b)(1) Infection prevention	405.2140(b)(1)	Procedures for infection control	494.30.
(b)(2) and (b)(4) Adequate treatment areas/ Heating and ventilation systems.	405.2140(b)(2) and (b)(4)	Physical environment	494.60 (introductory text) and (c).
(b)(3) Nursing station	405.2140(b)(3)	Governance	494.180(g)(2).
(b)(5) Special dialysis solutions	405.2140(b)(5)	Deleted.	
(c) Contamination prevention	405.2140(c)	Infection control	494.30(a).
		Reuse of hemodialyzers	494.50.
(d) Emergency preparedness	405.2140(d)	Emergency preparedness	494.60(d).
Reuse of hemodialyzers and other dialysis supplies.	405.2150 (introductory text)	Reuse of hemodialyzers and bloodlines.	494.50 (introduction).
(a) Hemodialyzers	405.2150(a)(1) and (a)(2)	Reprocessing requirements for the reuse of hemodialyzers and bloodlines.	494.50(b).
	405.2150(a)(3)	Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.	494.50(c).
(b) Transducer filters	405.2150(b)	Deleted.	
(c) Bloodlines	405.2150(c)	General requirements for the reuse of hemodialyzers and bloodlines.	494.50(a).
		Reprocessing requirements for the reuse of hemodialyzers and bloodlines.	494.50(b).
Affiliation agreement or arrangement	405.2160(a), (b)(1), (b)(3)	Governance	494.180(g)(3).
	405.2160(b)(2)	Transfer of patient record information.	494.170(d).
Director of a renal dialysis facility or renal dialysis center.	405.2161	Personnel qualifications	494.140 (introductory text).
		Medical director	494.140(a).
		Responsibilities of the medical director.	494.150.
Staff of a renal dialysis facility or renal dialysis center.	405.2162 (introductory text)	Governance	494.180(b).
(a) Registered nurse	405.2162(a)	Governance	494.180(b)(2).
		Personnel qualifications	494.140(b)(1).
(b) On-duty personnel	405.2162(b)	Governance	494.180(b)(1).
(c) Self-care dialysis training personnel	405.2162(c)	Care at Home	494.100(a)(2).
		Personnel qualifications	494.140(b)(2).
Minimal service requirements for a renal dialysis facility or renal dialysis center.	405.2163	Patient plan of care	494.90 (introductory text).
(a) Outpatient dialysis services	405.2163(a)(1)	Patient plan of care	494.90 (introductory text).
	405.2163(a)(2)	Patient plan of care	494.90 (introductory text).
		Care at home	494.100 (introductory text).
(b) Laboratory services	405.2163(b)	Laboratory services	494.130.
(c) Social services	405.2163(c)	Assessment criteria	494.80(a)(7).
		Support services	494.100(c).
		Psychosocial services	494.90(a)(6).
(d) Dietetic services	405.2163(d)	Assessment criteria	494.80(a)(5) and (a)(6).
		Patient plan of care	494.90(a)(2) and (a)(3).
(e) Self-dialysis support services	405.2163(e)	Support services	494.100(c).
(f) Participation in recipient registry	405.2163(f)	Deleted.	
(g) Use of erythropoietin at home	405.2163(g)	Patient assessment	494.80(a)(2), (4).
		Patient plan of care	494.90(a)(4).
		Care at home	494.100(a).
(h) Responsibilities of the physician/facility for use of erythropoietin at home.	405.2163(h)	Care at home	494.100(b) and (c).
Conditions for coverage of special purpose renal dialysis facilities.	405.2164	Special purpose renal dialysis facilities.	494.120.
(a) Special purpose renal renal dialysis facilities.	405.2164(a)	Special purpose dialysis facilities.	494.120.

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
(b) Consult patient's physician	405.2164(b)	Physician contact	494.120(d).
(c) Approval period	405.2164(c)	Approval period	494.120(a).
(d) Service limitation	405.2164(d)	Service limitation	494.120(b).
Termination of Medicare coverage	405.2180	Termination of Medicare coverage and alternative sanctions for ESRD facilities.	488.604.
Alternative sanctions	405.2181	Alternative sanctions	488.606.
Notice of sanction and appeal rights: Termination of coverage.	405.2182	Notice of appeal rights: Termination of coverage.	488.608.
Notice of appeal rights: Alternative sanctions	405.2184	Notice of appeal rights: Alternative sanctions.	488.610.

VI. Collection of Information Requirement

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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

A. ICRs Regarding Payment for Home Dialysis Equipment, Supplies and Support Services (§ 414.330)

Section 414.330 states that suppliers must report to the ESRD facility providing support services, at least every 45 days, all data for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

The burden to ESRD facilities associated with this requirement is the time and effort necessary to collect all data for each patient receiving home dialysis care with respect to services and items furnished. We estimate that there are approximately 24,657 patients receiving home dialysis care (approximately 5 percent of all dialysis patients), and that it would take a dialysis facility 1.5 hours annually to collect data for each patient. Therefore, we estimate a total annual burden of 36,986 hours.

B. ICRs Regarding Special Procedures for Approving End-Stage Renal Disease Facilities (§ 488.60)

Section 488.60 states that an ESRD facility wishing to be approved, or wishing to be approved for an expansion of dialysis services, for Medicare coverage, in accordance with part 494 of this chapter, must submit the documents and data as outlined in § 488.60(a)(1) through (a)(4).

As of the spring of 2007, there were 4,746 Medicare approved dialysis facilities (*http://www.medicare.gov/Download/DownloadDB.asp*). From 1998 to 2004, the average yearly growth (using USRDS data) in dialysis facilities seeking approval was 4.4 percent. We anticipate a similar rate of growth in dialysis facilities over the next few years. Thus, we believe that 218 new and renovated dialysis facilities will request Medicare approval in 2009 and that over the five-year period from 2009 to 2013 a total of 1,191 new and renovated dialysis facilities will request Medicare approval. We estimate the average number of new facilities per year requesting approval would be 238 facilities per year, over 5 five years. Since we are requiring compliance with the provisions of this rule 180–300 days after publication of this final rule, we are using 2009 estimates of the numbers for new and renovated dialysis facilities for one-time burdens.

We estimate that it will take 40 hours for each of the 238 new and renovated facilities to gather and submit the necessary documentation for consideration by the Secretary. The estimated annual burden is 9520 annual hours.

C. ICRs Regarding Infection Control (§ 494.30)

Section 494.30 discusses the conditions for infection control programs. Specifically, § 494.30(a)(1)(ii) states that when dialysis isolation rooms as required by § 494.30(a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new facility may request a waiver of the isolation requirement. The burden associated with this requirement is the time and effort necessary to draft and submit a waiver request to the Secretary. We estimate that 90 percent (about 214 per year) of new dialysis facilities would request a waiver. We estimate that it will take each facility approximately 1 hour to comply with this information collection request. The total estimated annual burden is 214 hours.

Section 494.30(b) outlines the standards for infection control program oversight. Section 494.30(b)(1) states that a facility must monitor and implement biohazard and infection control policies and activities within the dialysis unit. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, and monitor the biohazard and infection control policies. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.30(b)(3) states that a facility must require all clinical staff to report infection control issues to the dialysis facility's medical director and the quality improvement committee. We estimate that it would take staff 5 minutes per incident to notify the medical director and the quality improvement committee. Such infection control issues are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. Therefore, for 54 facilities, we estimate a total annual burden of 4.5 hours.

Section 494.30(c) contains a reporting requirement. The facility must report incidences of communicable diseases as required by Federal, State, and local regulations. The burden associated with this requirement is the time and effort necessary to report incidences of communicable diseases to the appropriate Federal, State, or local agency. While this requirement is subject to the PRA, we believe the

burden is exempt as stated in 5 CFR 1320.3(b)(3). Facilities must report as required by Federal, State, and local regulations. The burden associated with this reporting requirement would exist in the absence of the Federal requirement contained in this regulation. Consequently, the burden is exempt from the PRA.

D. ICRs Regarding Water and Dialysate Quality (§ 494.40)

Section 494.40(b)(1) states that a facility's water treatment system must include a component or carbon tank which removes chlorine/chloramines along with a backup component or second carbon tank in series for chlorine/chloramines removal. Section 494.40(b)(1)(ii) further specifies the required course of action if the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section. As stated in § 494.40(b)(1)(ii)(c), the facility must immediately notify the medical director. We estimate that it would take staff 5 minutes per incident to notify the medical director. Such incidents are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. Therefore, for 54 facilities, we estimate a total annual burden of 4.5 hours.

Additionally, § 494.40(c) requires a facility to create a corrective action plan that ensures patient safety. Specifically, when water testing results, including but not limited to chemical, microbial, and endotoxin levels which meet AAMI levels or deviate from the AAMI standards, the dialysis facility must develop a corrective action plan. The burden associated with this requirement is the time and effort necessary to develop and implement a corrective action plan. We estimate that it would take 54 facilities 30 minutes each to develop and implement a corrective action plan that ensures patient safety. Therefore, we estimate a total annual burden of 27 hours.

Section 494.40(d) states that a dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated, the facility must perform the tasks listed in § 494.40(d)(1)–(3). The burden associated with these requirements is the time and effort required to maintain active surveillance of patient reactions during and following dialysis. In addition, there is burden associated with the tasks listed in § 494.40(d)(1)–(3). While all of the requirements in § 494.40(d) are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA.

E. ICRs Regarding the Reuse of Hemodialyzers and Bloodlines (§ 494.50)

Section 494.50(c)(1) states that a dialysis facility must monitor patient reactions during and following dialysis. As stated in § 494.50(c)(2), a facility must obtain blood and dialysate cultures and endotoxin levels, and undertake evaluation of its dialyzer reprocessing and water purification system. The burden associated with these requirements is the time and effort necessary to monitor and record patient reactions and to perform the tasks listed in § 494.50(c)(2)(i)–(ii). While these requirements are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA.

Section 494.50(c)(2)(iii) requires a facility to report any adverse outcomes to FDA and other Federal, State, or local government agencies as required by law. The burden associated with this requirement is the time and effort necessary to report the adverse outcomes to the FDA and other Federal, State, or local government agencies as required by law. While this requirement is subject to the PRA, the burden is exempt as stated in 5 CFR 1320.3(b)(3). Facilities must report as required by law to Federal, State, and local government agencies. The burden associated with this reporting requirement would exist in the absence of the Federal requirement contained in this regulation. Consequently, the burden is exempt from the PRA.

F. ICRs Regarding Physical Environment (§ 494.60)

As required by § 494.60(b), a dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. The burden associated with this requirement is the time and effort necessary to develop, implement, and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.60(d) contains the standard for emergency preparedness. Specifically, § 494.60(d)(1) states that a facility must provide appropriate training and orientation in emergency preparedness to the staff as specified in this section. Staff training must be provided and evaluated at least annually. Section § 494.60(d)(2) states that a facility must provide appropriate training and orientation in emergency preparedness to patients as specified in this section. The burden associated with this requirement is the time and effort necessary to provide emergency preparedness training and orientation to the staff and patients. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.60(d)(4)(i)–(iii) lists the facility requirements for emergency plans. Section 494.60(d)(4)(i) states that a facility must have a plan to obtain emergency medical system assistance when needed. Section 494.60(d)(4)(ii) requires a facility to, at least annually, evaluate the effectiveness of emergency and disaster plans and update them as necessary. Section 494.60(d)(4)(iii) states that a facility must contact its local disaster management agency at least annually to ensure that such agency is aware of the dialysis facility's needs in the event of an emergency. The burden associated with the requirements in § 494.60(d) is the time and effort necessary to develop, maintain, and annually evaluate emergency and disaster plans. In addition, there is also burden associated with contacting its local disaster management agency on an annual basis. We estimate that it will take each of the 238 new facilities 5 hours to comply with the requirements in this section. We estimate that it will take 1 hour each for 5,415 existing facilities (estimated number of existing facilities per year, over five years, assuming 4.4 percent growth) to annually comply with the

requirements in this section. The total estimated annual burden for new and existing facilities is 6,605 hours.

G. ICRs Regarding Patients' Rights (§ 494.70)

Section 494.70 states that a dialysis facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment. In addition, the dialysis facility must prominently display a copy of the patients' rights in the facility, including the current State agency and ESRD Network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

We estimate that it will take 5,415 facilities (estimated number of existing facilities per year, over five years, assuming 4.4 percent growth) 1.5 hours each on an annual basis to update their patient rights materials to comply with this requirement. While this requirement is subject to the PRA, the burden is currently is approved under OMB control number 0938–0386 with an expiration date of March 31, 2010.

H. ICRs Regarding Patient Assessment (§ 494.80)

Section 494.80 states that a facility's interdisciplinary team is responsible for providing each patient with an individualized and comprehensive patient assessment of his or her needs. Sections 494.80(a) through 494.80(d) discuss the standards for the components of the patient assessment. In addition to meeting the aforementioned standards, the comprehensive patient assessment must be documented and maintained in the patient's medical record.

The burden associated with the requirements in § 494.80 is the time and effort necessary for the interdisciplinary team to develop and implement an individual assessment for each patient and maintaining the assessment in the patient's medical record. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

I. ICRs Regarding Patient Plan of Care (§ 494.90)

Section 494.90(a) states that a facility's interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that meets the all of the requirements of § 494.90. The burden associated with this requirement is approved under OMB #0938–0386, with an expiration date of March 31, 2010.

J. ICRs Regarding Care at Home (§ 494.100)

Section 494.100 details the conditions for care at home. Specifically, a facility's interdisciplinary team must provide training to the home dialysis patient, the designated caregiver, or the self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10 of this part) and when the home dialysis caregiver or home dialysis mortality changes. Section 494.100(a) outlines the standards for training. As a requirement of the standards for home dialysis monitoring discussed in § 494.100(b), the dialysis facility must document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training. In addition, the facility must retrieve and review complete self monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months and maintain this information in the patient's medical record. While these requirements are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA. In addition, facilities are required to meet these requirements as stated under Federal, State, and local laws and thereby exempt under 5 CFR 1320.3(b)(3).

Section 494.100(c) contains the standards for support services. As required by § 494.100(c)(1)(i), a facility must periodically monitor the patient's home adaptation. Section 494.100(c)(1)(ii) requires a member of the facilities interdisciplinary team to coordinate the home patient's care. Section 494.100(c)(1)(iii) requires a facility to develop and periodically review each patient's plan of care. Section 494.100(c)(1)(v) requires that the facility must monitor the quality of water and dialysate used by home hemodialysis patients. The monitoring must include onsite evaluations and tests of the water and dialysate system. We estimate that facilities would have to meet these requirements for 24,657 care at home patients, and that it would take them approximately 6 hours per patient, per year. We estimate a total annual burden of 147,942 hours.

Section 494.100(c)(2) states that the dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. The burden associated with this requirement is the time and effort necessary to develop a recordkeeping system and to maintain the records to ensure continuity of care and patient privacy. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

K. ICRs Regarding Quality Assessment and Performance Improvement (§ 494.110)

Section 494.110 discusses the conditions for quality assessment and performance improvement. The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program that reflects the complexity of the dialysis facility's organization and services. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

Specifically, as part of the program scope in § 494.110(a)(2), a dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. The standard for monitoring performance improvement, § 494.110(b), states that a facility must continuously monitor its performance, take actions that result in performance improvement, and track performance to ensure improvements are sustained over time.

The burden associated with all of the requirements of this section is the time and effort necessary to develop, implement, maintain, evaluate, and demonstrate evidence of a quality assessment and performance improvement program. We believe that an overwhelming majority of dialysis facilities already have established and sustained QAPI programs. We estimate that only 10 percent of dialysis facilities need to develop and implement QAPI programs. It would take 517 facilities (10 percent of the estimated number of existing facilities in 2009 of 5,173, assuming 4.4 percent annual growth) each approximately 48 hours to meet these requirements. The one-time burden associated with this requirement is estimated to be 20,016 hours.

Additionally, all facilities would be subject to an annual burden to maintain, evaluate, and demonstrate evidence of a quality assessment and performance

improvement program. The facility must analyze and document the incidence of infection and identify trends and establish baseline information on infection incidence; and develop recommendations and an action plan to minimize infection transmission, promote immunization, and take actions to reduce future incidents. The burden associated with this requirement is the time and effort it would take for a facility to document the incidence of infection and develop recommendations and an action plan to reduce future incidents. We estimate it would take 5,415 facilities 12 hours annually each to meet this requirement, for a total annual burden of 64,980 hours.

L. ICRs Regarding Special Purpose Renal Dialysis Facilities (§ 494.120)

As required by § 494.120(d), a facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the plan of care (described in § 494.90 of this part). The burden associated with this requirement is the time and effort necessary to contact the patient's physician to discuss the patient's current condition and to ensure that the care provided by the special purpose renal dialysis facility is consistent with the patient plan of care. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.120(e) requires that a facility document all patient care provided in the special purpose facility and forward the documentation to the patient's dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility. The burden associated with this requirement is the time and effort necessary to document the patient care and to forward the documentation to the patient's dialysis facility. The burden associated with this requirement is approved under OMB #0938–0386, with an expiration date of March 31, 2010.

M. ICRs Regarding Responsibilities of the Medical Director (§ 494.150)

In the proposed rule that published February 4, 2005 (70 FR 6184) we discussed the responsibilities of the medical director. However, we erroneously reported that the requirements were previously approved under OMB control number 0938–0086. This section does not impose any burden associated with information collection requirements.

N. ICRs Regarding Medical Records (§ 494.170)

Section 494.170 requires that a dialysis facility maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services, and on all other home dialysis patients whose care is under the supervision of the facility. The burden associated with this requirement is the time and effort necessary to maintain the required documentation in the medical record. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.170(a)(3) requires that a dialysis facility obtain written authorization from the patient or legal representative before releasing information that is not authorized by law. The burden associated with this requirement is the time and effort necessary to draft the authorization form and to obtain the signature of the patient or the patient's legal representative. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.170(c) contains a recordkeeping requirement. Facilities must maintain all patient records on file for 6 years from the date of the patient's discharge, transfer, or death. The burden associated with this requirement is the time and effort necessary to maintain the patient records for 6 years. While the burden associated with this requirement is approved under OMB #0938–0386, this information must be maintained in accordance with other Federal, State, and local laws. We believe this requirement is exempt under 5 CFR 1320.3(b)(3); the burden would exist in the absence of the Federal requirement contained in this regulation.

Section 494.170(d) states that when a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer. The burden associated with this requirement is the time and effort necessary to disclose all requested medical record information to the receiving facility. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

O. ICRs Regarding Governance (§ 494.180)

Section 494.180(e) discusses the standard for a facility's internal grievance process. This section requires that the facility's internal grievance process be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. In addition, § 494.180(e)(1)–(3) details the required contents of the process. The burden associated with this requirement is the time and effort necessary to develop and implement the internal grievance process. There is also burden associated with making patients aware of the process. We believe that all existing facilities already have internal grievance processes, as they are already required in conjunction with participation in ESRD Network activities. We acknowledge that there may be a very small number of facilities that do not have grievance processes in place, so we estimate that it would take 2 facilities 1.5 hours each to develop grievance processes and inform patients about them. Therefore, we estimate a total one time burden of 3 hours.

As required by § 494.180(f)(4), the interdisciplinary team must document the patient reassessments, ongoing problem(s), and efforts made to resolve the problem(s) and enter the information into the patient's medical record. In addition, the facility must notify the patient with a 30-day written notice of planned involuntary discharge, and also notify the ESRD Network that services the area and the State agency of the discharge.

The burden associated with this requirement is the time and effort necessary to document the reassessments in the medical records and the time and effort necessary to notify the patient and ESRD Network 30 days prior to the involuntary discharge and the State agency at the time of involuntary discharge. We estimate it would take 10 minutes per incident to record the documentation and provide such notification.

While this requirement is subject to the PRA, we have no way to accurately quantify the number of affected individuals. Our best estimate is that each facility would have less than one patient involuntarily discharged on a yearly basis. We estimate that the total annual burden for 5,415 facilities would be 903 hours.

The interdisciplinary team must obtain a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's

discharge or transfer from the facility. They must also document any attempts to place the patient in another facility and notify the State survey agency of the involuntary transfer or discharge.

The burden associated with this requirement is approved under OMB #0938–0386, with an expiration date of March 31, 2010. However, the requirement for the second signature from the medical director is new. We estimate that it would take 5 minutes for the medical director to sign the discharge order. While this requirement is subject to the PRA, we have no way to accurately quantify the burden. Our best estimate is that each facility would have less than one patient involuntarily discharged on a yearly basis. We estimate that the total annual additional burden for 5,415 facilities would be 451 hours.

Section 494.180(g) discusses the standard for emergency coverage. As required by § 494.180(g)(2), the dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached. We estimate that it would take 5,415 facilities 10 minutes each to develop such a roster. We estimate that the total one-time burden would be 903 hours.

Section 494.180(g)(3) contains the requirement that a dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis, and other hospital services, and emergency medical care that is available 24 hours a day, 7 days a week. The burden associated with this requirement is the time and effort necessary for the dialysis facility to draft the agreement and to finalize the agreement with hospital. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.180(h) states that a dialysis facility must furnish data and information electronically to CMS at intervals specified by the Secretary, which meet the requirements referenced in this section. The information collection activities discussed in this section are approved under the following OMB control numbers:

OMB control No.	Collection title	Expiration date
0938–0046	End-Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration	09/30/2010
0938–0386	Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services & Suppt Regs. at 42 CFR 405.2100–.2171.	03/31/2010
0938–0657	End State Renal Disease Network Semi-annual Cost Report Forms	12/31/2009
0938–0658	ESRD Network Business Proposal Forms	02/28/2010

These requirements are subject to the PRA, and are currently approved under the following OMB approval numbers: 0938–0046, 0938–0360, 0938–0386, 0938–0657, and 0938–0658.

Section 494.180(j) contains the standard for disclosure of ownership. In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency. The burden associated with this requirement is the time and effort necessary to disclose ownership interests to CMS. This requirement is subject to the PRA; the burden is currently approved under OMB control number 0938–0086 with an expiration date of December 31, 2008.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 414.330	0938–New	24,657	24,657	1.5	36,986
§ 488.60(a)(1–4)	0938–New	238	238	40	9520
§ 494.30(a)(1)(ii)	0938–New	214	214	1	214
§ 494.30(b)(1)	0938–0386				
§ 494.30(b)(1(ii)(c)	0938–New	54	54	.05	4.5
§ 494.40(c)	0938–New	54	54	.50	27
§ 494.60(b)	0938–0386				
§ 494.60(d)(2)	0938–0386				
§ 494.60(d)(4)(i)–(iii)	0938–New	238/5,415	238/5,415	5/1	6,605
§ 494.70	0938–0386				
§ 494.80	0938–0386				
§ 494.90	0938–0386				
§ 494.100(c)(1)(i)(ii)(iii)(v)	0938–New	24,657	24,657	6	147,942
§ 494.100(c)(2)	0938–0386				
§ 494.110	0938–New	5,415	5,415	12	64,980
§ 494.120	0938–0386				
§ 494.120(e)	0938–0386				
§ 494.170	0938–0386				
§ 494.170(a)(3)	0938–0386				
§ 494.170(c)	0938–0386				
§ 494.170(d)	0938–0386				
§ 494.180(e)(1)–(3)	0938–New	2	2	1.5	3
§ 494.180(f)(4)	0938–New	5,415	5,415	.10	903
§ 494.180(f)(4)(iii)	0938–New	5,415	5,415	.10	451
§ 494.180(g)(3)	0938–0386				
§ 494.180(h)	0938–0046	100,000	100,000	.75	75,000
	0938–0657	18	36	3	108
	0938–0658	18	36	30	1080

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 494.180(j)	0938–0086	125,000	125,000	.5	62,500
Total					336,803

** There are multiple regulation sections approved under this OMB control number. There is uniform burden per response.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. In addition, any burden requirements previously approved under an OMB control number will be re-examined and updated during the next OMB PRA review cycle.

VII. 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 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

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 ($100 million or more in any 1 year).

This rule is a revision of the Medicare conditions for coverage for end-stage renal disease (ESRD) dialysis facilities. The conditions for coverage are the basic health and safety requirements that an ESRD supplier of services must meet in order to receive payment from the Medicare program. This final rule incorporates new scientific advances and current medical practices utilized in treating ESRD while removing numerous burdensome process and procedural requirements contained in the 42 CFR part 405, subpart U conditions for coverage. While it is not possible at this point to determine definitively the additional costs and cost savings to the Medicare program resulting from this rule, we do not believe that the impact will be above the $100 million economically significant threshold; and therefore, believe that this final rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Kidney dialysis centers with revenues at or below $31.5 million are small entities *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf,* see Sector 62). According to 2004 revenue data, nearly 163 dialysis facilities (5.2 percent of all establishments) could be considered to be small entities. This rule will not have a significant economic impact on small entities. This regulation could cost these small facilities an average of $2,392 (about 2.4 percent of $100,000) for upgrades and improvements, and save small facilities up to $5,043 in the first year, resulting in an average net first-year cost savings of up to $2,651. The Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. Since this final rule applies only to dialysis facilities, it has no impact on small rural hospitals. The Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $130 million. This rule has no impact on the expenditures of State, local or tribal governments, and the impact on private sector expenditures is estimated to be less than $130 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on State and local governments.

B. Anticipated Effects

1. Subpart A—General Provisions

Subpart A ''General Provisions,'' addresses the basis and scope (§ 494.1) of this regulation, definitions used in the new conditions for coverage (§ 494.10), as well as compliance with Federal, State, and local laws and regulations (§ 494.20). These provisions do not result in any new economic impact as the definitions do not include any new requirements and facility compliance with laws and regulations is consistent with the existing requirements at § 405.2135. We have removed the requirements found in 42 CFR part 405, subpart U, which specify qualifications that the dialysis facility CEO must have. This change may relieve a degree of burden for small businesses, as a greater number of candidates would qualify for this position, thereby affording facilities greater hiring flexibility. We have also removed the 42 CFR part 405, subpart U, medical record practitioner requirement (§ 405.2102, definition of ''Qualified Personnel'' at (c)). This may provide some burden relief specifically for small businesses. The medical record practitioner cost savings is computed in this impact analysis under the medical record condition for coverage.

2. Subpart B—Patient Safety

a. § 494.30 Infection Control

This final rule requires (at § 494.30(a)) compliance with the CDC ''Recommendations for Preventing

Transmission of Infections Among Chronic Hemodialysis Patients.'' Many of these infection control precautions are standard care practices and do not present any additional burden for dialysis facilities. We did receive a comment regarding the infection control precaution that calls for the use of disposables or dedication to single patient use those items that cannot be cleaned and disinfected. This commenter stated that use of disposable blood pressure cuffs is impractical, as is dedication of blood pressure cuffs for single patient use, and that disposable blood pressure cuff covers are not currently available.

However, according to information available on the Internet, disposable blood pressure cuffs are available (at a cost of approximately $6 each), as are disposable blood pressure cuff covers. A blood pressure cuff sleeve is available for 12 cents. In addition, easy-to-clean, one-piece, nylon latex-free blood pressure cuffs that are universally compatible with all blood pressure monitors, are available for about $7.00. The estimated burden for complying with the CDC infection precautions would be $7.00 per dialysis station with the cost varying depending on the size of the facility. Smaller dialysis facilities would have a smaller burden than large dialysis facilities. Since the CDC ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' were published in 2001, some dialysis facilities have already updated their practices and are adhering to the CDC guidelines regarding dedicated use of non-cleanable items or use of disposables. We estimate that 75 percent of dialysis facilities still need to change their blood pressure cuff use practices to comply with the 2001 CDC infection control precautions. We estimate that in 2008 there will be 70,892 dialysis stations (based on an annual growth rate of 4.4 percent and USRDS data showing 79,567 dialysis stations in 2004) that need to be upgraded with a cleanable reusable blood pressure cuff. The associated first year cost is estimated to be $496,244 ($7.00 × 70,892 stations). The annual cost thereafter is estimated to be $49,624, to account for up to 10 percent of the blood pressure cuffs that may need to be replaced annually due to extreme contamination or damage.

One commenter stated that the CDC precautions regarding separate staff to care for HBV positive and HBV negative/susceptible patients will produce unintended adverse implications for smaller facilities and/or smaller dialysis shifts. This commenter further stated that this requirement may make it cost prohibitive for small facilities (< 9 stations) to admit HBV positive patients. The CDC ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' incorporated by reference in this final rule, state that staff members caring for HBsAG-positive patients should not care for HBV susceptible patients at the same time. This means a staff member could care for HBV protected dialysis patients who have been vaccinated and have developed sufficient antibodies to HBV while caring for an HBsAG-positive patient. The prevalence of HBsAG positivity and incidence of HBV infection in hemodialysis patients was 1.0 and 0.12 percent, respectively, in 2002 and had not changed substantially during the previous 10 years (Finelli, *et al.,* ''National Surveillance of Dialysis-Associated Diseases in the United States, 2002, Seminars in Dialysis—Vol. 18, No. 1 (January–February) 2005, pp. 52–61). We note that the hepatitis B vaccination is now administered universally in the U.S. as part of standard childhood immunizations. Dialysis facilities also offer the HBV vaccination and the number of patients immunized approaches 32 percent in hemodialysis patients age 65 and older (2004 USRDS data). Therefore, the number of dialysis patient acute hepatitis B cases is not expected to be great and the number of HBV immunized patients is expected to grow. We believe that when there is appropriate patient scheduling, the separate staff requirement will present minimal burden to dialysis facilities.

This final rule calls for adherence to the pertinent sections of the Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines for catheter-related infection prevention at § 494.30(a)(2). We heard from nephrology nurses in their comments that their organization ''has recognized the 'Guideline for Preventing Intravascular Device-Related Infections' as the appropriate standard of care. We encourage CMS to do likewise in the Final Rule.'' We believe that these HICPAC catheter infection prevention guidelines are the professional nursing standard of practice and no additional burden is imposed by this requirement.

We are requiring at § 494.30(a) that new dialysis facilities have an isolation room unless a waiver is requested and approved by the Secretary. Section 494.30(a)(1)(ii) states that when dialysis isolation rooms are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of the isolation room requirement, subject to the approval of the Secretary. According to CDC data, the 2004 reported U.S. rate of viral hepatitis B cases was 2.1 per 100,000 population, and has decreased almost every year since a high of 11.5 per 100,000 in 1985 (*http://www.cdc.gov/hepatitis*). The prevalence of HBsAG positivity and incidence of HBV infection in hemodialysis patients was 1.0 and 0.12 percent respectively in 2002 and had not changed substantially during the previous 10 years (Finelli, *et al.,* ''National Surveillance of Dialysis-Associated Diseases in the United States, 2002, Seminars in Dialysis—Vol. 18, No. 1 (January–February) 2005, pp. 52–61). As stated earlier, the hepatitis B vaccination is now administered universally as part of standard childhood immunizations in the U.S. Therefore, the number of dialysis patient acute hepatitis B cases is expected to be small, and we believe that a large number of new dialysis facilities will request an isolation room waiver. We also believe that this process allows for variation in geographic isolation room needs that may present as the local population changes. We expect that the development and submission of this waiver will require the involvement of the facility administrator. This individual will need to determine the number of dialysis isolation rooms available in the facility's geographic area that could sufficiently serve its patients, prepare the waiver request, and submit the request to us. We believe that these tasks will require about 1 hour and should cost about $54.81 (*http://www.swz.salary.com*).

As of the spring of 2007, there were 4,746 Medicare approved dialysis facilities (DFC data: *http://www.medicare.gov/Download/DownloadDB.asp*). From 1998 to 2004, the average yearly growth (using USRDS data) in dialysis facilities was 4.4 percent. We anticipate a similar rate of growth in dialysis facilities over the next few years. Thus, we believe that 218 new dialysis facilities will request Medicare approval in 2009 and that over the five-year period from 2009 to 2013 a total of 1,191 new dialysis facilities will request Medicare approval. Since we are requiring compliance with this isolation room requirement 300 days after publication of this final rule, we are using 2009 estimates of the numbers for new and renovated dialysis facilities.

COST OF ISOLATION ROOM WAIVER REQUESTS

Year	New dialysis facilities (4.4% annual increase)	Ninety percent of new dialysis facilities	Estimated total cost for waiver requests ($54.81 × waiver requests from 90% of new facilities)
2009	218	196	$10,743
2010	228	205	11,236
2011	238	214	11,729
2012	248	223	12,223
2013	259	233	12,771
Total	1,191	1,071	[1] 58,702

[1] 5-year cost.

We believe that approximately 90 percent of the new dialysis facilities will request a waiver of the isolation room requirement. Thus, the estimated first year cost of complying with this waiver requirement is $10,743, and the estimated total five-year implementation cost for this requirement is $58,702.

Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary. We do not have data that shows the current percentage of dialysis providers that open new dialysis facilities with isolation rooms under the 42 CFR part 405, subpart U, requirements, nor do we currently have data that show whether there is a shortage of isolation rooms in some areas. The CMS regional offices will monitor and evaluate local dialysis isolation room needs. Since existing facilities may use a separate area, rather than an isolation room, it is likely that some HBsAg-positive patients dialyze in units without isolation rooms. Commenters shared concerns about the costs involved in converting existing dialysis facilities to include an isolation room. Some commenters questioned the need for an expense of an isolation room in all new dialysis units as specified in the CDC infection control precautions incorporated by reference. We have responded to isolation room comments by requiring existing facilities only to have a separate demarcated area, consistent with CDC recommendations, and allowing new dialysis facilities to request an isolation room waiver.

We believe the infection control provisions at § 494.30(a)(3) and (4) are consistent with the requirements at § 405.2140(c) and do not produce additional burden. In addition, we have moved some of the infection control requirements to the QAPI provisions at § 494.110(a)(ix). We have also removed the requirement at proposed § 494.30(b)(2) regarding the designation of an RN to act as an infection control officer. Several commenters stated that this proposed requirement would be unnecessarily burdensome. One commenter stated a burden of $67,000 in compensation for an additional full-time RN. We have modified the oversight requirements and removed the RN infection control officer provision; therefore, no additional burden is imposed. Infection control issues must be reported to the facility medical director and the quality improvement committee. We believe that it is standard practice to track incidents and identify problems related to infection control and that this requirement will not produce any additional burden. Dialysis facilities must also report incidences of communicable diseases as required by Federal, State, and local regulations. We expect that facilities are already compliant with communicable disease reporting requirements and that this provision does not represent any additional burden.

b. § 494.40 Water Quality

The water quality condition for coverage requires compliance with the ANSI/AAMI RD:52:2004 ''Dialysate for hemodialysis.'' These guidelines developed for dialysis facilities are the professional standard of practice and have been available for about 3 years. A facility's water treatment equipment, equipment maintenance and monitoring processes, and water testing procedures need to be consistent with the RD52 guidelines to provide sufficiently pure dialysate. We believe dialysis facilities strive to deliver dialysate for use in hemodialysis and in the reuse process that meets the AAMI water purity guidelines. The American Nephrology Nurses Association stated that they believe most facilities in the U.S. have already implemented a two carbon tank water treatment system with a minimum of 10 minutes empty bed contact time to prevent the exposure of patents to chloramines. We received several comments regarding the burden associated with the proposed frequency of chlorine/chloramine testing. We have modified the proposed water quality requirements and the frequency of chlorine/chloramines testing and require compliance with the AAMI RD:52 guidelines in this final rule. Since we believe that the vast majority of dialysis facilities adhere to the AAMI RD52 guidelines, this requirement would result in little additional burden.

c. § 494.50 Reuse of Hemodialyzers and Bloodlines

The Reuse of hemodialyzers condition for coverage requires compliance with the AAMI guidelines published in ''Reuse of Hemodialyzers'', third edition, ANSI/AAMI RD47:2002/A1:2003, which is incorporated by reference. These 2003 guidelines update RD47, second edition, published in 1993, which is incorporated by reference in 42 CFR part 405, subpart U. The majority of dialysis facilities choosing to perform hemodialyzer reuse likely have already updated their procedures and practices to conform to the current professional standard of practice in the area of reuse.

At § 494.50(c)(2) we require that blood and dialysate cultures and endotoxin levels be obtained when clinically indicated, while the former requirement at § 405.2150(a)(3) requires ''appropriate blood cultures'' and system evaluation. The dialysate cultures and endotoxin levels to be obtained when an adverse patient reaction to reuse is suspected may present a small additional burden to facilities. A colony count (culture) costs approximately $6, while the LAL endotoxin test costs about $10 to $35 per test, depending on the method utilized. We expect that since dialysis facilities must adhere to the new AAMI RD47 guidelines, adverse reactions related to hemodialyzer reuse occur infrequently and the cost burden is small. The remaining provisions of

§ 494.50 primarily provide clarifications that do not add burden. We did not receive any comments related to burden imposed by this condition for coverage.

d. § 494.60 Physical Environment

The ''Building'' and ''Equipment maintenance'' standards at § 494.60(a) and (b) contain requirements similar to some of the provisions at § 405.2140(a), and we believe do not impose any additional burden. Standard (c) ''Patient care environment'' is consistent with requirements at § 405.2140(b)(2). The provision regarding a comfortable room temperature closely resembles § 405.2140(b)(2). However, the requirement to ''make reasonable accommodations for the patients who are not comfortable at this temperature'' is new. Facilities could meet this requirement by providing blankets to patients as many other healthcare providers do, which could entail added burden, or the facility could simply allow patients to bring a clean blanket or cover to the dialysis facility. Although a facility would be required to adhere to infection control precautions if a patient's blanket became soiled during the dialysis session, we do not believe this second option would add any significant burden for the dialysis facility.

We are requiring, similar to § 405.2140(b)(2), that the dialysis facility make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required. We believe that the vast majority of dialysis facilities are equipped with the movable privacy screens, partitions, or curtains that would be needed in order to meet this requirement.

Emergency preparedness requirements are found at § 494.60(d) in this final rule and correspond with the provisions at § 405.2140(d). The existing 42 CFR part 405, subpart U regulations require dialysis facilities to have written policies and procedures for handling emergencies with annual reviews, testing, and revisions, and staff training to handle any emergency or disaster. This final rule requires that the staff be able to demonstrate the ability to manage emergencies that are likely to occur in the facility's geographic area. Although an annual review will be required, the final rule does not require the involvement of the CEO in this activity. We estimate that a typical facility will expend 4 hours less of administrator's time for this activity at $51.93 per hour (*http://www.swz.salary.com*), with a net savings of $207.72 per year per facility for an overall savings for 4955 facilities of $1,029,253.

We added a clarification to the 42 CFR part 405, subpart U requirement that the staff inform patients of where to go during an emergency. Thus, this final rule requires that these instructions include direction for when the geographic area of the dialysis facility is evacuated. Some dialysis facilities may already include this level of detail in their emergency preparedness instructional materials; however, we expect that many facilities do not include this information. Adding these instructions to the patient educational materials may present a small burden for some dialysis facilities. A staff member would need to develop the instructions and materials. We estimate that it would take 2 to 3 hours to develop the instructions and material needed. Assuming that 90 percent of the dialysis facilities need to add this patient training to their program, we estimate a first year cost (using $39.14 per hour compensation (*http://www.swz.salary.com*) for a RN staff nurse) of $523,634 (4955 × 0.90 × $117.42).

The final rule also adds a requirement to the 42 CFR part 405, subpart U provision that the dialysis staff must instruct the patients about who to contact during an emergency, so that when the dialysis facility is not operational, there is an alternate emergency telephone number (unless the facility has the ability to forward calls to another working phone number). Some facilities already may have a second emergency phone number or call forwarding for their patients to use in an emergency. Many phone service packages include call forwarding as a feature. In addition, some facilities may have obtained call forwarding or a second telephone line following the 2005 hurricane season in the south. Nevertheless, we believe many facilities may need to establish a communication system that would meet the intent of this rule, by for example, obtaining call forwarding service or an alternate number. Utilizing business phone services pricing figures available on the Internet, we estimate a monthly fee of $6.00 for remote access call forwarding services added onto a business phone service package. Alternately, we estimate the cost of an additional separate business phone number at less than $50 per month. If 25 percent of all dialysis facilities need to set up new remote call forwarding and another 25 percent initiate a new separate emergency phone number, we estimate the cost of this requirement to be approximately $69,384 (1239 × $6, plus 1239 × $50).

This final rule requires at § 494.60(d)(1)(ii) that dialysis facility patient care staff maintain current cardiopulmonary resuscitation (CPR) certification. We believe that CPR training is provided for direct patient care staff in dialysis facilities in the U.S. and some units also offer CPR training and certification to staff that do not care directly for patients. One commenter stated that while many providers may certify patient care staff in CPR annually or every 2 years, there are also many who conduct CPR training without the expense of actual certification. The commenter further stated that CPR certification is too onerous and costly ($67,600 per dialysis facility to cover the cost of one full-time RN) as it may require a CPR instructor on staff. The commenter also stated that there is an American Heart Association (AHA) fee of $25 per person for certification. A search on the Internet reveals that AHA-certified CPR classes for healthcare professionals cost an average of $25 per person with group discounts available. The cost for the class members to become certified CPR instructors averages about $200 with a certification period of up to 2 years. We did not find a $25 AHA CPR certification fee that is separate from the class fees that are charged. Thus, if a dialysis facility chose to have a staff RN certified as an instructor, it would likely require only two to four half-day group CPR classes per year. We believe that CPR training provided to dialysis facility direct care staff should meet AHA standards and that CPR training with certification is the standard of practice among health care providers. We do not have data on any dialysis facilities that offer CPR training without AHA CPR certification, nor did the commenter provide data. No other commenters stated concerns about CPR certification costs for patient care staff. We believe the vast majority of dialysis facilities provide AHA certified CPR training to protect patient safety and to mitigate liability risk, and we believe that the costs associated with this training and certification are part of the usual and customary costs assumed by healthcare providers.

We are requiring that facilities have available a defibrillator or an automated external defibrillator (AED). Several commenters stated that an AED was more desirable and less burdensome than a traditional non-automated defibrillator, because the staff training and certification costs are much lower when an AED is used. Some commenters stated that use of non-automated defibrillators require staff to

be certified in Advanced Cardiac Life Support (ACLS) and that ACLS courses are not readily available to dialysis facilities, and are time consuming and costly. Commenters pointed out that AED training can be accomplished along with the usual CPR staff training. We have responded to commenters who were concerned about the burdensome costs of ACLS certification and training costs associated with the use of non-automated defibrillators by including AEDs as an acceptable alternative device in this final rule.

We are also requiring that certain emergency equipment be immediately available in the facility including oxygen, airways, suction, defibrillator or AED. The comparable 42 CFR part 405, subpart U requirement (§ 405.2140(d)(3)) is less specific and calls for an on-the-premises emergency tray, including emergency drugs, medical supplies, and equipment. We received comment that all 190 of the dialysis facilities owned by Dialysis Clinic, Inc. (DCI), a non-profit dialysis organization, are equipped with AEDs. Comments from Gambro noted that more than a third of their facilities are equipped with AEDs. According to USRDS data, in 2004 there were 585 Gambro dialysis facilities (34 percent equals 198 facilities equipped with AEDs). If we use 34 percent as our AED equipped estimate for the remaining dialysis facilities (1118 Fresenius, 626 DaVita, 417 Renal Care Group, 27 National Nephrology Associates, 934 independent—using 2004 USRDS data) the total number of dialysis facilities equipped with AEDs would be 1061. We presume that the 837 hospital based dialysis facilities (2004 USRDS data) already may have met the requirement, since they likely have immediate access to an in-hospital defibrillator. Based on the above figures we would expect that 2,286 dialysis facilities already are equipped with AEDs or defibrillators (DCI—190, Gambro—198, hospital-based—837, and 34 percent of all others—1061). We estimate that the remaining 2,669 dialysis facilities would need to purchase an AED or traditional defibrillator to comply with this final rule.

Commenters suggest that the cost of an AED is approximately $2,500. Our research shows that the sales price of an AED ranges from $900 to $2,600. Using a $2,000 price, we estimate that it will cost $5,338,000 for 2,669 dialysis facilities to purchase AEDs. One commenter stated that we should recognize the costs of maintaining an AED. The American Heart Association Web site suggests that, in general, AEDs require fairly low upkeep, but regular maintenance will ensure their readiness in the event of an emergency. AED maintenance includes preventive maintenance checks according to the manufacturer's recommendations and verifying battery installation and expiration, checking the status/service indicator light, inspecting exterior components and sockets for cracks or other damage, and checking AED related supplies (*http://www.americanheart.org/downloadable/heart/110262192170770-2272%20ImplementGuide.pdf*). We believe these visual checks will take about 5 minutes and can be done by a biomedical or patient care technician. Using an hourly compensation rate of $20.45 (*http://www.swz.salary.com*), this 5 minute task will cost $1.70 each month, times 12 months to equal $20.45 annually. If we multiply $20.45 times the 2,669 facilities that will need to purchase AEDs, the cost will be $54,581 per year.

Two commenters stated that suction machines are costly to maintain and are seldom used. However, suction machines are necessary emergency medical devices that are used to clear the airway of secretions or vomit. To comply with 42 CFR part 405, subpart U, the huge majority of dialysis facilities are equipped with suction machines and have the tubing and suction catheter available in the packaging available for use.

This final rule requires the facility to have a plan to obtain emergency medical system assistance when needed and to evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary, consistent with § 405.2140(d) requirements. A new provision calls for the facility to contact the local disaster management official at least annually to ensure that the agency is aware of dialysis facility needs in the event of an emergency. We believe this task will require one hour of time from either the administrator or the nurse manager. If we estimate the total compensation (wages plus benefits) for each as $54.81 and $51.93 respectively (*http://www.swz.salary.com*), and average them, we arrive at a cost of $53.37 per hour. Since there would be 4,955 dialysis facilities that need to comply, we estimate the burden associated with this requirement to be $264,448 during the first year.

This final rule requires that the facility meet the 2000 edition of Life Safety Code (LSC) requirements of the National Fire Protection Association. Most dialysis facilities currently meet most of the provisions required in Chapter 21 of the LSC, ''Existing Ambulatory Health Care Occupancies,'' because of state and local building codes as well as facilities' interest in liability mitigation. Commenters were most concerned about the cost of retrofitting sprinkler systems in existing dialysis facilities and the implications for facilities housed in a multi-tenant building. Commenters were also concerned with the effort and expense incurred in submitting a request for a LSC sprinkler waiver to the Secretary. In response to comments, we are defining compliance with the 2000 LSC to include ''grandfathering'' existing facilities without sprinkler systems that would have needed to comply with the LSC sprinkler provision or request a waiver. New dialysis facilities or facilities undergoing extensive renovation would need to install a sprinkler system, depending on the type of construction materials and facility location within the building. An example of a dialysis facility that would likely require a sprinkler system would be one housed in a wooden construction three-story building, or in a high rise building. High rise buildings are generally built with sprinkler systems to satisfy State and local regulations. We estimate that few newly constructed dialysis facilities would be burdened by the 2000 LSC sprinkler requirements in this final rule because current local and state fire safety building requirements must be met. However, there may be some burden for existing facilities with regard to the installation and maintenance of the fire department alarm connection. Based on information we received from the dialysis industry, we estimate that approximately 10 percent of dialysis facilities (496) will need to be upgraded to meet this requirement. In the proposed rule we estimated that the one-time cost to install a fire department or central monitoring station connection was $1,000 per facility and that the monthly fee for the monitoring station and telephone cost was about $80. We received a comment that the installation cost of an automated notification system in the Orlando, Florida area would exceed $3,000 and the monthly monitoring costs would be approximately $186 per month. The commenter stated that the CMS calculation was too low because it did not include the required back-up phone line, which would itself cost about $106 per month. Another commenter stated that the monthly monitoring cost would be about $180. Another provider informed us that the monthly monitoring cost was about $30 and the cost of installing a monitoring and

automatic notification system ranges from $10,000 to $25,000 depending on the building characteristics. We will use $136 as our estimated monthly cost of automatic notification system monitoring ($106 phone line fee plus $30 monitoring fee), and $5,000 as our estimated installation cost. Thus, we estimate the additional overall cost of compliance for 496 facilities that would need to perform upgrades in the first year will be $3,289,472 ($2,480,000 installation cost plus $809,472 monitoring costs), with the annual cost thereafter being $809,472 ($136 per month × 12 months × 496 facilities).

This estimate does not take into account any specific waivers or acceptance of a State code in lieu of the LSC that may decrease the burden. Some commenters were concerned about the cost of installing smoke barriers in buildings that are over 5000 square feet, which could be a significant cost because air ducts for heating and air conditioning would have to be updated with smoke partitions. If the health and safety of patients and staff are not adversely affected, this final rule would permit us to waive specific provisions of the LSC, which, if rigidly applied, would result in an unreasonable hardship on the facility. In addition, the proposed rule specifies that the Secretary may accept a State code in lieu of the LSC, if it adequately protects patients. We cannot estimate how many dialysis facilities will request a LSC waiver as many facilities already meet the 2000 LSC due to State and local regulations and liability mitigation efforts. Additionally, facilities would only consider applying for a waiver after a LSC inspection found that LSC provisions were not adequately implemented.

e. § 494.70 Patients' Rights

The 42 CFR part 405, subpart U regulations require dialysis facilities to have written patients' rights policies and procedures and sets out a list of persons to whom such patient rights policies must be made available. This final rule details basic information that must be provided to patients (to include for example, information regarding advance directives, how to contact entities in regard to complaints, and dialysis modalities not offered by the facility including scheduling options for working patients) and requires that patients' rights be prominently displayed. Some commenters stated that their facilities have already developed advance directive procedures that would help the facilities comply to the provision as stated in the proposed rule. One commenter recognized that many facilities are already informing patients of their right to have advance directives. Requiring minimum contents in the patients' rights condition, and requiring only that these rights be posted, will limit the administrative burden. We estimate that this will save the typical facility about 2 hours of staff (social worker) time at $34.52 per hour (*http://www.swz.salary.com*), that is, $69.04 annually, for an overall savings of $342,093 (4,955 facilities times $69.04).

The 42 CFR part 405, subpart U regulations required the facility to use translators when a significant number of patients exhibit language barriers. This final rule modifies this requirement and specifies that information be given to patients in a manner that assures their understanding. However, translators could still be used and facilities will have more flexibility in overcoming language barriers in lieu of hiring translators. This may result in a net reduction in facility costs.

The previous regulations required that advance notice be given to patients who are being terminated from a dialysis facility. This final rule is more specific and requires that written notice be given 30 days in advance. However, since involuntary terminations are a relatively infrequent occurrence and we are only adding a requirement regarding when the advance notice of involuntary discharge must be given, we consider the financial impact on dialysis facilities to be negligible.

We expect that each facility must update their patient rights materials to meet the requirements of this final rule. If this task required 1 hour of social worker time at $34.52 per hour compensation, this provision would cost $171,047 (4,955 facilities times $34.52).

f. § 494.80 Patient Assessment

The ''Patient assessment'' condition for coverage includes assessment criteria that must be included in each comprehensive patient assessment. The frequency of assessment is identified as initial, 3 months after the initial assessment, and annually for stable patients and monthly for patients who are not stable. The adequacy of the patient's dialysis prescription must be assessed at least monthly for dialysis patients and every four months for peritoneal patients. Commenters agreed that quality oriented dialysis facilities meet these new requirements already and that the patient assessment condition for coverage should not present any new burden to most dialysis facilities.

g. § 494.90 Patient Plan of Care

The ''Patient plan of care'' condition for coverage requires that the facility write and implement a plan of care after performing the comprehensive assessment. The facility must address eight clinical areas in the plan of care, utilizing standards that are consistent with accepted professional standards of practice. In this final rule, we have included a ''psychosocial status'' care plan component that requires that professional social work services be provided and that a standardized mental and physical assessment tool be utilized. The 42 CFR part 405, subpart U requirements were similar and included a provision requiring that the qualified social worker be responsible for conducting psychosocial evaluation, and that the social services provided maximize the social functioning and adjustment of the patient (§ 405.2163(c)). We do not believe that this final rule requirement adds new burden.

Title 42 CFR part 405, subpart U provisions call for an initial short term care plan, an initial long term care plan, an updated short term plan of care every 6 months for stable patients or monthly for unstable patients, and an annual review of the long-term care plan. The short term patient care plan is developed by a professional team consisting of at least the ESRD physician, an RN, the social worker, and the dietitian. The annual long-term program must be developed by a team which includes the dialysis facility physician-director, a physician-director of a self-care center, a transplant surgeon, an RN, a social worker, and a dietitian. This final rule removes the requirement for a separate long-term care program and reduces the frequency of formal care planning (after the first six months that a patient is on dialysis) from biannually to annually and reduced the burden of facility staff. We estimate that the burden associated with formal full interdisciplinary team care planning will be lessened by more than 50 percent starting in the seventh month that a stable patient is on dialysis. Assuming the team meets formally to review and update the plan of care and spends at least 15 minutes on each care plan we estimate an annual cost savings of about $57.11 per patient per year for stable patients after the first year of dialysis.

INTERDISCIPLINARY TEAM SHORT TERM CARE PLANNING COSTS UNDER PREVIOUS REGULATION

	Hourly compensation (*swz.salary.com*)	
Staff Registered Nurse	$39.14	
Dietitian	36.74	
Social Worker	34.52	
Attending Physician	118.05	
Total per hour	228.45 per hour	Cost of 15 minutes of team time for 1 care plan for 1 patient = $57.11.

According to the USRDS, in 2004 there were 335,963 dialysis patients. If we add a 3 percent annual growth rate, our 2008 estimate of patients would be 378,129. We will assume that about 90 percent of dialysis patients are stable (378,129 × 0.90 = 340,316 stable patients). If we multiply the cost savings of $57.11 times the estimated number of stable point prevalent dialysis patients we find an annual costs savings estimate of $19,435,447. If we divide this total savings by the number of dialysis facilities (4,955) we see an average cost savings of $3,922 for each dialysis facility annually. There are further savings not shown here associated with the new patient plan of care requirements because the self-care dialysis physician-director, medical director, and the transplant surgeon do not need to participate in routine long-term care planning, as was previously required. One commenter stated that this change ''will be beneficial to transform the current paper shuffling process into a practical course of action.'' Another commenter stated that deletion of care plan review by the transplant surgeon is a positive change and allows more efficiency. This reduction in burden may be particularly helpful for small businesses, as process is reduced as well as the amount of staff time required for care planning, allowing more time for direct patient care.

This final rule includes transplantation referral tracking, at least annual communication with the transplant center, and patient education and training. In response to comments regarding the burden of quarterly communications, we are requiring at least annual communication with the transplant center, rather than quarterly contact as in the proposed rule. We believe that many dialysis facilities do track the status of their transplant referred patients and also provide patient education on a regular basis. We believe these requirements fall within the scope of reasonable services that a dialysis facility should provide and do not represent new burden. We received comment that the new patient assessment and patient plan of care provisions would increase burden because dialysis facilities would need to redesign their standards and procedures, modify their electronic medical record systems, develop processes for implementing these requirements across all facilities, and retrain all employees. We expect that quality oriented dialysis facilities already meet the majority of requirements contained in this final rule. Dialysis facilities must update systems, processes, and staff training on a regular basis as part of their usual business practices, in order to stay current and respond to new technology and new medical information that becomes available. Our goal is to provide a burden analysis of costs that are newly required by this final rule. Facilities may choose to make additional changes to systems, processes, and staff's training that go beyond what is specifically required by this final rule. These additional costs cannot be predicted, and we have not included usual or optional facility activities and their associated costs in this burden analysis.

h. 494.100 Care at Home

Many of the requirements in the ''Care at home'' condition for coverage are consistent with 42 CFR part 405, subpart U requirements and statutory provisions and do not represent new burdens. New requirements in this final rule include the retrieval and review of self-monitoring patient data at least every 2 months and inclusion of services furnished by a durable medical equipment supplier in the record-keeping system. We believe that this task would present a minimal burden to home dialysis facilities.

We received comments that the economic impact of this condition for coverage would be moderate to significant because it requires that self-care training be conducted by a RN, and according to the commenter, facilities would likely have to hire additional personnel. We do not agree with this comment that additional burden is imposed by this final rule. The 42 CFR part 405, subpart U regulations required at § 405.2162(c) that ''if the facility offers self-care training, a qualified nurse is in charge of such training (see § 405.2102).'' Section 405.2102 requires that an RN who is in charge of self-care dialysis training must have at least 3 months of the total required (18 months) ESRD experience in training patients in self-care. This final rule requires at § 494.140(b)(2) that the self-care training nurse be an RN with at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training (15 months experience in total). The requirement at § 494.100 provides that self-care training must be conducted by a registered nurse who meets the requirements of § 494.140(b)(2). In both the previous regulations and this final rule, self-care dialysis training must be ''conducted,'' that is, led, guided, and managed by an RN with the specified dialysis experience.

i. § 494.110 Quality Assessment and Performance Improvement

This final rule requires dialysis facilities to develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program. Facilities will use quality data internally, in a formal Quality Assessment and Performance Improvement (QAPI) program that each facility has the flexibility to develop in accordance with its own priorities. The two-thirds of dialysis facilities that are part of large dialysis organizations are likely already complying with this requirement and many other facilities also use quality data as part of their standard practices. We estimate that the

QAPI requirements would impose a new burden on no more than 10 percent of the dialysis facilities.

Assuming that a facility was initiating a QAPI program only as a result of this final rule, this may entail a one-hour meeting of four staff persons monthly, that is, 48 staff hours of meeting time. Assuming a staff cost of $234.83 per hour (combined costs using hourly compensation figures as follows; nurse manager—$41.58, social worker—$34.52, dietitian—$36.74 and medical director—$121.99 per hour), the total additional cost to the facility would be $2,817.96 annually. The total cost for 496 facilities would be $1,397,708.

j. § 494.120 Special Purpose Renal Dialysis Facilities

We do not believe that this condition for coverage imposes any new burdens.

k. § 494.130 Laboratory Services

We do not believe that this condition for coverage imposes any new burdens.

l. § 494.140 Personnel Qualifications

This condition for coverage delineates the qualifications personnel must have to provide care in a Medicare certified dialysis facility. We do not believe any additional burden is imposed by the qualification provisions for medical directors, nurses, dietitians, or social workers. The final rule patient care technician qualifications include new requirements including a high school diploma or equivalency, completion of a training program, and state certification within 18 months of being hired or within 18 months of the effective date of this final rule.

This final rule adds new technician qualification requirements, including completion of a training program for water treatment system technicians and a written training program for dialysis patient care technicians that addresses operation of kidney dialysis equipment and machines and the provision of patient care. The training programs would be developed or adopted by the facility and must be approved by the medical director and the governing body of the facility. The training program may include written, audiovisual, and computer based instruction. Since the major dialysis organizations all have training programs for their dialysis patient care technicians and water treatment technicians, and the majority of dialysis facilities are affiliated with these chains, a large portion of facilities already meet this requirement. In addition, at least 11 States already have some form of credentialing (training; competency exam; certification) requirements for dialysis patient care technicians. Even facilities that are not affiliated with major dialysis organizations and are in a State where there are no credentialing requirements for dialysis technicians are not likely to be burdened with the requirement to develop a dialysis training program, since they can request medical director and governing body approval to use a packaged curriculum, which has been developed by organizations in the renal field and is currently available to any dialysis facility without cost.

During the comment period, many commenters voiced concerns related to the proposed rule provision that required 3 months of dialysis patient care technician experience following a training program must be under the ''direct supervision of a registered nurse.'' Commenters asserted that this requirement presented a large burden, as RNs do not have time to constantly directly oversee technicians in training and recommended that LPNs and experienced technicians be allowed to assist with directing patient care technician trainees. In response to comments, we revised this requirement in this final rule, so that the patient care technician training program must be under the direction of an RN and constant one-on-one RN supervision is not required (unless mandated by state provisions). This would allow other staff to act as preceptors under the supervision of an RN. State board of practice provisions must be adhered to so that technicians in training as well as experienced technicians function under the auspices of licensed nurses.

Patient care technician certification under a state certification program or a nationally recognized certification program is required in this final rule, in response to commenter concerns of patient safety and increased risks associated with the prevalent and increasing use of uncertified personnel providing clinical patient care. Hemodialysis technicians, who may be uncertified and unlicensed, commonly perform clinical duties, which include dialysis machine setup, clinical observations and assessments of patients, cannulation, and administering local anesthetics, drugs including heparin, and saline solutions (subject to state nursing board of practice provisions). Several states already require certification of dialysis patient care technicians including California, Connecticut, Kentucky, New Mexico, Ohio, Oregon, Virginia, and West Virginia. According to the Nephrology Nursing Certification Commission (NNCC) ''2005–2006 Annual Report Certification: Your Commitment to Quality'' (*www.nncc-exam.org/about/annualReport2007.pdf*) as of December 2005, there were 1,425 Certified Clinical Hemodialysis Technicians (CCHT), while the Board of Nephrology Examiners Nursing and Technology (BONENT) states in a private communication there are 2,445 BONENT certified hemodialysis technicians. We do not have data on the number of National Nephrology Certification Organization (NNCO) certified nephrology technicians. Although there are three different certification exams available nationally, only one, the Certified Clinical Hemodialysis Technician (CCHT) examination, is specifically geared towards entry level dialysis technicians. Eligibility to take the CCHT exam includes a recommended six months (1,000 hours) of experience in nephrology technology, while the other two exams (given by BONENT and NNCO) require 12 months of experience prior to the exam. We would expect that the majority of dialysis patient care technicians seeking certification to meet our requirement would take the CCHT examination offered by the NNCC.

Hemodialysis technicians applying to take the CCHT examination must be high school graduates or have GEDs, successfully complete a training program for hemodialysis patient care technicians that includes both classroom instruction and supervised clinical experience, and meet state experience requirements. Currently, the examination application fee is $125 and the certification maintenance fee is $50 every 2 years. The exam is offered at hosting ANNA chapters and dialysis facilities around the country, as well as in unison with dialysis conferences. A dialysis facility may host an examination when there are at least five participants, and, if there are at least 10 participants, the NNCC exam manager fee of $150 is refunded. We believe that the flexibility of CCHT examination scheduling will alleviate the need for dialysis technicians to travel or incur overnight costs in order to become certified. We are allowing an 18-month time period so that patient care technicians have sufficient time to successfully complete the certification examination. The cost of taking the certification examination and maintaining certification would likely be borne by the technician, just as nurses, dietitians, and social workers frequently bear the costs of professional examination, registration, and licensing fees. Dialysis patient care technicians will need to complete a training program before taking the exam and would likely be employed by a dialysis

center at the time when taking the examination and so would have an income from which to pay the necessary fee. Dialysis facilities have the option of whether to provide a certification fee benefit.

We have retained the proposed requirement that water treatment system technicians complete a training program that has been approved by the medical director and the governing body. This requirement is in keeping with 42 CFR part 405, subpart U requirements (§§ 405.2136(c)(3)(viii), 405.2136(d)(6), 405.2161(b)(2), and 405.2162), which specify governing body and medical director responsibilities related to proper orientation and training of staff, and we do not believe that this training requirement will result in new burdens.

m. § 494.150 Responsibilities of the medical director

We have revised and clarified the responsibilities (found at §§ 405.2161, 405.2136(f), and 405.2137(a)(1)) and accountability of the medical director in this final rule. We do not believe that these requirements add new burdens.

n. § 494.170 Medical Records

In this final rule, essential requirements in regard to retention, preservation, and transfer of medical records are retained. However, the existing regulations are highly prescriptive in not only requiring the designation of a medical records supervisor, but in detailing that person's duties, specifying categories of information to be included in the medical record, requiring written policies and procedures to protect medical records information, and even addressing spatial issues in regard to the maintenance and processing of medical records. This final rule deletes many of these requirements, giving the facility flexibility in deciding how the medical records are to be maintained and what is to be in them, as long as they facilitate positive patient outcomes. This reduces burden on the dialysis facilities. We estimate that this will save the typical facility about 40 hours of a medical records professional's time, at $21.09 per hour (*http://www.swz.salary.com*), that is, $844 annually, for an overall savings of $4,180,038.

o. § 494.180 Governance

This condition for coverage updates § 405.2136, entitled ''Governing body and management'' and deletes several of the process requirements (for example, those under standard (b), ''operational objectives,'' and (d) ''personnel policies and procedures''). We believe the updated standards related to the CEO or administrator, adequate number of qualified and trained staff, medical staff appointments, furnishing services, emergency coverage, and disclosure of ownership do not produce any additional burdens over previous 42 CFR part 405, subpart U requirements. We do note that 42 CFR part 405, subpart U requires the presence of a licensed physician, RN, or LPN when patients are being dialyzed, and our final rule specifies an RN presence. We believe that the majority of dialysis facilities strive to maintain a RN presence in the facility whenever patients are being dialyzed and expect that this modification would produce little additional burden.

Standard (e) of the Governance condition for coverage requires a facility to implement an internal grievance process. The previous requirement at § 405.2138(e) stated that all patients would be encouraged and assisted to understand and exercise their rights, and that grievances and recommended changes in policies and services could be addressed to facility staff, administration, the network organization, etc. We believe that many dialysis facilities have implemented an in-house grievance process; however, it is likely that approximately 15 percent of dialysis facilities may not have processes that would meet our new requirements. We estimate that it would take eight hours for a nurse manager (at $41.58 per hour) to develop and implement an appropriate grievance process at a cost of $333 per facility. The estimated total cost for 15 percent (743) of facilities to meet this requirement is $247,152.

This final rule implements a discharge process that must be used if facilities must discharge patients against their will. We expect that this process would be needed infrequently (less than once per year) and only be used as a last resort.

Furnishing Data and Information for the ESRD Program

This final rule requires that all dialysis facilities furnish data and information electronically and in intervals specified by the Secretary, including cost reports, administrative forms, patient survival data, ESRD Clinical Performance Measures (CPMs) data, and any future standards developed in accordance with a voluntary consensus standards process identified by the Secretary. While submission of data and information is an existing requirement in § 405.2133 and electronic submission of cost report data and information is an existing requirement in § 413.24, the requirement to provide CPM data above the national statistical sample is new. Additionally, the requirement to provide necessary administrative and CPM data in electronic format is a change from the paper-based process that has historically been used to support the ESRD program.

We previously proposed using the VISION application as the electronic medium for the data collection required by the new conditions for coverage (70 FR 6231). VISION was a patient-specific, stand-alone, facility-based information system with software that would reside on facility computers, which presented challenges for updating the software. We agree with commenters that VISION did not represent the best technology for wide-spread collection of data from dialysis organizations. As discussed earlier in this preamble (under section § 494.180(h)), we are now implementing a new web-based application, CROWNWeb, for this purpose. This new approach is superior to the VISION application in that it will increase the efficiency of data collection, improve data quality, provide a more stable and accessible platform for continual improvements in functionality, and complement existing information infrastructures used by many dialysis facilities. We have recalculated the burden and cost savings related to electronic data reporting using CROWNWeb.

The collection and reporting of ESRD CPMs has, to date, been an effort among CMS, the ESRD Networks, dialysis facilities, and other interested stakeholders to assess the care of a representative statistical sample of individuals receiving dialysis, and all pediatric, and Veteran's Administration dialysis patients, in the areas of adequacy of dialysis, anemia management, nutrition (serum albumin), and more recently, vascular access (Centers for Medicare & Medicaid Services. 2006 Annual Report, ESRD Clinical Performance Measures Project, *http://www.cms.hhs.gov/CPMProject*). The ESRD CPMs were developed to implement section 4558(b) of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33). This provision required the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare no later than January 1, 2000.

The collection and reporting of ESRD CPMs has been an effective tool to facilitate ESRD quality improvement, and has allowed us to track overall positive improvements in several intermediate outcomes for individuals

receiving dialysis. We believe an expansion of the CPMs from the statistical sample of about five percent to all individuals with ESRD and receiving dialysis will create minimal additional burden. During the last 3 years, over 70 percent of dialysis facilities have demonstrated an ability to successfully submit data to CMS that could be used to compute all 13 of the existing CPMs for all their patients.[2] Two of the primary reasons provided by the large dialysis organizations for their participating in this activity included:

1. They believed it was less of a burden to electronically submit data for all of their patients than for facility staff to spend 30 minutes to fill out each entire CPM form for the sample of about five percent.

2. They believed more transparency in the ESRD Program would allow favorable quality of care comparisons to other dialysis organizations.

We received a comment that this electronic data submission requirement would produce a burden to dialysis facilities due to the need to perform information technology enhancements for increased data transmission. Two commenters stated that the software necessary to report data and information electronically in the specified format should be made available to all dialysis providers free of charge. Commenters further stated that CMS should also provide funding for travel related to training and financial relief for the abstracting and key-entry of CPM data and internet service provider (ISP) costs. Some commenters recommended that software implementation should not require duplicate data entry into multiple systems. Commenters did not provide data or dollar figures that would assist us in determining the cost of our electronic data reporting requirement.

We believe that because of the streamlining of data submissions with the CROWNWeb application, these new requirements for additional electronic data will actually result in less overall facility burden compared to existing data submissions. We also believe this activity will lead to a substantial long-term return on investment for all stakeholders-patients, facilities, and the public. We have invested the necessary time and resources to develop a stable and accessible platform, CROWNWeb, for the submission of electronic data. CROWNWeb includes two methods for electronically submitting data, a single-user interface (SUI) and electronic data interchange (EDI). With the SUI, users can log-on to CROWNWeb and enter required data through the interface while with EDI, technologically advanced users can submit required data in batches from their own clinical information systems and thus greatly reduce any facility burden necessary to meet these new requirements.

CROWNWeb enables the protection of the privacy, confidentiality, and security of information transmitted electronically. It uses Web-based technology and is available free-of-charge to all facilities with Internet access and has little to no impact on facility computer systems. CROWNWeb meets all applicable security criteria included in the CMS Information Security Acceptable Risk Safeguards (ARS) policy (*http://www.cms.hhs.gov/InformationSecurity/14_standards.asp*), which contains a broad set of CMS security controls based upon National Institute of Standards and Technology (NIST) requirements. Additionally, CROWNWeb does not leave persistent files on a facility's computer because temporary files stored locally during a CROWNWeb session are purged when the user exits CROWNWeb. The only persistent files that will be left on the facility's computer are related to the installation of Adobe Acrobat Reader, which is a free, universal tool that is necessary to view some reports generated by CROWNWeb. Also, CROWNWeb currently requires a Windows XP service pack 2 or greater, and Internet Explorer 6 or greater.

Any potential facility burden related to electronic data reporting falls into three main categories: (1) Technology hardware and enhancements, (2) personnel time and travel for training, and (3) personnel time for submitting the additional data. We believe very few dialysis facilities would have to purchase computer hardware to implement this requirement, possibly no more than 155 (3 percent of total number of facilities projected in 2009; when electronic data submission will be required). Our estimate on the number of facilities required to purchase computer hardware is derived from data revealing that a majority of dialysis facilities currently submit some kind of electronic data to CMS and thus, have the necessary computer hardware to support CROWNWeb. We estimate the cost, with installation to be $1,000. Thus, the total cost for purchasing hardware would be $155,000, and this cost would only apply in the initial year of implementation. We estimate new ISP costs for a minimal broadband connection to be $360 annually ($360 × 155 facilities = $55,800), and this would be an on-going annual cost. Facilities without access to a broadband connection might have an interruption of other services while using CROWNWeb, and they may choose instead to contract with a third party to submit data on their behalf.

Based on feedback we have received from facilities involved in CROWNWeb testing, we do not believe dialysis facilities will need more than the basic training that CMS will provide free-of-charge over the internet in order to use CROWNWeb. CMS will provide geographically representative in-person training sessions that will be available for those facilities who would like to receive their training in-person, but we do not believe this type of training is required in order to use CROWNWeb. Additionally, we expect that ESRD Networks will play a valuable role in educating facilities and that the ESRD Networks as well as our IT contractor will provide technical assistance to facilities. For personnel time, we estimate that each of the 5,173 facilities (the number of facilities projected in 2009, using 4.4 percent annual growth rate) will have at least one person at the level of nurse manager ($41.58) or higher that will take the Web-based training in order for the facility to meet the new requirement. Thus, we estimate the cost of training in the initial year to be at least $430,187 (5,173 users×2 hours×$41.58). Many facilities will also want to train the unit secretary; therefore, we are also adding the training costs of $227,612 for secretaries who are compensated at approximately $22.00 per hour (5,173 facilities×2 hours×$22.00). Therefore, our total training cost estimate is $657,799.

Table 1 shows the estimated 2009 costs of the data submissions from dialysis facilities, utilizing 2006 methods. In 2006 data were submitted to CMS and the ESRD Networks under the following categories: laboratory data, Fistula First vascular access data, CPMs, quarterly patient rosters, network patient activity report (NPAR), the medical evidence form (CMS–2728), and the death notification form (CMS–2746). For each category, the table shows the associated factors for all the 2006 methods of submitting data, which include paper submissions, EDI submissions, and a hybrid combination submission method that includes both EDI and paper. Column A shows the number of dialysis facilities estimated to participate in 2009 data submissions, while column B shows the number of forms submitted for each year. Column C reveals the annual frequency of data submission. Column D shows the estimated number of labor minutes that

[2] These organizations collect data on all 13 CPMs and their advanced information capability is detailed in the 2002 OIG series, ''Clinical Performance Measures for Dialysis Facilities,'' OEI–01–99–00052.

would be required for the submission of a single form. The number of forms; times the annual frequency; times the number of labor minutes, is totaled and converted to hours in column E. Other additional facility data reporting costs, such as mailing costs, are shown in column F. The total dollar figures shown in column G reflect the sum of the hours shown in column E times $22.00 in labor costs; plus the costs shown in column F. The $3,966,601 total at the bottom of table 1 reflects the estimated dialysis facility costs of submitting data to CMS and the ESRD Networks in 2008, using the data submission methods available prior to implementation of this final rule.

TABLE 1.—ESTIMATED 2009 ANNUAL FACILITY DATA BURDEN UNDER EXISTING DATA SUBMISSION METHODS

Project (level of data)	Method	A. Number of facilities	B. Number of forms	C. Data frequency	D. Time to collect/enter data (minus)/ each	E. Total labor time (approximate hours)	F. Other facility costs	G. Total facility costs
Lab Data (patient)	paper	542	41192	annual	25	17163	* $1,512	$379,098
	EDI	3622	275272	annual	0	0	0	0
Fistula First (summary)	paper	1551	1551	monthly	10	3102	0	68,244
	EDI	3622	3622	monthly	0	0	0	0
CPM <5 percent (patient) ‡	paper	1551	3655	annual	30	1828	** 5,099	45,315
	hybrid	3622	8531	annual	15	2133	** 5,927	52,853
NPAR (patient) ‡‡	paper	5173	5173	monthly	30	31038	0	682,836
	EDI	0	0	monthly	0	0	0	0
Quarterly Roster (pt) ‡‡	paper	5173	5173	quarterly	120	41384	0	910,448
	EDI	0	0	quarterly	0	0	0	0
2728 (patient)	paper	5173	111705	once	15	27926	** 623,314	1,237,686
	EDI	0	0	once	0	0	0	0
2746 (patient)	paper	5173	91396	once	10	15233	** 254,995	590,121
	EDI	0	0	once	0	0	0	0
Total								3,966,601

Note: For ease of interpretation and since the number of users is very small, this table does not include any consideration of facility-use of CROWNWeb's predecessor software, VISION.
EDI: Electronic Data Interchange.
B: For patient-level data, assumes the average facility size of 76 patients.
E: Total Time (hours) = B * C * D ÷ 60.
F: Includes mailing costs but not long-distance fax charges or paper/printing costs. Note: certified mailing is in the process of being required for all communications involving personal health information.
G: Total Costs ($) = E * ($22 dollars per hour wage for medical secretary) + F.
* Assumes first class certified mailing of $2.79 for every facility.
** Assumes first class certified mailing of $2.79 for each patient and for the 2728, a second mailing to the Social Security Administration (SSA).
‡ CPM sample has been stable at about 12,000 each year.
‡‡ With the Network Patient Activity Report (NPAR), facilities notify networks of incremental changes whereas with the Quarterly roster, facilities verify all patients.

We recreated Table 1 to estimate the burden of data submission under this final rule using the CROWNWeb process (shown in Table 2). Using the new process, the personnel time necessary to submit data to meet the new requirements (columns D and E) is markedly decreased.

TABLE 2.—ANNUAL FACILITY DATA BURDEN UNDER FINAL RULE § 494.180(H)

Project (level of data)	Method	A. Number of facilities	B. Number of forms	C. Data frequency	D. Time to collect/enter data (minus)/ each	E. total time (approximate hours)	F. Other facility costs	G. Total facility costs
ClinicalPART (patient) ‡	paper	0	0	annual	30	0	$0	$0
	SUI	1035	78660	annual	25	32775	0	721,050
	EDI	4138	314488	annual*	0	0	0	0
AdminPART (patient) ‡‡	paper	0	0	monthly	70	0	0	0
	SUI	1035	1035	monthly	70	14490	0	318,780
	EDI	4138	4138	monthly	0	0	0	0
2728 (patient)	paper	0	0	annual	15	0	0	0
	hybrid	5173	111705	annual	15	27926	*306,900	921,272
	EDI	**NA	0	annual	0	0	0	0
2746 (patient)	paper	0	0	annual	10	0	0	0
	hybrid	5173	91396	annual	5	7616	0	167,552
	EDI	**NA	0	annual	0	0	0	0
Total								2,128,654

EDI: Electronic Data Interchange.
SUI: Single-user web interface.
B: For patient-level data, assumes the average facility size of 76 patients.
E: Total Time (hours) = B * C * D / 60.

F: Includes mailing costs but not long-distance fax charges or paper/printing costs. Note: certified mailing is in the process of being required for all communications involving personal health information.

G: Total Costs ($) = E * ($22 dollars per hour wage for medical secretary) + F.

* Assumes first class certified mailing to SSA of $2.79 for each patient.

** Based on prioritization due to volume, facility preferences, and need to include SSA in EDI, all of the data necessary for the complete submission of the 2728 and 2746 are not included in the EDI functionality for initial CROWNWeb releases.

*** The Fistula First data included in ClinicalPART will also be required monthly.

† The required Clinical Patient Attributes and Related Treatment (ClinicalPART) dataset replaces the previous lab data, Fistula First, and CPM data submissions.

‡‡ The required Administrative Patient Attributes and Related Treatment (AdminPART) dataset replaces both the Network Patient Activity Report (NPAR) and the Quarterly roster.

By creating efficiencies via integrating various datasets and complementing the advanced information systems used by most dialysis facilities, we will be able to expand the CPM data collection from about a five percent statistical sample to 100 percent of dialysis patients, while also reducing facility data collection and data entry burden by about $1.8 million (the sum of Table 2 subtracted from the sum of Table 1 equals $1,837,947). Table 3 computes the estimated costs discussed above for computer hardware, Internet access, training costs for two facility staff members, and the labor cost savings for data entry and data submission. Our total of about minus $0.97 million reflects an overall first year cost savings that accompanies implementation of electronic data submission required by this final rule. The estimated $1.8 million annual labor cost savings is expected every subsequent year (not counting inflation) on an ongoing basis.

TABLE 3.—COST ESTIMATE FOR § 494.180(H)

$155,000	Computer hardware (first year).
55,800	Broadband internet access (first year and ongoing).
657,799	Training (first year).
2,128,654	Labor (first year and ongoing) (Represents a savings of $1,837,947 which is the difference between total costs in Table 1 and total costs in Table 2).
$2,997,253	Total Cost (first year).
$969,348	Total Cost savings (first year) (Represents the difference between total costs in Table 1 and the first year costs of $2,997,253).

In addition to the short-term return on investment to facilities, we believe that there is also an ongoing return on this investment for all other primary stakeholders—including patients, dialysis practitioners, and the public. CROWNWeb will allow for the more timely, accurate, and efficient use of data to support administration of the ESRD program by replacing the predominately paper process that currently exists with an electronic process that respects the capabilities of providers and has tangible benefits for dialysis facilities, individuals who have or may develop ESRD, and other stakeholders. CROWNWeb will allow facility submission of required data directly from their electronic health records rather than redundant data entry, freeing facility personnel to concentrate more on patient care. Another expectation is that claims payment will be improved due to improved quality and timeliness of patient eligibility and enrollment information. In the future, we expect that the system could include claims data, and serve to inform a facility of, for example, patient hospitalization. A major benefit of the new system for facilities will be reports that will allow facilities to compare their patient outcomes with those of their peers. CPM electronic data collection for all dialysis patients allows facility level comparisons and tracking. Information about patient outcomes will be available in a much more timely fashion than currently exists, and performance improvement activities may be implemented and evaluated in quicker succession to optimize patient outcomes. For individuals with ESRD, CROWNWeb will increase the transparency of the health care system and empower patients to find better health care value and quality, while assuring access to care, especially in times of disaster/emergency. For ESRD Networks, CROWNWeb will not only provide timelier, more accurate, and more complete information to inform quality improvement, it will make unnecessary certain activities that require a significant amount of Network resources. For example, CROWNWeb will be able to recreate the data included on the CMS 2744 Annual Facility Survey in a more timely fashion then is currently possible, and will free up Network resources that currently perform a four month manual reconciliation process. And for all primary stakeholders, we expect that the new system will either facilitate or provide timelier reports that will allow them to compare individual facilities and facility groups with various peer groups and national and local benchmarks.

Impact Summary

The following chart provides an overall estimate of the impact of the final rule on dialysis facilities:

Requirement	First year costs	Second year costs
BP Cuffs (cleanable or disposable)	$496,244	* $49,624
Isolation Room Waiver Process	0	* 10,743
Evacuation Instructions	523,634	0
Emergency Phone Number	69,384	* 69,384
Automated External Defibrillator (AED)	5,338,000	0
AED Maintenance	54,581	* 54,581
Contacting Local Disaster Official	264,448	* 264,448

Requirement	First year costs	Second year costs
LSC Automatic Notification System	3,289,472	* 809,472
Update of Patient Rights	171,046	0
QAPI Program Implementation	1,397,708	* 1,397,708
Develop New Grievance Process	247,151	0
ESRD CPM Electronic Reporting:		
Hardware	.....	155,000
Internet access	.....	* 55,800
Training	.....	657,799
Total Cost	11,851,668	3,524,559
Cost savings	**First year savings**	**Second year savings**
CEO Emergency Preparedness Time	$1,029,253	* $1,029,253
Patient Rights decreased administrative burden	342,093	* 342,093
Patient Plan of Care, annually not biennially	19,435,447	* 19,435,447
Medical Records Personnel no longer required	4,180,038	* 4,180,038
Data Submission Labor	.....	* 1,837,947
Total Cost Savings	24,986,831	26,824,778
Net Savings	13,135,163	23,300,219

* Ongoing annual costs/cost savings.

Effects on the Medicare and Medicaid Programs

This final rule contains provisions that will protect patient health and safety and lead to improvements in patient care. Several of the expected improvements in patient care may also result in more efficient, cost effective care. For example, improved infection control practices may lead to fewer hospitalizations and better patient quality of life. An increased focus on the transplantation modality may lead to a greater number of patients on the transplant list, and perhaps more living-donor transplantations.

This final rule contains several provisions that directly and indirectly promote the use of the most optimal dialysis access for each patient. These provisions include § 494.80(a)(8), § 494.90(a)(5), § 494.90(d), § 494.110 (a)(2), § 494.140 (e)(3)&(4), § 494.180 (c)(3), and § 494.180 (h)(3)(iv). We expect that these new requirements are improvements that will result in lower rates of access failure and an increase in the number of working arteriovenous fistulas (AVF). AVFs offer the most benefits to patients of the three possible hemodialysis access types. Examples of these benefits include longer average patency of all access types, very low rate of infection, need for only a minor surgery, and healing and sealing post-cannulation (*http://www.fistulafirst.org/tools.htm#Education*). According to the 2006 USRDS Atlas, the per patient per year (pppy) Medicare costs using 2004 data for dialysis patients with an AVF was $55,112; the pppy cost with a graft was $65,556; and the pppy costs with a catheter $75,345. Although this is raw data, we can see that there is a significant Medicare savings associated with AVF. According to 2005 ESRD CPM project, 31 percent of hemodialysis patients were dialyzing using an AVF in 2004 (*http://www.cms.hhs.gov/CPMProject*). More current Fistula First October 2006 data (*http://www.simsproject.com/downloads.php?p=ff*) shows an AVF rate of 44.4 percent for patients. If the AVF rate further improves by 5 percent in all hemodialysis patients (309,269 in 2004 according to USRDS data) 15,464 more patients would have AVFs (with an average pppy savings of $15,000). If this were to occur the potential Medicare savings could be approximately $230 million per year. For purposes of this Impact Analysis, we have used the savings ($230 million) that could result from 5 percent additional AVF patients. We believe savings are possible assuming the medical costs associated with creating AVFs for these 5 percent additional patients are in line with current costs, and that the cost differential between patients with AVFs and those with catheters remain comparable.

This final rule also promotes patient independence and the use of home dialysis whenever appropriate. The provisions that encourage home dialysis include § 494.70(a)(7), § 494.80(a)(9), § 494.90(a)(7), and § 494.90(d). We expect that the requirements of this rule will increase the percentage of patients on home dialysis. According to USRDS data the 2004 hemodialysis pppy Medicare costs equal $67,733, while the peritoneal pppy costs equal $48,796. We do not have USRDS home hemodialysis pppy Medicare costs although home hemodialysis is less costly than in-center hemodialysis and home peritoneal dialysis is less costly than home hemodialysis. Approximately 92 percent of U.S. dialysis patients receive in-center hemodialysis. Based on the difference between 2004 hemodialysis and peritoneal pppy costs, savings of as much as $18,937 pppy could be obtained with patients opting for peritoneal dialysis. If 5 percent additional patients were to opt for home peritoneal dialysis, which provides added health and quality of life benefits, that could account for 15,464 patients. The potential annual savings for these 5 percent additional patients (15,464 × $18,937) could be as much as $295 million. Combining potential savings from 5 percent additional patients who opt for AVFs and 5 percent additional patients who opt for home dialysis, the total Medicare allowed charges could be reduced by up to $525 million annually. However, these examples are only illustrative in nature and are based on limited analytics. Therefore, they are not incorporated in the quantitative cost analysis of the RIA, but are presented to illustrate the possibility for Medicare savings.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/OMB/circulars/A004/A-4.PDF*) in the table below, we have prepared an accounting statement

showing the classification of the expenditures and savings associated with the provisions of this final regulation. This table provides our best estimate of the total annualized monetized costs and savings.

PRIMARY ESTIMATE FOR 2008

Annualized monetized facility costs	$11,851,668
Annualized monetized facility cost savings	24,986,831
Annualized monetized facility net cost savings	13,135,163
Effects on State, local, and tribal governments	0
Benefit effects on small businesses	2,651

D. Alternatives Considered

1. Maintenance of Existing Regulations

One alternative would be to keep the existing regulations. However, the current regulations inhibit our ability to ensure better outcomes of patient care, collect electronic data for quality assurance and quality improvement, incorporate new CDC and AAMI guidelines and fire safety standards and reduce current facility burden by eliminating numerous process and procedural requirements.

2. Infection Control

One alternative was not including an exception to the CDC recommendation for monthly and semiannual screening for hepatitis C. We retained the exception because blanket screening for hepatitis C is not a Medicare-covered service.

Another alternative was to include only the ''Recommended Infection Control Practices for Hemodialysis Units At a Glance'' (At a Glance) precautions found in the CDC RR05 report and not including the narrative section explaining the infection control precautions. Our proposed inclusion of only the ''At a Glance'' two-pager synopsis of the CDC hemodialysis infection control precautions caused confusion as evidenced by the comments we received requesting clarification of various precautions. A third alternative was to require compliance with AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities. The AIA guidelines provide instructions regarding dialysis unit design as it relates to infection control. While some states have adopted specific AIA guidelines as minimal standards, we believe it would be too burdensome on dialysis facilities to incorporate AIA guidelines as federal requirements. Commenters did not support inclusion of the AIA guidelines in these conditions for coverage.

3. Water Quality

One alternative was to require compliance with portions of the previous AAMI guidelines—ANSI/AAMI RD5: 1992 Appendix B5. However, this document has been rescinded by ANSI/AAMI and has been replaced by updated documents. Although we proposed compliance with portions of the AAMI document—RD62: 2001, which is directed to manufacturers, we are including in this final rule an incorporation by reference of ANSI/AAMI RD52:2004. This RD52 document reflects the state-of-the-art water quality guidelines for end users of water purification systems. Commenters urged us to include the RD52:2004 incorporation by reference as the most appropriate set of recommendations for dialysis facilities.

4. Reuse of Hemodialyzers

One potential cost-saving alternative was to remove the requirement that dialyzers exposed to more than one germicide were acceptable for reuse. We decided against this because exposure to different germicides may cause membrane leaks and we have no scientific evidence to support the safety of using hemodialyzers exposed to more than one germicide. Commenters agreed with this approach.

5. Physical Environment and Emergency Preparedness

One alternative was to remove the requirement that every dialysis facility have a defibrillator. We retained this proposed provision because a Seattle study (Becker, pp. 1509–1512) identified dialysis centers as having a relatively high incidence of cardiac arrests over a seven year period. Also, automated external defibrillators are now required on airliners and in other public places because the technology is simple to use, staff can be trained on the use of such equipment, and the technology has been proven to save lives.

A second alternative was to allow a waiver or phase-in period for defibrillators in small rural dialysis facilities. Many commenters agreed that dialysis facilities should be equipped with a defibrillator, preferably an AED. Commenters urged that a waiver not be available to rural facilities and stated that these dialysis facilities may have the greatest need for AEDs since emergency medical technical support may be located a long distance from the dialysis facility.

6. Patients' Rights

One alternative was to remove the patients' right to be informed of the availability of advance directives. We retained this proposal nonetheless because of the nature of ESRD and the aging dialysis population.

Another alternative considered was not including that dialysis facilities have an internal grievance procedure. We did not adopt this alternative because we believe an internal grievance process is essential to allow patients to express their concerns directly to the facility in which they receive dialysis.

7. Patient Assessment

One alternative was to include ''extremely frail patients'' in the provision to reassess unstable patients monthly. This proposal was not adopted in order to ensure that dialysis facilities retain the flexibility to make clinical determinations on a case-by-case basis.

Another alternative was to remove the proposed 3-month timeframe to reassess new patients. However, we believe that initial patient adjustment to dialysis is crucial in setting the stage for successful treatment of ESRD and the reassessment done at 3 months will facilitate better patient outcomes.

8. Patient Plan of Care

One alternative was to retain the existing requirement for an individualized care plan with a six month review and a long-term program with an annual review. We did not adopt this approach because it was less burdensome to include a single individualized plan of care (without a long-term program) to be reviewed annually for stable patients.

9. Quality Assessment and Performance Improvement

One alternative was to require a QAPI program without specific criteria. We determined, based on the work of the NFK–K/DOQI committees (adequacy, nutrition, anemia, and vascular access), AAMI guidelines (reuse), specific recommendations from the OIG (medical error identification and patient satisfaction), and public comments on our proposed rule, that there was a sufficient basis to include basic criteria.

10. Special Purpose Renal Dialysis Facilities

One alternative was to remove this condition entirely based on historically low levels of participation. We determined that eliminating this condition would be detrimental to the small number of vacation camps that choose to participate and it would also

inhibit access to care during natural disasters.

Another alternative was to retain the current certification requirements. We believe that the current certification requirements are onerous; we believe that this is demonstrated by the lack of participation in Medicare by vacation camps. We believe reducing the number of certification requirements addresses this issue. The final rule requirements represent a reduction in administrative burden for special purpose units.

11. Personnel Qualifications

One alternative was to retain the existing requirement that a licensed practical nurse, RN, or physician must be on the premises during dialysis. We are requiring that a registered nurse be on the premises during dialysis to protect patient health and safety and believe that this does not represent a significant increase in burden for dialysis facilities. In response to comments, we included a provision for the temporary use of an experienced LPN for infrequent occasions when the lack of an RN would force the facility to close for the day.

Other options were to propose no or merely minimal Federal requirements for dialysis technicians. We determined that Federal requirements are needed at this time because dialysis technicians are the primary caregivers in most dialysis facilities. Commenters support the inclusion of qualification criteria for patient care technicians.

12. Medical Director

One alternative was to propose to eliminate the medical director condition and propose that other health care professionals run dialysis facilities. However, a June 2000 OIG report strongly recommended that we strengthen the role of the facility's medical director. In response to that recommendation, we have retained the condition with a clarification of the medical director's responsibilities to include overseeing both the QAPI program and all involuntary patient transfers or discharges. We do not believe that this approach would impose an additional cost burden on dialysis facilities.

13. Governance

One alternative considered was to remove the proposal for a 30-day advance notice before involuntary patient discharge or transfer and retain the previous requirement (see § 405.2138(b)(2)) for patients to be ''given advance notice to ensure orderly transfer or discharge.'' We did not adopt this alternative because: (1) A 30-day advance notice for discharge and transfer has been consistent with the existing requirements in NFs, SNFs, and hospital swing-beds for over 12 years; (2) the dialysis patient population is increasingly older and many are nursing home residents with co-morbid conditions; and (3) large dialysis organizations have emerged that can offer more flexibility and options for a patient involuntarily discharged from a facility by providing numerous units nearby or within commuting distance of that patient's place of residence. We have retained the proposed provision to waive the 30-day notice under extraordinary circumstances.

This final rule contains a requirement for every dialysis facility to report ESRD CPM Project data to CMS. One option considered was to require that less than 100 percent of facilities participate. However, section 4558(b) of Pub. L. 105–33 requires CMS to monitor the quality of care delivered to dialysis patients. To date, CMS has been collecting a five percent CPM patient sample on a voluntary basis. CPM electronic data collection has been pilot-tested and is expected to be ready for general use in 2008. The large dialysis organization facilities and many other dialysis facilities already collect this data for benchmarking and quality improvement purposes, and therefore, this will not create a significant new burden for the industry. However, small rural facilities may need time to come into compliance, and therefore, we are including a phase-in period.

E. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

■ 1. The authority citation for part 405, subpart U is revised to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

§ 405.2100 and § 405.2101 [Removed and Reserved]

■ 2. Section 405.2100 and § 405.2101 are removed and reserved.

■ 3. Section 405.2102 is amended by adding the definition of ''ESRD Network organization'' in alphabetical order to read as follows:

§ 405.2102 Definitions.

* * * * *

ESRD Network organization. The administrative governing body to the network and liaison to the Federal government.

* * * * *

§ 405.2131 and § 405.2133 through § 405.2140 [Removed and Reserved]

■ 4. Section 405.2131 and § 405.2133 through § 405.2140 are removed and reserved.

§ 405.2150 [Removed and Reserved]

■ 5. Section § 405.2150 is removed and reserved.

§ 405.2160 through § 405.2164 [Removed and Reserved]

■ 6. Sections 405.2160 through § 405.2164 are removed and reserved.

§ 405.2180 through § 405.2182 [Removed and Reserved]

■ 7. Sections 405.2180 through § 405.2182 are removed and reserved.

§ 405.2184 [Removed and Reserved]

■ 8. Section 405.2184 is removed and reserved.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 9. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395(m), 1395hh, and 1395ddd).

§ 410.5 [Amended]

■ 10. In § 410.5(a), the reference ''Part 405, subpart U: End-Stage Renal Disease Services,'' is revised to read ''Part 494: End-Stage Renal Disease Facilities.''

§ 410.50 [Amended]

■ 11. In § 410.50(b), the reference ''§ 405.2163(b)'' is revised to read ''§ 494.130''; and the reference ''subpart M of part 405'' is revised to read ''part 494.''

§ 410.52 [Amended]

■ 12. Section § 410.52 is amended as follows:

■ A. In paragraph (a)(4), the reference to ''§ 405.2163'' is revised to read ''§ 494.90(a)(4).''

■ B. In paragraph (a)(4), the word ''epoetin (EPO)'' is revised to read ''erythropoeisis-stimulating agents.''

■ C. In paragraph (b), the parenthetical statement ''(Section 405.2137 of this chapter contains specific details.)'' is revised to read ''(Section 494.90 of this chapter contains details on patient plans of care).''

§ 410.152 [Amended]

■ 13. In § 410.152(e)(1), ''subpart U of part 405'' is revised to read ''part 494.''

§ 410.170 [Amended]

■ 14. In § 410.170(c), the reference to ''§ 405.2137(b)(3)'' is revised to read ''§ 494.90.''

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 15. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

■ 16. In § 413.170, paragraph (a) is revised to read as follows:

§ 413.170 Scope.

* * * * *

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of a dialysis facility under part 494 of this chapter (referred to as ''facility''). For purposes of this section and § 413.172 through § 413.198, ''outpatient maintenance dialysis'' means outpatient dialysis provided by a dialysis facility, home dialysis or self-dialysis as defined in § 494.10 of this chapter and includes all items and services specified in § 410.50 and § 410.52 of this chapter.

* * * * *

■ 17. In § 413.172, paragraph (b) is revised to read as follows:

§ 413.172 Principles of prospective payment.

* * * * *

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis. Approved ESRD facility means—

(1) Any independent or hospital-based facility (as defined in accordance with § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

* * * * *

§ 413.198 [Amended]

■ 18. In § 413.198(a), the phrase ''approved under subpart U of part 405,'' is revised to read ''under part 494.''

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 19. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

§ 414.330 [Amended]

■ 20. Section 414.330 is amended as follows:

■ A. In paragraph (a)(2)(iii)(B), the reference ''subpart U of part 405'' is revised to read ''part 494.''

■ B. In paragraph (a)(2)(iii)(B)(*1*), the references ''subpart U (Conditions for Coverage of Suppliers of ESRD Services)'' are revised to read ''part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities).''

■ C. In paragraph (a)(2)(iii)(B)(*7*), the references ''subpart U (Conditions for Coverage of Suppliers of ESRD Services)'' are revised to read ''part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities).''

■ D. Paragraph (a)(2)(iii)(C) is added to read as follows:

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) * * *

(iii) * * *

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 21. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1895hh); Continuing Resolution Pub. L. 110–149 H.J. Res 72.

■ 22. Section 488.60(a) is revised to read as follows:

§ 488.60 Special procedures for approving end-stage renal disease facilities.

(a) *Consideration for approval.* An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this chapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

* * * * *

Subpart G [Added and Reserved]

■ 23. A new subpart G is added and reserved.

■ 24. A new subpart H is added to read as follows:

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

Sec.
488.604 Termination of Medicare coverage.
488.606 Alternative sanctions.
488.608 Notice of alternative sanction and appeal rights: Termination of coverage.
488.610 Notice of appeal rights: Alternative sanctions.

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

§ 488.604 Termination of Medicare coverage.

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.180(i) of this chapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of alternative sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

§ 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

(a) *Notice of alternative sanction.* CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

§ 488.610 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply an alternative sanction specified in § 488.606(b), the following rules apply:

(a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

■ 25. A new part 494 is added to read as follows:

PART 494—CONDITIONS FOR COVERAGE FOR END–STAGE RENAL DISEASE FACILITIES

Subpart A—General Provisions

Sec.
494.1 Basis and scope.
494.10 Definitions.
494.20 Condition: Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

494.30 Condition: Infection control.
494.40 Condition: Water and dialysate quality.
494.50 Condition: Reuse of hemodialyzers and bloodlines.
494.60 Condition: Physical environment.

Subpart C—Patient Care

494.70 Condition: Patient rights.
494.80 Condition: Patient assessment.
494.90 Condition: Patient plan of care.
494.100 Condition: Care at home.
494.110 Condition: Quality assessment and performance improvement.
494.120 Condition: Special purpose renal dialysis facilities.
494.130 Condition: Laboratory services.

Subpart D—Administration

494.140 Condition: Personnel qualifications.
494.150 Condition: Responsibilities of the Medical director.
494.160 [Reserved]
494.170 Condition: Medical records.
494.180 Condition: Governance.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. l302 and l395hh).

Subpart A—General Provisions

§ 494.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(3) Section 1861(s)(2)(F) of the Act, which describes ''medical and other health services'' covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(4) Section 1862(a) of the Act, which specifies exclusions from coverage.

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(b) *Scope.* The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions.

As used in this part—

Dialysis facility means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.

Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part.

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

§ 494.20 Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

Subpart B—Patient Safety

§ 494.30 Condition: Infection control.

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

(a) *Standard: Procedures for infection control.* The facility must demonstrate that it follows standard infection control precautions by implementing—

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.* The recommendation found under section header ''HBV-Infected Patients'', found on pages 27 and 28 of RR05 (''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients''), concerning isolation rooms, must be complied with by February 9, 2009.

(ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

(2) The ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' entitled ''Recommendations for Placement of Intravascular Catheters in Adults and Children'' parts I–IV; and ''Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients,'' Morbidity and Mortality Weekly Report, volume 51 number RR–10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.*

(3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and

(4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage, and disposal of potentially infectious waste; and

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

(b) *Standard: Oversight.* The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;

(2) Ensure that clinical staff demonstrate compliance with current

aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

(3) Require all clinical staff to report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee.

(c) *Standard: Reporting.* The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

§ 494.40 Condition: Water and dialysate quality.

The facility must be able to demonstrate the following:

(a) *Standard: Water purity.* Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ''Dialysate for hemodialysis,'' ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, 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/code_of_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(b) *Standard: Chlorine/chloramines.*

(1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal;

(2) (i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested;

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

(B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and

(C) Immediately notify the medical director; and

(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.

(c) *Standard: Corrective action plan.* Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.

(d) *Standard: Adverse events.* A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must—

(1) Obtain blood and dialysate cultures and endotoxin levels;

(2) Evaluate the water purification system; and

(3) Take corrective action.

(e) *Standard: In-center use of preconfigured hemodialysis systems.* When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

§ 494.50 Condition: Reuse of hemodialyzers and bloodlines.

(a) *Standard: General requirements for the reuse of hemodialyzers and bloodlines.* Certain hemodialyzers and bloodlines—

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

(2) Must be reused only for the same patient; and

(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in ''Reuse of Hemodialyzers,'' third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, 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/code_of_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(2) Reprocess hemodialyzers and bloodlines—

(i) By following the manufacturer's recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

(c) *Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.* In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

(2) When clinically indicated (for example, after adverse patient reactions), the facility must—

(i) Obtain blood and dialysate cultures and endotoxin levels; and

(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this

evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) *Standard: Building.* The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

(c) *Standard: Patient care environment.*

(1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must:

(i) Maintain a comfortable temperature within the facility; and

(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).

(d) *Standard: Emergency preparedness.* The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

(1) *Emergency preparedness of staff.* The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:

(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and

(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(2) *Emergency preparedness patient training.* The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section.

(3) *Emergency equipment.* Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.

(4) *Emergency plans.* The facility must—

(i) Have a plan to obtain emergency medical system assistance when needed;

(ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary; and

(iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.

(e) *Standard: Fire safety.*

(1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744(a)(1)(i) of this chapter).

(2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008. Utilizing non-sprinklered buildings on such date may continue to use such facilities if such buildings were constructed before January 1, 2008 and State law so permits.

(3) If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

(4) After consideration of State survey agency recommendations, CMS may waive, for individual dialysis facilities and for appropriate periods, specific provisions of the Life Safety Code, if the following requirements are met:

(i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and

(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.

Subpart C—Patient Care

§ 494.70 Condition: Patients' rights.

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

(a) *Standard: Patients' rights.* The patient has the right to—

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

(2) Receive all information in a way that he or she can understand;

(3) Privacy and confidentiality in all aspects of treatment;

(4) Privacy and confidentiality in personal medical records;

(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

(6) Be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives;

(7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis),and in-facility hemodialysis. The patient has the right to receive resource information for dialysis

modalities not offered by the facility, including information about alternative scheduling options for working patients;

(8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

(9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

(11) Be informed of services available in the facility and charges for services not covered under Medicare;

(12) Receive the necessary services outlined in the patient plan of care described in § 494.90;

(13) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

(14) Be informed of the facility's internal grievance process;

(15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and

(17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

(b) *Standard: Right to be informed regarding the facility's discharge and transfer policies.* The patient has the right to—

(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and

(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in § 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.

(c) *Standard: Posting of rights.* The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

(a) *Standard: Assessment criteria.* The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including co-morbid conditions.

(2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.

(3) Laboratory profile, immunization history, and medication history.

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).

(5) Evaluation of factors associated with renal bone disease.

(6) Evaluation of nutritional status by a dietitian.

(7) Evaluation of psychosocial needs by a social worker.

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).

(9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes.

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

(11) Evaluation of family and other support systems.

(12) Evaluation of current patient physical activity level.

(13) Evaluation for referral to vocational and physical rehabilitation services.

(b) *Standard: Frequency of assessment for patients admitted to the dialysis facility.* (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

(2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.

(c) *Standard: Assessment of treatment prescription.* The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1), must be assessed on an ongoing basis as follows:

(1) *Hemodialysis patients.* At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) *Peritoneal dialysis patients.* At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

(d) *Standard: Patient reassessment.* In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted—

(1) At least annually for stable patients; and

(2) At least monthly for unstable patients including, but not limited to, patients with the following:

(i) Extended or frequent hospitalizations;

(ii) Marked deterioration in health status;

(iii) Significant change in psychosocial needs; or

(iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.

§ 494.90 Condition: Patient plan of care.

The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.

(a) *Standard: Development of patient plan of care.* The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:

(1) *Dose of dialysis.* The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve

and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

(2) *Nutritional status*. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

(3) *Mineral metabolism*. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

(4) *Anemia*. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

(5) *Vascular access*. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

(6) *Psychosocial status*. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

(7) *Modality*. (i) *Home dialysis*. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

(ii) *Transplantation status*. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the—

(A) Plan for transplantation, if the patient accepts the transplantation referral;

(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10).

(8) *Rehabilitation status*. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.

(b) *Standard: Implementation of the patient plan of care*.

(1) The patient's plan of care must—

(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and

(ii) Be signed by team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.

(2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).

(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must—

(i) Adjust the plan of care to reflect the patient's current condition;

(ii) Document in the record the reasons why the patient was unable to achieve the goals; and

(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

(c) *Standard: Transplantation referral tracking*. The interdisciplinary team must—

(1) Track the results of each kidney transplant center referral;

(2) Monitor the status of any facility patients who are on the transplant wait list; and

(3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.

(d) *Standard: Patient education and training*. The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

§ 494.100 Condition: Care at home.

A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

(a) *Standard: Training*. The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10) and when the home dialysis caregiver or home dialysis modality changes. The training must—

(1) Be provided by a dialysis facility that is approved to provide home dialysis services;

(2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and

(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD.

(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's

prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.

(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.

(iv) Availability of support resources and how to access and use resources.

(v) How to self-monitor health status and record and report health status information.

(vi) How to handle medical and non-medical emergencies.

(vii) Infection control precautions.

(viii) Proper waste storage and disposal procedures.

(b) *Standard: Home dialysis monitoring.* The dialysis facility must—

(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and

(3) Maintain this information in the patient's medical record.

(c) *Standard: Support services.*

(1) A home dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company. Services include, but are not limited to, the following:

(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in § 494.90 of this part.

(iv) Patient consultation with members of the interdisciplinary team, as needed.

(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with—

(A) The recommendations specified in the manufacturers' instructions; and

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

(*1*) Analysis of the water and dialysate quality indicates contamination; or

(*2*) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

§ 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

(a) *Standard: Program scope.*

(1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Mineral metabolism and renal bone disease.

(iv) Anemia management.

(v) Vascular access.

(vi) Medical injuries and medical errors identification.

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(viii) Patient satisfaction and grievances.

(ix) Infection control; with respect to this component the facility must—

(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and

(C) Take actions to reduce future incidents.

(b) *Standard: Monitoring performance improvement.* The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

(c) *Standard: Prioritizing improvement activities.* The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

(a) *Standard: Approval period.* The period of approval for a special purpose

renal dialysis facility may not exceed 8 months in any 12-month period.

(b) *Standard: Service limitation.* Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

(c) *Standard: Scope of requirements.*

(1) *Scope of requirements for a vacation camp.* A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage—

(i) Infection control at § 494.30;

(ii) Water and dialysate quality at § 494.40 (except as provided in paragraph (c)(1)(viii) of this section);

(iii) Reuse of hemodialyzers at § 494.50 (if reuse is performed);

(iv) Patients' rights and posting of patients' rights at § 494.70(a) and § 494.70(c);

(v) Laboratory services at § 494.130;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and § 494.150(d);

(vii) Medical records at § 494.170; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100(c)(1)(v) (home monitoring of water quality), in place of § 494.40 (water quality).

(2) *Scope of requirements for an emergency circumstance facility.* A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with paragraph (c)(1) of this section and addition to complying with the following conditions:

(i) Section 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) Section 494.60 (physical environment).

(iii) Section 494.70(a) through section 494.70(c) (patient rights).

(iv) Section 494.140 (personnel qualifications).

(v) Section 494.150 (medical director).

(vi) Section 494.180 (governance).

(d) *Standard: Physician contact.* The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90).

(e) *Standard: Documentation.* All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

(a) *Standard: Medical director.*

(l) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.

(b) *Standard: Nursing services.*

(1) *Nurse manager.* The facility must have a nurse manager responsible for nursing services in the facility who must—

(i) Be a full time employee of the facility;

(ii) Be a registered nurse; and

(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

(2) *Self-care and home dialysis training nurse.* The nurse responsible for self-care and/or home care training must—

(i) Be a registered nurse; and

(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

(3) *Charge nurse.* The charge nurse responsible for each shift must—

(i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and

(iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

(4) *Staff nurse.* Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

(c) *Standard: Dietitian.* The facility must have a dietitian who must—

(1) Be a registered dietitian with the Commission on Dietetic Registration; and

(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian.

(d) *Standard: Social worker.* The facility must have a social worker who—

(1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or

(2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1).

(e) *Standard: Patient care dialysis technicians.* Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

(3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients. The training program must include the following subjects:

(i) Principles of dialysis.

(ii) Care of patients with kidney failure, including interpersonal skills.

(iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.

(iv) Possible complications of dialysis.

(v) Water treatment and dialysate preparation.

(vi) Infection control.

(vii) Safety.

(viii) Dialyzer reprocessing, if applicable.

(4) Be certified under a State certification program or a national commercially available certification program, as follows—

(i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or

(ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.

(f) *Standard: Water treatment system technicians.* Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

§ 494.150 Condition: Responsibilities of the medical director.

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. Medical director responsibilities include, but are not limited to, the following:

(a) Quality assessment and performance improvement program.

(b) Staff education, training, and performance.

(c) Policies and procedures. The medical director must—

(1) Participate in the development, periodic review and approval of a ''patient care policies and procedures manual'' for the facility; and

(2) Ensure that—

(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f).

§ 494.160 [Reserved]

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) *Standard: Protection of the patient's record.* The dialysis facility must—

(1) Safeguard patient records against loss, destruction, or unauthorized use; and

(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:

(i) The transfer of the patient to another facility.

(ii) Certain exceptions provided for in the law.

(iii) Provisions allowed under third party payment contracts.

(iv) Approval by the patient.

(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

(3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.

(b) *Standard: Completion of patient records and centralization of clinical information.*

(1) Current medical records and those of discharged patients must be completed promptly.

(2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation.* In accordance with 45 CFR § 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.

(d) *Standard: Transfer of patient record information.* When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

§ 494.180 Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.

(a) *Standard: Designating a chief executive officer or administrator.* The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;

(2) Fiscal operations;

(3) The relationship with the ESRD networks; and

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in § 494.110.

(b) *Standard: Adequate number of qualified and trained staff.* The governing body or designated person responsible must ensure that—

(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and

(4) All employees have an opportunity for continuing education and related development activities.

(c) *Standard: Medical staff appointments.* The governing body—

(1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists; and

(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in § 494.110.

(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.

(d) *Standard: Furnishing services.* The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100).

(e) *Standard: Internal grievance process.* The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include:

(1) A clearly explained procedure for the submission of grievances.

(2) Timeframes for reviewing the grievance.

(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

(f) *Standard: Involuntary discharge and transfer policies and procedures.* The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—

(1) The patient or payer no longer reimburses the facility for the ordered services;

(2) The facility ceases to operate;

(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or

(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—

(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;

(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;

(iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;

(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and

(v) Notifies the State survey agency of the involuntary transfer or discharge.

(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.

(g) *Standard: Emergency coverage.*

(1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

(i) *Standard: Relationship with the ESRD network.* The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

(j) *Standard: Disclosure of ownership.* In accordance with § 420.200 through § 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Approved: July 12, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 10, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 08–1102 Filed 4–3–08; 8:45 am]

BILLING CODE 4120–01–P

Federal Register

Tuesday,
April 15, 2008

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 423

Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4130–F]

RIN 0938–AO74

Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule codifies clarifications of existing policies associated with the Medicare Prescription Drug Benefit (also known as Medicare Part D), including the following: guidance that certain supplies associated with the administration of insulin are included in the definition of a Part D drug; guidance regarding the statutory exclusion from the definition of a Part D drug of any drug when used for the treatment of sexual or erectile dysfunction, unless that drug is used for an FDA-approved purpose other than sexual or erectile dysfunction; a recent statutory change that allows for the payment of vaccine administration under Part D for Part D covered vaccines; and guidance on plan-to-plan reconciliation and reconciliation with a payer other than the Part D plan of record. This final rule also codifies clarifications of existing policies associated with the Retiree Drug Subsidy (RDS) program, including guidance on aggregating plan options for purposes of meeting the net test for actuarial equivalence and guidance on applying the Medicare supplemental adjustment when calculating actuarial equivalence.

In addition, new clarifications and modifications in this final rule include establishing standards with respect to the timely delivery of infusible drugs covered under Part D and modifications to the retiree drug subsidy regulations. This final rule also codifies certain technical corrections to our regulations and clarifies our intent with respect to certain preamble discussions in a prior final rule implementing the Medicare prescription drug benefit.

EFFECTIVE DATES: These regulations are effective on June 9, 2008.

FOR FURTHER INFORMATION CONTACT:

Alissa DeBoy (410) 786–6041	General questions regarding the final rule.
Vanessa Duran (410) 786–8697	Subpart B—approval of marketing and materials and enrollment forms; procedures to determine and document creditable status of prescription drug coverage; Subpart C—the definition of a long-term care facility; the definition of a contracted pharmacy network; the waiver or reduction of Part D cost-sharing by pharmacies; access to covered Part D drugs, including adequate access to home infusion pharmacies; Subpart E—organization compliance with State law and preemption by Federal law; and Subpart K—application procedures and contracts with Part D plan sponsors.
Gregory Dill (312) 353–1754	Subpart C—definition of a Part D drug, including the exclusion of drugs used to treat erectile dysfunction, the exclusion of drugs related to morbid obesity, supplies associated with the delivery of insulin into the body, and vaccine administration fees.
Meghan Elrington (410) 786–8675	Subpart F—timing of payments.
Deondra Moseley (410) 786–4577	Subpart G—payment appeals; and Subpart P—low-income benchmark premium amount, and premium subsidy for late enrollment penalty.
Deborah Larwood (410) 786–9500	Subpart J—coordination of Part D plans with other prescription drug coverage.
John Scott (410) 786–3636	Subpart M—grievances, coverage determinations, and appeals.
Christine Hinds (410) 786–4578	Subpart P—premiums and cost-sharing subsidies for low-income individuals.
David Mlawsky (410) 786–6851	Subpart R—payments to sponsors of retiree prescription drug plans.
Christine Hinds (410) 786–4578	Subpart S—special rules for States.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended section 1871(a)(3) of the Social Security Act (the Act) and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 1871(a)(3)(B) of the Act also states that the timelines for these regulations may vary, but shall not exceed 3 years after publication of the preceding proposed or interim final regulation, except under exceptional circumstances. This final rule finalizes provisions set forth in the May 25, 2007 proposed rule (72 FR 29403), hereinafter referred to as the May 2007 proposed rule. In addition, this final rule has been published within the 3-year time limit imposed by section 1871(a)(3)(B) of the Act. Therefore, we believe our final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

B. General Overview

The Medicare Prescription Drug Benefit (also known as Part D) is a voluntary prescription drug benefit program enacted into law on December 8, 2003 in section 101 of title I of the MMA. The Retiree Drug Subsidy (RDS) program, which provides payments to employer and union sponsors of qualified retiree prescription drug plans for Part D drug costs within certain limits, was also enacted as part of MMA. The final rule implementing the provisions of Part D appeared in the **Federal Register** on January 28, 2005, and these provisions became effective March 22, 2005. We hereinafter refer to this rule as the January 2005 final rule. Since publication of the January 2005 final rule, we have issued several clarifications or interpretations of the final rule by way of interpretive guidance documents. In addition, we have issued guidance explaining how we will interpret a change to the Act that excludes drugs used in the treatment of erectile dysfunction from Part D, with a certain exception. In order to ensure public awareness of our policies, as well as to avoid potential confusion regarding them, we explained many of the respective clarifications or interpretations in the May 2007 proposed rule. We also proposed to codify some of these clarifications in regulation, as well as to make certain technical corrections. Finally, due to our experience to date in implementing the Part D program, we proposed several new clarifications of our policy for Part D plans on which we specifically invited public comment.

II. Provisions of the Proposed Rule With an Analysis of and Response to Public Comments

We received approximately 60 items of timely correspondence containing comments on the May 2007 proposed rule. Commenters included health plans and health plan associations, pharmacies and pharmacist associations, prescription benefit managers (PBMs), physicians and other health care professionals, beneficiary advocacy groups, representatives of hospitals, Part D beneficiaries, and others.

In this final rule, we address all relevant comments we received regarding the provisions of our proposed rule with the exception of the provisions on what may be included in the drug costs Part D sponsors use as the basis for calculating beneficiary cost sharing and reporting drug costs to CMS for the purposes of reinsurance reconciliation and risk sharing, as well as submitting bids to CMS. We are not finalizing these provisions at this time. We intend to revisit this issue in future rulemaking and will address the comments at that time. We appreciate the comments and will take them under consideration as we continue to assess the underlying policy and its associated impact.

Most of the comments addressed multiple issues. The areas of our proposed rule that we are finalizing that received the most comment include the provisions on ensuring adequate access to home infusion pharmacies and the provisions addressing the coordination of Part D plans with other prescription drug coverage. Generally, the vast majority of commenters expressed strong support for the provisions of our proposed rule, declaring them essential to the success and continued operation of the Medicare Part D program. This was especially true with regard to our proposal to establish a standard for the timely delivery of home infusion drugs. A significant subset of the comments regarding home infusion access suggested even more rigorous standards for ensuring the timely delivery of Part D infusible drugs.

We also received a significant number of comments that addressed our proposed clarifications on permissible activities vis-à-vis provider marketing and the coverage of drugs when used to treat morbid obesity. In general, commenters supported our clarifications or technical corrections. However, on some issues, commenters asked for reinterpretations of the statute.

In this final rule, we address comments received on the May 2007 proposed rule largely in the numerical order of the related regulation sections.

A. Subpart B—Eligibility and Enrollment

1. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

In our May 2007 proposed rule (70 FR 4223), we clarified that when we used the term ''market'' in the preamble to the January 2005 final rule in the context of our discussion of the approval process for marketing materials and enrollment forms, we used it in a more general sense to mean assisting in enrollment or education directed at beneficiaries, and not marketing per se as the term is understood to mean in the commercial context. This clarification was necessary to distinguish our preamble discussion and our narrower definition of the term ''marketing'' in the Medicare Marketing Guidelines, which were issued subsequent to our publication of that final rule. (See Centers for Medicare & Medicaid Services, Medicare Marketing Guidelines for Medicare Advantage Plans (MAs); Medicare Advantage Prescription Drug Plans (MA–PDs); Prescription Drug Plans (PDPs); 1876 Cost Plans *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf* (last updated July 25, 2006).) The Guidelines define ''marketing'' as ''[s]teering, or attempting to steer, an undecided potential enrollee towards a plan, or limited number of plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities.'' (Medicare Marketing Guidelines, page 8.) This definition further clarifies that neither ''[a]ssisting in enrollment'' nor ''education'' constitute ''marketing'' as those terms are defined in The Guidelines (Medicare Marketing Guidelines, page 8). The Medicare Marketing Guidelines specify that ''assisting in enrollment'' consists of assisting a potential enrollee with the completion of an application and objectively discussing characteristics of different plans to assist a potential enrollee with appraising the relative merits of all available individual plans, based solely on the potential enrollee's needs; further, the individual or entity performing these activities may not receive compensation directly or indirectly from a plan for such assistance in enrollment (Medicare Marketing Guidelines, page 6). ''Education'' is defined in the Medicare Marketing Guidelines as informing a potential enrollee about Medicare Advantage or other Medicare programs, generally or specifically, but not steering, or attempting to steer, a potential enrollee towards a specific plan or limited number of plans (Medicare Marketing Guidelines, page 6). Thus, our intent in the preamble of the January 2005 final rule was to acknowledge that providers and pharmacies are free to engage in either ''assisting in enrollment'' or ''education,'' including provider promotional activities as permitted under the Medicare Marketing Guidelines, but not to ''market'' to beneficiaries, as the term is defined in the Medicare Marketing Guidelines. We maintain this clarification in the final rule, as noted in our response to comment.

Additionally, we proposed to clarify the provision that currently states that in conducting marketing activities, a Part D plan may not ''[u]se providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless the providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors (70 FR 4532).'' We believed it was necessary to clarify this provision because it was possible to infer from it that when a Part D plan used providers, provider groups, or pharmacies to distribute printed information comparing the benefits of the Part D plans with which they contracted, they would also have to accept and display printed information comparing the benefits of different plans with which they did not contract. Our concern was that this interpretation could lead to situations in which a beneficiary made a plan selection and realized too late that the provider or pharmacist from whom they obtained printed information about a particular plan was not in fact contracted with that plan. Therefore, in the proposed rule, we clarified that a Part D plan could use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans, provided those providers, provider groups, or pharmacies accepted and displayed printed information comparing the benefits of all the different Part D plans with which they contract. However, the providers, provider groups, or pharmacies were not obliged to accept and display any comparative information regarding those Part D plans with which they did not contract. We stipulated that this clarification would apply to comparative marketing materials and was in accord with the Medicare Marketing Guidelines (Medicare Marketing Guidelines, page 125). In this final rule, we codify this policy by revising § 423.50(f)(1)(v).

Comment: A large number of commenters supported our clarification that providers and pharmacies that are contracted with plan sponsors may not market to beneficiaries but may assist in enrollment, including participating in provider promotion activities within the parameters established in the Marketing Guidelines, and educate enrollees. However, two commenters believed that CMS should withdraw this clarification given that it is based on a term we use in the Medicare Marketing Guidelines, which is not a regulatory document. Further, these commenters questioned the validity and utility of the Medicare Marketing Guidelines in the long-term care setting.

Response: The two commenters who asked us to withdraw this clarification did so based on arguments about the validity of the Medicare Marketing Guidelines, which we believe are outside the scope of this regulation. In the proposed rule and in this final rule, we are merely clarifying our policy so as to avoid any confusion arising from the broader use of the term ''market'' in a response to comment in the January 2005 final rule.

Comment: Several commenters supported our proposed revision to § 423.50(f)(1) allowing Part D plans to use providers, provider groups and pharmacies to distribute printed information comparing the benefits of different plans only if those providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which they contract. Two of these commenters were especially pleased with our clarification that providers, provider groups, or pharmacies are not obliged to accept and display any comparative information regarding those Part D plans with which they do not contract. However, another commenter believed that instead of requiring providers to accept and display information for every plan with which they have contracted, we should allow them to accept and display materials from a reasonable cross-section of contracted plans, as long as the provider posts a notice informing beneficiaries that the displayed material describes the benefits of only a subset of contracted plans and explains where beneficiaries may obtain information on the full array of benefits available to them.

Response: Our goal is to ensure that beneficiaries receive the information they need to make a plan selection that is based on their particular needs. We disagree with the commenter who believes that we should allow Part D

plan contracted providers, provider groups, and pharmacies to accept and display materials from only a subset of plans with which they contract—even if they direct beneficiaries to resources for obtaining information on all plans. We believe the proposed requirement strikes a balance between allowing providers and pharmacies contracted with Part D plans to provide enrollment assistance and education, while ensuring that beneficiaries are provided with information about the full array of plans with which that provider or pharmacy contracts—not on a limited subset that may reflect the provider's financial interest—and can make a plan selection that best meets their needs. Accordingly, we have adopted the revision to § 423.50(f)(1) as set forth in the proposed rule. However, we note that plans must provide contracted pharmacies with materials in order for pharmacies to display their plan information along with any other materials received from other contracted plans.

2. Procedures To Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56)

The regulation text of the January 2005 final rule (70 FR 4532) contained a typographical error in § 423.56(b)(6) that referenced § 423.205 for a definition of the term ''Medicare supplemental policy.'' However, the proper reference for the definition of the term ''Medicare supplemental policy'' is § 403.205. Therefore, we proposed revising the regulation text accordingly to state the correct reference—that is, § 403.205. We received no comments with regard to our proposed revision. Therefore, this final rule adopts this revision without change.

B. Subpart C—Benefits and Beneficiary Protections

1. Definitions (§ 423.100)

a. Part D Drug

(1) Erectile Dysfunction (ED)

On October 20, 2005, Congress amended section 1860D–2(e)(2)(A) of the Act to exclude erectile dysfunction (ED) drugs from the statutory definition of a Part D drug. Section 1860D(2)(e)(2)(A) of the Act excludes from the definition of Part D drugs those drugs or classes of drugs, or their medical uses, set forth under section 1927(d)(2) of the Act (other than subparagraph (E)). The ED drug exclusion is cited in section 1927(d)(2)(K) of the Act.

In the May 2007 proposed rule, we reiterated that beginning January 1, 2007, ED drugs would not be classified as Part D drugs under § 423.100 when they are used for the treatment of sexual or erectile dysfunction, unless they are used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration (FDA). We noted that ED drugs would also not meet the definition of a Part D drug for off-label uses that by definition are not approved by the FDA. This includes non-FDA-approved uses—including the treatment of a condition other than sexual or erectile dysfunction contained in one of the compendia listed in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. Because our definition of a Part D drug in § 423.100(2)(ii) excludes drugs which may be excluded under section 1927(d)(2) of the Act, we also noted that no regulation text change is required to implement this new statutory exclusion.

Comment: One commenter asked that we share our interpretation of the statutory ED drug exclusion with our independent review entity (IRE).

Response: Since October 20, 2005, we have provided information about the ED drug exclusion in our outreach efforts to beneficiaries, advocates, and our own contractors. Our guidance to Part D sponsors on the ED drug exclusion was included in *Chapter 6* (''Part D Drugs and Formulary Requirements'') of our Prescription Drug Benefit Manual, which is posted on the CMS Web site at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf*. As a result of our efforts, we believe stakeholders are now well aware of this statutory change.

(2) Morbid Obesity

Section 423.100 defines the term ''Part D drug'' and excludes from that definition ''[d]rugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents (70 FR 4534).'' In the corresponding preamble of the January 2005 final rule (70 FR 4228), we explained that this list of excluded drugs included agents when used for anorexia, weight loss, or weight gain and agents when used for cosmetic purposes or hair growth. However, in response to comment, we had erroneously asserted that to the extent that a drug was dispensed for a ''medically accepted indication'' as described in section 1860D–2(e)(1) of the Act, the drug could be covered for the treatment of morbid obesity (70 FR 4230). Both in the May 2007 proposed rule and in this final rule, we clarify that agents, when used for anorexia, weight loss, or weight gain, are specifically excluded from the definition of Part D drugs. A weight loss agent, even when not used for cosmetic purposes, is still ''an agent used for anorexia, weight loss, or weight gain'' for purposes of the exclusion from the definition of Part D drug.

Comment: We received several comments asserting that the clarification we made in the proposed rule regarding Part D coverage of drugs used to treat a medically accepted indication of obesity was a reversal of current Part D coverage policy.

Response: We disagree with these commenters. The clarification in our proposed rule did not expand or change our current policy regarding the exclusion from the definition of Part D drugs or agents used for anorexia, weight loss, or weight gain. Our policy with regard to coverage of these drugs has remained consistent since well before the Part D benefit was implemented on January 1, 2006 and is in accord with the statutory exclusion of such drugs from the definition of Part D drug as provided in section 1860D–2(e)(2) of the Act. In the May 2007 proposed rule, we simply clarified that we had made an error in the preamble of the January 2005 final rule by asserting that weight loss drugs could be potentially covered under the Part D program as part of a Part D basic prescription drug benefit. As discussed in the May 2007 proposed rule, we corrected this error via guidance to Part D sponsors and other stakeholders in July 2005.

Comment: A number of commenters asserted that our interpretation of the statutory exclusion of weight loss drugs was too narrow and that CMS was not appropriately distinguishing ''cosmetic'' weight loss from those clinical circumstances in which drugs are being specifically prescribed for an indication of obesity or significant weight management. Other commenters maintained that Congress intended for reimbursement of weight loss drugs when they were used in the treatment of defined disease states; that given the potential impact of obesity on American health care, as well as Medicare Part A coverage of obesity treatments, drugs when used to treat obesity should also be covered under Part D; and that Part D coverage of drugs used to treat obesity would be consistent with guidance and decision-making about these drugs by other DHHS agencies (for example, the

National Institute of Health's (NIH) treatment guidelines regarding obesity drugs and the Food and Drug Administration's (FDA) approval of drugs indicated for the treatment of obesity).

Response: Section 1860D–2(e)(2) of the Act specifically excludes from the definition of a Part D drug agents when used to treat anorexia, weight loss, or weight gain. Therefore, drugs when used to treat a medical indication of morbid obesity are not considered Part D drugs. While this statutory exclusion may create an inconsistency with regard to treatment approaches for morbid obesity under different parts of the Medicare program, Part D coverage policy is based on completely distinct statutory authority than Parts A and B. We note that similar to other drugs contained in section 1927(d)(2) of the Act that are excluded from the definition of Part D drugs (other than over-the-counter drugs), those Part D plans wishing to provide coverage of weight loss agents may do so as a supplemental benefit under enhanced alternative coverage, consistent with § 423.104(f).

Comment: A number of commenters asked that CMS clearly state that the Part D exclusion of weight loss drugs will not affect Part D coverage of drugs that may cause weight loss, but whose primary indication is not for obesity. A few other commenters noted that our exclusion of obesity drugs is inconsistent with CMS policy regarding Part D coverage of weight loss drugs under certain clinical situations (for example, Part D and Medicaid coverage for drugs when used to treat cachexia or AIDS wasting).

Response: Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act, provided they otherwise meet the requirements of section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act. A Part D drug's clinical side effect of weight loss would not permit its exclusion via section 1927(d)(2) of the Act since the drug's use was not prescribed for that purpose.

We have previously stated that we do not consider prescription drug products being used to treat AIDS wasting and cachexia as either agents used for weight gain or agents used for cosmetic purposes. Given the clinical complexities associated with AIDS wasting and cachexia, and the documented therapeutic action of these drugs to work beyond weight gain and prevent associated morbidity and mortality, the use of these products cannot be excluded from Part D by reference to section 1927(d)(2) of the Act. A summary of similar potential exclusions and their associated explanations can be found in Appendix B of Chapter 6 (Part D Drugs and Formulary Requirements of our Prescription Drug Benefit Manual), which is posted on the CMS Web Site at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf.*

(3) Insulin Inhalation Drugs and Supplies

With the passage of the MMA, Congress included within the definition of ''Part D drug'' found in section 1860D–2(e) of the Act ''medical supplies associated with the injection of insulin (as defined in regulations of the Secretary).'' In the January 2005 final rule, we interpreted the term ''medical supplies associated with the injection of insulin'' as comprising syringes, needles, alcohol swabs, gauze, and insulin delivery devices not otherwise covered by Part B, such as insulin pens, pen supplies, and needle-free syringes. On January 27, 2006, the FDA approved the first-ever inhaled insulin product. This inhaled medication is a dry powder inhaler (''DPI'') that requires a patient to place a small amount of powdered insulin into a hand-held chamber that permits inhalation of the insulin into the lungs. Subsequent to the FDA approval, we reviewed the issues surrounding inhaled insulin and concluded it would be appropriate to revise the definition of Part D drug to include certain supplies associated with the delivery of inhaled insulin. We proposed revising the definition of a Part D drug under § 423.100 to include ''[s]upplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin.'' We also indicated that our proposed change to the definition of a Part D drug was crafted consistent with our intention to narrowly construe what constitutes medical supplies associated with the delivery of insulin into the body in order to avoid an inappropriate expansion of the Part D benefit. Thus, we stated in the preamble to our proposed rule that we would expect Part D sponsors to apply drug utilization management tools to ensure the appropriate use of these supplies.

While we have learned since the publication of our May 2007 proposed rule that marketing of the first inhaled insulin product may be discontinued, the fact remains that this product is still approved for the U.S. market. Additionally, we received comments indicating that there are insulin products administered through routes other than injection in various stages of research and FDA approval. As a result, we believe our policy on inhaled insulin is still necessary and sound.

Comment: Most commenters on this issue supported our proposal to expand the definition of a Part D drug to cover those supplies directly associated with inhaled insulin. However, other commenters opined that the proposed definition was too narrow and CMS should broaden the definition of a Part D drug to encompass other potential mechanisms or supplies used for delivery of insulin into the body, such as novel insulin dosage forms and delivery systems that are currently under review by the FDA. Some commenters noted developments in diabetes treatment including new transdermal, intranasal and aerosolized insulin delivery methods. These commenters held that by not broadening the Part D drug definition to include insulin delivery supplies that are currently in the research and development pipeline, but which might someday be FDA-approved, CMS would be burdened with future rulemaking to modify the definition of a Part D drug when new FDA-approved products came to market. As a result, CMS might provide a competitive advantage to manufacturers whose insulin-related supplies are currently encompassed within the definition of a Part D drug over other manufacturers whose insulin supplies are also related to the direct delivery of insulin into the body but would not be covered under Part D in the absence of a further broadening of the definition of a Part D drug under § 423.100.

Response: We agree that our proposed rule too narrowly construed what constitutes medical supplies associated with delivery of insulin into the body for purposes of the definition of a Part D drug under § 423.100. Moreover, we believe that Congress intended to ensure diabetics' access to insulin by providing for coverage of the medical supplies directly associated with delivering insulin into the body. In light of continuing medical research and development of alternative mechanisms for insulin delivery, we believe it is consistent with Congressional intent that our definition of these supplies encompass all products that are directly associated with the delivery of insulin into the body, including future potential delivery mechanisms, and not limit coverage to supplies associated with the only two mechanisms of insulin

delivery (injection and inhalation) available to diabetics today. Consequently, we have removed our reference to the specific route of administration, ''through inhalation,'' in the definition of a Part D drug at § 423.100(i)(iv). Instead, our definition of a Part D drug will encompass supplies that are directly associated with delivering insulin into the body, such as the inhalation chamber used to deliver the insulin. We believe this modification will obviate the need for continued future rulemaking to ensure coverage of supplies that are directly associated with delivery of insulin into the body. In addition, we believe that our revised definition of the term Part D drug will level the playing field for the manufacturers of novel administration insulin supplies while avoiding an inappropriate expansion of the Part D benefit to insulin-related supplies in which the relationship to delivery into the body is more indirect. We have retained the example of the inhalation chamber in the definition of a Part D drug under § 423.100 only as an example of a product that is directly associated with the delivery of insulin into the body.

Comment: A few commenters suggested that we clarify that our proposed modification of the definition of a Part D drug excludes any insulin delivery device covered under the Part B durable medical equipment benefit.

Response: Paragraph (2)(i) of our existing definition of a Part D drug already excludes from Part D coverage those drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B. We believe that further clarification of this exclusion is unnecessary.

Comment: We received comments asking that CMS issue separate guidance indicating whether any novel insulin-related product will be covered under Part D.

Response: We disagree that we should issue product-specific Part D coverage guidance for all new FDA approvals. Part D sponsors and their Pharmacy and Therapeutics (P&T) Committees are required to evaluate new FDA-approved products and make timely coverage determinations that are consistent with the definition of a Part D drug under § 423.100. While we provide Part D sponsors with tools to assist sponsors with their reviews of new products, coverage determinations are ultimately a Part D sponsor's responsibility.

Comment: A number of commenters asked that we retract the statement we made in our proposed rule that we would expect Part D sponsors to apply drug utilization management tools to inhaled insulin supplies. These commenters stated that the application of such pharmacy based edits would impede access to these inhaled insulin supplies for beneficiaries who are appropriately qualified for this insulin delivery mechanism. Many of these same commenters stated that inhaled insulin supplies should be provided free of any utilization management tools to maximize use of this new therapy.

Response: We remind these commenters that all Part D sponsors, with the exception of Medicare Advantage private fee-for-service (PFFS) plans, are required under § 423.153(b) to establish reasonable and appropriate drug utilization management programs. As we stated in the May 2007 proposed rule, sponsors should ensure the appropriate and prudent use of all Part D drugs, including supplies associated with the direct delivery of insulin into the body and the use of drug utilization management tools, is appropriate to prevent inappropriate coverage and utilization of insulin-related supplies. In general, inhaled insulin supplies have either a specific life span based on the number of doses or actuations they deliver or, for more durable items, a manufacturer's recommended life span ranging from a few months to a year or more with proper cleaning and maintenance. It is therefore appropriate for a sponsor to evaluate claims for inhaled insulin supplies that are submitted for a period less than their recommended life span or period of use.

(4) Vaccine Administration Fee

On December 20, 2006, the Tax Relief and Health Care Act of 2006 was signed into law. Section 202(b) of that legislation amended the definition of a Part D drug at section 1860D–2(e)(1)(B) of the Act to include a reference to vaccine administration on or after January 1, 2008. In the May 2007 proposed rule (72 FR 29406) we indicated that we would amend the definition of Part D drug to conform to the statutory change. Accordingly, in this final rule, we have amended the definition of a Part D drug to include a reference to vaccine administration on or after January 1, 2008, consistent with the statute.

Comment: One commenter suggested we increase our outreach efforts regarding the availability of vaccine administration under Part D.

Response: We agree with this comment and have employed a number of methods to ensure that beneficiaries and providers are aware of this statutory change. We have updated our beneficiary outreach materials with specific information on Part D vaccine administration reimbursement, including the addition of a section to the annual evidence of coverage (EOC) notice that was mailed to all currently enrolled beneficiaries in advance of the 2008 Part D contract year. We have also incorporated information regarding Part D vaccine administration into our provider programs and have conducted a number of national level outreach programs addressing the availability of reimbursement under Part D for this new benefit in 2008. We have generated MedLearn Matters Articles on Part D vaccines and vaccine administration for display on the CMS Web site (*http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0727.pdf*). We have also issued guidance to Part D sponsors on vaccine administration so they can prepare for covering these services and address beneficiary questions. We plan on continuing various tiers of communication on Part D vaccine administration into 2008 and subsequent years.

Comment: One commenter asked that we monitor billing and payment for Part D vaccine administration over the next several months to identify and resolve issues that may arise with implementation of this new benefit under Part D.

Response: We agree with this comment. We intend to work very closely with our Part D sponsors on resolving any issues that arise with covering Part D vaccine administration in 2008 and subsequent years. We have developed a number of communication channels to solicit feedback from various stakeholders regarding the ongoing implementation of this new benefit, and we will take appropriate actions to address any issues with our Part D sponsors as they occur.

Comment: One commenter specifically suggested that we amend § 423.100 to add the following language to the definition of a Part D drug under paragraph (1)(v) of that definition: ''and for vaccine administration on or after January 1, 2008, its administration.''

Response: We agree with this comment. We are changing the definition of a Part D drug at § 423.100 to conform to the statutory change made by the Tax Relief and Health Care Act of 2006 to section 1860D–2(e)(1)(b) of the Act. Accordingly, we are modifying § 423.100 to include vaccine administration for Part D-covered vaccines on or after January 1, 2008.

b. Long-Term Care Facilities

In the January 2005 final rule (70 FR 4534), the term ''long-term care facility''

is defined in § 423.100 as a ''skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or a nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.'' However, in our corollary discussion of that term in the preamble of the January 2005 final rule (70 FR 4236), we inadvertently omitted institutions for mental disease (IMDs) from the list of facilities that meet the definition of a long term care (LTC) facility.

In the May 2007 proposed rule, we clarified that the definition of an LTC facility would include an IMD that is a nursing facility or other medical institution (which is a term defined at 42 CFR 4435.1009) and receives Medicaid payment for its services to an institutionalized individual under section 1902(q)(1)(B) of the Act. In other words, to the extent that a nursing facility or medical institution that is an IMD has as an inpatient any institutionalized individual (which means any full benefit dual-eligible individual for whom payment is made for IMD services under Medicaid throughout a month, as provided in section 1902(q)(1)(B) of the Act), that IMD will fall within the definition of a LTC facility in § 423.100.

We also clarified that as medical institutions, hospitals (including long-term care hospitals) that receive payments under section 1902(q)(1)(B) of the Act can meet the definition of an LTC facility. To the extent that inpatients in these hospitals exhaust their Part A inpatient days benefit, and payment is no longer available under Part A or Part B for drugs that would otherwise meet the definition of a Part D drug, such drugs are Part D drugs. Consequently, we indicated that Part D sponsors must ensure that they provide convenient access to network LTC pharmacies (which, in the case of a hospital, is typically the hospital's in-house pharmacy) for all of their enrollees who: (1) Need drugs for which payment is no longer available under Part A or Part B and otherwise meet the definition of a Part D drug; and (2) are inpatients in a hospital where the hospital is a ''medical institution'' under section 1902(q)(1)(B) of the Act and therefore would meet the Part D definition of an LTC facility.

Comment: Several commenters supported our clarification that an IMD may meet our definition of a long-term care facility and that, consequently, Part D plans must provide convenient access to a network long-term care pharmacy to the residents of such facilities. One commenter supported our proposed policy clarification but noted that there were significant practical implications. For example, plans might not receive notice that their members are IMD patients until after prescriptions have been filled and claims are submitted. Both this and the fact that most of these facilities use only in-house, State-run pharmacies to fill prescriptions often prevent plans from anticipating the need for contracts with these institutional LTC pharmacies. Another commenter echoed this statement, noting that Part D sponsors have experienced difficulty contracting with certain LTC pharmacies. One commenter asked us to clarify that we would determine a Part D plan to be in compliance with our convenient access requirements if it limited itself to pursuing contracts only with institutional LTC pharmacies that proactively sought inclusion in a plan's pharmacy network, consistent with the ''any willing pharmacy'' requirement. Another commenter asked us to clarify that plans would be considered compliant with the convenient access requirements even if they did not come to terms with an institutional LTC pharmacy, provided they made a good faith effort to contract.

Response: The fact that a Part D plan has met our LTC pharmacy network submission requirements as part of the application approval process does not preclude it from continuing its contracting efforts with LTC pharmacies as needed. In fact, continued contracting likely will be necessary in order for plans to meet the convenient access standard articulated at § 423.120(a)(5). This is particularly true as plans continue to identify LTC facilities and LTC pharmacies, and as they examine their auto-enrollment assignments and incoming enrollments. To the extent that a beneficiary is enrolled in a plan that does not have a contract with a LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a plan to take is to contract with the facility's contracted LTC pharmacy or—if that pharmacy will not sign a contract—with another LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary to ensure coverage for enrollees in a particular facility. For example, if a Part D sponsor becomes aware that one or more of its enrollees resides in a LTC facility that is not serviced by one of its network LTC pharmacies and cannot immediately either identify a network LTC pharmacy that can serve this particular facility or negotiate a contract with the facility's contracted LTC pharmacy, a retroactive contract might be necessary to ensure convenient access for the enrollees in question. This would particularly be the case if the facility's contracted pharmacy makes a good faith effort to negotiate but the sponsor does not quickly finalize a contract. We emphasize that plans will not be compliant with our LTC convenient access standard if they do not provide access to covered Part D drugs via a LTC pharmacy in their network for all of their enrollees who reside in LTC facilities.

We understand that there sometimes may be issues associated with contracting with the in-house, and often State-run and operated, pharmacies that many ICFs/MR, IMDs, and LTC hospitals use to provide drugs and pharmacy services to their patients—for example, multiple claim formats, post-consumption billing, and potential delays in billing due to systems and other start-up issues—that could delay or complicate contracting negotiations. In some States, licensing laws preclude facilities from obtaining prescription drugs and LTC services for their residents from anywhere but the facility's in-house pharmacy. Further, States may not be able to agree to certain standard clauses in some LTC standard contracts because of constitutional and legal restraints on States. For example, contractual provisions that require arbitration may be problematic for States that are legally precluded from going to arbitration. In these situations, Part D plans should be prepared to readily negotiate with States to address these issues. To the extent that plan contracting efforts involve communication with State-run and operated pharmacies, we have consistently encouraged sponsors to coordinate their efforts through a single point of contact at the State level. We provide lists of State contacts for IMDs and ICFs/MR on the CMS Web site at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_PartDContacts.asp#TopOfPage.*

Comment: Several commenters supported our clarification that plans must provide convenient access to a LTC pharmacy to inpatients in hospitals who have exhausted their Part A inpatient days benefit and whose drugs qualify as Part D drugs given that coverage is not available under Part A or Part B. One commenter expressed concern that our policy clarification was confusing and could create an unintended expansion of the Part D benefit. This commenter urged CMS to provide more specific guidance, consistent with the Part D statutory and regulatory framework, regarding the

circumstances under which Part D coverage would be available to patients who have exhausted their Part A inpatient days and for whom Part B coverage is not available.

Response: Section 1860D–2(e)(2)(B) of the Act requires the exclusion of coverage under Part D of any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual. In the preamble to January 2005 final rule, we clarified that this requirement meant that if payment could be available under Part A or Part B to that individual for such drug, then it would not be covered under Part D. This means that if an individual could sign up for Parts A or B, payment could be available under Part A or Part B, regardless of whether they actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. All individuals who are entitled to Part B only are almost never eligible for premium-free Part A but are eligible to buy into Part A for a premium. Consequently, for all Part D eligible individuals, drugs covered under Parts A and B are available if they choose to pay the appropriate premiums. However, drugs provided in an inpatient setting to an individual who has exhausted his or her lifetime inpatient hospital benefit under Part A are not drugs that could be covered under Part A for that individual. Unlike a beneficiary who, for example, chooses not to buy into Part B, there is no way for an individual who has exhausted his or her Part A inpatient stay benefit to obtain coverage under Part A for his or her drugs. Thus, once a Part D enrollee exhausts his or her Part A inpatient days benefit, any drugs that cannot be covered under Part B are Part D drugs provided they otherwise meet the definition of a Part D drug at § 423.100. The LTC convenient access standard is implicated when these individuals reside in hospitals that meet our definition of a LTC facility. However, because we envision it will be rare (and typically unforeseen) that an individual exhausts his or her inpatient Part A hospital benefit and remains hospitalized—and that the hospital meets the definition of a LTC facility—we expect that the need to contract with hospital pharmacies to provide Part D drugs to these individuals will be quite rare, and that contracting will be undertaken only on an as-needed basis. As discussed elsewhere in this preamble, to the extent that a beneficiary is enrolled in a plan that does not have a contract with a LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a plan to take is to contract with the facility's contracted pharmacy or—if that pharmacy will not sign a contract—with another network LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary to ensure coverage for enrollees in a particular facility. Part D plans will not be compliant with our LTC convenient access standard if they do not provide access to covered Part D drugs via a LTC pharmacy in their network for all of their enrollees who reside in LTC facilities. We will take appropriate compliance action if LTC enrollees' access to covered Part D drugs is compromised due to the unavailability of a network LTC pharmacy.

c. Contracted Pharmacy Network

Section 423.100 defines the ''contracted pharmacy network'' as ''pharmacies,'' including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees. In the January 2005 final rule (70 FR 4535), we made a technical error by inadvertently omitting clarifying language indicating that a pharmacy in a contracted pharmacy network must be licensed. We view this change as necessary in order to bring it in line with our term ''retail pharmacy'' which requires that a retail pharmacy be ''licensed.'' We proposed revising the definition of ''contracted pharmacy network'' to state that a pharmacy participating in a contracted pharmacy network must be licensed.

We received only one comment on this clarification, which supported our proposed revision. Accordingly, we are adopting the revised definition of ''contracted pharmacy network'' as set forth in the proposed rule without change.

2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)—Waiver or Reduction of Part D Cost-Sharing by Pharmacies

In the January 2005 final rule (70 FR 4240), we stated that we would allow waivers or reductions of cost-sharing by pharmacies to count as incurred costs. However, our statement was limited to pharmacies that are not also acting as other wrap-around coverage that generally would not count toward incurred costs (or true-out-of-pocket, (TrOOP) costs). We did not intend to allow pharmacy waivers to count as incurred costs in cases where a pharmacy also meets the definition of a group health plan, insurance or otherwise, or a third party payment arrangement, as those terms are defined in § 423.100.

In response to numerous requests for clarification of our policy with regard to waiver or reduction of Part D cost-sharing by network pharmacies, particularly by safety-net pharmacies, we clarified in the proposed rule that although we will generally allow waivers or reductions of Part D cost-sharing by pharmacies to count as incurred costs, this will not be the case for pharmacies affiliated with entities whose wrap-around coverage does not count as an incurred cost. This includes pharmacies operated by entities that are group health plans, insurance, government-funded health programs, or third party payment arrangements with an obligation to pay for covered Part D drugs. As noted in our response to comments below, we maintain our position in this final rule.

Comment: One commenter disagreed with our proposed clarification regarding the applicability to TrOOP of pharmacy waivers or reductions of Part D cost-sharing made by certain entities. This commenter believes that our clarification penalizes Part D sponsors that, as non-profit organizations, have historically and responsibly provided financial assistance (and now pharmacy waivers) to financially needy members as part of their mission. The commenter recommended that CMS either allow all or no pharmacy waived cost-sharing to count toward TrOOP, since every pharmacy is affiliated with one or more Part D sponsors and any pharmacy waiver can serve the economic interests of both the pharmacy and the sponsor. The commenter believes it is preferable for CMS to develop standards under which Part D sponsors could—through cost-sharing waivers granted by affiliated network pharmacies—assist non-LIS eligible enrollees with a demonstrated financial need and have that waived cost-sharing count toward TrOOP.

Response: We disagree with this commenter's recommendation. While we appreciate the fact that some Part D sponsors are non-profit entities with charitable missions, we note that a pharmacy owned and operated by an insurer is acting on behalf of an insurer. Because a Part D drug costs paid or reimbursed by an insurer, as that term is defined in § 423.100, cannot count as an incurred cost, per the definition of the term ''incurred cost'' in § 423.100, allowing pharmacy waivers funded by an insurer to count toward an enrollee's TrOOP balance would essentially be an

end run around our rules regarding incurred costs.

Comment: Two commenters did not support our policy clarification regarding the applicability to TrOOP of pharmacy waivers or reductions of Part D cost-sharing made by safety-net pharmacies, including Federally-qualified health centers (FQHCs). Given that many safety-net providers are fully or partially funded through government grants, their waivers or reductions of cost-sharing may leave many low-income individuals unable to reach the catastrophic coverage portion of their Part D benefits. These commenters assert that although safety-net providers rely on a variety of revenue sources—both public and private—to provide health care services, unlike other programs identified as ''government-funded health programs'' in the preamble to the January 2005 final rule, FQHCs do not necessarily use government funds to pay the cost of Part D drugs and should not necessarily be categorized as government-funded health programs. One of these commenters believes that recent operational guidance released by CMS indicating that DSH funds could count toward TrOOP further supports its position that health center-subsidized cost-sharing should count toward TrOOP. The commenter asserts that the receipt of any source of Federal funding should not automatically result in excluding health center cost-sharing from TrOOP expenditures.

Response: Payments made for Part D enrollees' Part D cost-sharing by any entity—including an FQHC or other safety-net pharmacy—that has an obligation to pay for covered Part D drugs on behalf of Part D enrollees, or which voluntarily elects to use public funds, in whole or in part, for that purpose, will not count toward that beneficiary's TrOOP expenditures. We understand that safety-net providers use a mix of private and public revenue sources to provide health care services and prescription drugs. As we stated in the January 2005 final rule, to the extent that an entity pays for the cost of drugs using a mix of private and public funds, the entity is considered a government-funded health program, and all of its Part D drug spending is excluded from TrOOP. However, if an entity can demonstrate to a Part D sponsor that it uses only non-public funds to pay for the cost of Part D drugs, that sponsor may allow for cost-sharing waivers or reductions in cost-sharing paid for by that entity's pharmacies to count toward TrOOP. Part D sponsors remain ultimately accountable for correctly tracking their enrollees' TrOOP expenditures.

We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services. In other words, receipt of Medicaid or Medicare DSH payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a ''government-funded health program.'' Even though DSH funds are not considered government funding streams that would render an entity a government-funded health program, DSH hospitals may be government-funded health programs given other government funding streams they receive. An entity that receives DSH funds but uses non-DSH government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will still meet our definition of a government-funded health program, and any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee's TrOOP balance. The same logic applies to FQHC pharmacies, meaning that cost-sharing waivers or reductions applied by an FQHC or other safety-net provider pharmacy that uses government funding streams to provide or pay on behalf of an individual the costs of Part D drugs, the costs of these drugs will not count toward a beneficiary's TrOOP balance.

Comment: One commenter asked us to clarify that only cost-sharing reductions that are in fact paid for by group health plans, government-funded health programs, or other third party payment arrangements will not count toward ''incurred costs'' and that cost-sharing waivers by a pharmacy, even if the pharmacy is affiliated with a payer, will count toward incurred costs. This commenter is particularly concerned that this language could be misconstrued to disallow waivers by pharmacies that are affiliated with Part D sponsors providing supplemental benefits under enhanced alternative coverage. The commenter also stated that this prohibition should apply only if the reduction or waiver is part of the coverage provided by a health plan or other third party payment arrangement, and not a waiver funded by the affiliated pharmacy itself.

Response: As we have previously stated, pharmacy waivers or reductions of Part D cost-sharing will count toward TrOOP when the pharmacy waiving or reducing the Part D cost-sharing does not meet the definition of a group health plan, insurance, government-funded health program, or party to a third party payment. A pharmacy is not subject to this prohibition simply because it is contracted with a Part D sponsor as a network pharmacy. We note that any cost-sharing associated with non-Part D drugs covered under a supplemental benefit does not meet the definition of an incurred cost per the definition of that term in § 423.100 and, therefore, any pharmacy waiver or reduction of such cost-sharing would have no impact on a beneficiary's TrOOP balance in any case.

3. Access to Covered Part D Drugs (§ 423.120)

a. Applicability of Some Non-Retail Pharmacies to Standards for Convenient Access (§ 423.120(a)(2))

In the January 2005 final rule (70 FR 4537), we made a technical error in § 423.120(a)(2) by inadvertently referring to ''rural health clinics'' as ''rural health centers.'' The correct terminology for those facilities is ''rural health clinics.'' Accordingly, we proposed to revise the regulatory text to correctly reference these entities in § 423.120(a)(2) by removing the phrase ''rural health centers'' and adding in its place ''rural health clinics.'' We received no comments with regard to this proposed revision. Therefore, this final rule adopts the proposed revision to § 423.120(a)(2) without change.

b. Adequate Access to Home Infusion Pharmacies (§ 423.120(a)(4))

We proposed to codify in regulation, at § 423.120(a)(4) (70 FR 4537), guidance that we issued with regard to access to home infusion pharmacies by Part D sponsors subsequent to our publication of the January 2005 final rule. This codification would ensure that our regulations provide specificity to the requirement that Part D enrollees receive adequate access to Part D-covered home infusion therapy. We specifically proposed to revise § 423.120(a)(4) to expressly require that a Part D plan's contracted pharmacy network provide adequate access to home infusion pharmacies through a contracted pharmacy network that, at a minimum: (1) Is capable of delivering home infused drugs in a form that can be administered in a clinically appropriate fashion; (2) is capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies; and (3) ensures that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing home infusion drugs.

In addition, we invited comments on the specification of a reasonable timeframe for the timely delivery of

home infusion drugs under Part D. We proposed a new requirement, at § 423.120(a)(4)(iv) of the proposed rule, that Part D plan sponsors provide covered home infusion drugs within 24-hours of discharge from an acute care setting. Except as otherwise noted below, this final rule adopts the requirements related to ensuring adequate home infusion access set forth in our proposed rule. Although the requirement for the timely delivery of home infusion drugs covered under Part D will be effective within 60 days of this final rule's appearance in the **Federal Register**, Part D sponsors will not be expected to implement this provision until January 1, 2009.

Comment: A number of commenters supported our proposal to codify in regulation how Part D sponsors were to ensure that enrollees have adequate access to home infusion pharmacies. Commenters specifically expressed support for our proposals to codify requirements that Part D plans ensure that their network pharmacies are capable of delivering home infused drugs in a manner than can be administered in a clinically appropriate fashion; provide infusible Part D drugs for both short-term and long-term chronic care therapies; and ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs. However, several other commenters requested clarification regarding our proposed language at § 423.120(a)(4)(iii), which would require Part D plans to ensure that their network pharmacies receive assurances that the professional services and ancillary supplies necessary for home infusion therapy be in place prior to delivery of a Part D home infusion drug. Some of these commenters recommended that we clarify that Part D plans—and not their network pharmacies—are ultimately responsible for ensuring this requirement is met. One commenter believed it was incumbent upon us to clarify that contracted pharmacies providing Part D enrollees with home infusion drugs need not make arrangements for the ancillary supplies and professional services themselves and that, instead, could meet the requirement by seeking and relying upon assurances from the discharging entity that infusion therapy supplies and services had been arranged. Another commenter believed that this proposed requirement fell outside the scope of the responsibilities of both Part D sponsors and their contracted pharmacies. This commenter pointed to the definition of dispensing fees at § 423.100, which does not encompass professional services, supplies, or equipment related to the administration of home infusion drugs, to bolster its argument that the professional services and ancillary supplies are not Part D-covered and, as such, outside the scope of benefits Part D sponsors are responsible for providing or even coordinating. Instead, this coordination should be the clinical responsibility of those health care providers—including hospitals, home health agencies, outpatient facilities, and physician offices—that are responsible for the implementation of continued care following a patient's discharge from an acute care setting.

Response: Although the Part D benefit does not cover equipment, supplies, and professional services associated with home infusion therapy, it does cover the ingredient costs and dispensing fees associated with infused Part D drugs. We disagree with the position that, because coverage under the Part D benefit is limited to the ingredient cost and dispensing fees associated with a Part D infusible drug, it is not within the scope of a Part D sponsor's responsibilities (or its home infusion network pharmacies' responsibilities) to ensure that the items and services that are necessary for providing home infusion therapy are in place prior to delivery of a home infusion drug. It is poor clinical practice to simply deliver a drug to an enrollee without assurances that these items and services—regardless of their source of coverage—have been arranged for prior to dispensing a Part D home infusion drug. We clarify that neither Part D plans nor their network pharmacies must directly make arrangements for the provision of the components needed to safely administer home infusion drugs (save for delivery of the drug itself) prior to an enrollee's discharge from an acute care setting; generally, facility discharge planners, in collaboration with a patient's physician, are responsible for ensuring that those components have been arranged for upon a patient's discharge. However, when plans' home infusion network pharmacies do not themselves supply the necessary supplies and services (which, again, are not covered under the Medicare Part D benefit), the Part D sponsor through its home infusion network pharmacy delivering the infusible Part D drug must, at a minimum, ensure that another entity, such as a home health agency, DME supplier, or the discharging hospital, has arranged for the provision of these supplies and services. In order for sponsors to comply with this requirement, their home infusion network pharmacies may seek and rely upon assurances from another entity (such as a home health agency, DME supplier, or discharging hospital) that the supplies and services in question have been arranged. Under our regulations at § 423.153(c), a Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions, and to improve medication use. We consider the follow-up to ensure that home infusion supplies and services are in place essential to ensuring that home infused drugs are administered in a clinically appropriate manner. Because this follow-up improves the use of home infusion medications and facilitates home infusion therapy more generally, we believe it is a minimum quality assurance standard under § 423.153(c).

As specified in § 423.120(a)(4), we expect that Part D sponsors will meet the requirements for ensuring adequate home infusion access through their contracted home infusion pharmacies. However, we clarify that, as provided in § 423.505(i), Part D sponsors remain ultimately responsible for compliance with all Part D requirements, even when they delegate services or activities to a contractor such as a network pharmacy, and that delegation of any of their Part D responsibilities must be consistent with the requirements of § 423.505(i)(4).

Coverage under the Part D benefit is limited to the ingredient cost and dispensing fees associated with a Part D infusible drug. Although the Part D benefit does not cover equipment, supplies, and professional services associated with home infusion therapy, there are instances in which some of the supplies and professional services can be covered under Part A or Part B. If a Medicare beneficiary is under an active home health plan of care and is receiving Medicare home health services, the cost of some of the infusion supplies (if the infusion is provided via gravity feed method) and the professional services are included in the Medicare home health 60-day episode payment. A list of supplies consolidated under the home health prospective payment system (HH PPS) is available on the CMS home health Web site at *http://www.cms.hhs.gov/HomeHealthPPS/03_coding&billing.asp#TopOfPage*.

Comment: We received a significant number of comments regarding our proposed requirement in § 423.120(a)(4)(iv) of the proposed rule that Part D plans provide covered home infusion drugs within 24 hours of discharge from an acute care setting.

Many commenters supported this proposed new requirement. Two commenters expressed concern that the proposed requirement is unfair and burdensome to the extent that it applies directly to the Part D plan itself. Because these commenters contend that our proposed requirement would result in plans having to build costly reporting processes and protocols to ensure compliance by contracted pharmacies, they recommend that we clarify that Part D sponsors will be in compliance with this provision if they include a requirement in their network pharmacy contracts that pharmacies provide covered home infusion drugs within the timeframes established by CMS.

A number of other commenters recommended that CMS strengthen its proposed requirement such that plans must provide covered home infusion drugs by the next required dose because patients that are discharged on home infusion therapy that is administered more frequently than at 24-hour intervals may not receive their drugs in a clinically acceptable timeframe. These commenters believe that modification of this requirement would bring it in line with industry best practices to make infusion drugs available by either the next required dose or within 24 hours. Another commenter expressed concern that the establishment of a 24-hour requirement is arbitrary and could create situations in which a contracted pharmacy is required to deliver products well in advance of the next scheduled dose. This commenter recommended that we modify our proposed requirement such that plans must ensure that the prescribed infusion drugs are delivered at the later of 24 hours after discharge or the time the product is required for the first post-discharge dose. Finally, several commenters asked us to clarify that the provision of home infusion drugs within 24-hours of discharge from an acute care setting should be contingent on the pharmacy being notified of the discharge by the enrollee or acute care provider prior to the discharge.

Response: We recognize that home infusion therapy may serve as a vehicle to promote early hospital discharge. Although we have learned—in our discussions with home infusion providers—that best practices involve the availability of infusion services upon discharge from an acute care setting either by the next required dose or within 24 hours of the discharge, we deliberately chose to phrase our proposed requirement at § 423.120(a)(4)(iv) such that home infusion drugs were to be provided within 24 hours of discharge from an acute care setting, and not by either the next required dose or within 24 hours of discharge. We believe our proposed timely delivery requirement struck a reasonable balance between ensuring the timely delivery of drugs needed for home infusion therapy and ensuring plan compliance with our standard. Because the timing of the next required dose post-discharge will vary by beneficiary and by drug, monitoring compliance with a ''next available dose'' requirement would be very difficult. For this reason, we are maintaining our proposed requirement that plans provide delivery of home infusion drugs within 24 hours of discharge. However, we did find some merit to the point raised by one commenter that the next required dose could be later than within 24 hours after discharge from an acute care setting and that it would be unfair to penalize a plan that did not deliver the necessary home infusion drug until sometime after the 24 hours post-discharge have elapsed, even if such delivery is consistent with the prescription as written. For this reason, our final rule modifies our proposed requirement by requiring delivery within 24 hours after discharge, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. Plans may contractually delegate the responsibility for ensuring timely delivery of home infusion drugs to their network pharmacies provided they meet the requirements of § 423.505(i) regarding relationships with pharmacies or other providers, related entities, contractors, subcontractors, and first tier and downstream entities. We also clarify that in order to comply with § 423.120(a)(4)(iv), a Part D plan or one of its home infusion network pharmacies must receive notification from a facility discharge planner or a similar entity of an acute care discharge and the need for home infusion therapy. However, we do not believe that Part D sponsors must build ''costly reporting processes and protocols'' to comply with our requirement at § 423.120(a)(4)(iv).

Comment: Two commenters urged us to ensure that Part D sponsors do not implement policies that could potentially delay or restrict beneficiary access to home infusion therapies, such as imposing prior authorization or utilization management edits on home infusion therapies, in order to facilitate a timely and efficient hospital discharge. Another commenter asked us to instruct plans to make available through their network pharmacies home infusion drugs in manufacturer-prepared, ready-to-use premixed formats or pharmacy filled single-use infusion devices, as these formats promote enhanced patient safety.

Response: We agree that Part D sponsors should not implement coverage restrictions that unduly limit access to infusible Part D drugs. CMS, in conjunction with industry partners, has identified a list of acute care drugs that are most commonly utilized in the home infusion setting. This list is available as part of our formulary guidance to Part D sponsors in Chapter 6 of our Prescription Drug Benefit Manual (see *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf*). The use of these drugs or drug classes often results in an earlier hospital discharge and reduced health care costs, and rapid access to these agents is imperative to these health care transitions. It is our expectation that Part D sponsors will not implement policies that could potentially delay or restrict beneficiary access to these important agents. In general, should prior authorization or other utilization management edits apply to any of these agents, we expect Part D sponsors to handle these edits in an expedited manner in order to facilitate hospital discharge within appropriate timeframes. To the extent that we receive complaints from plan enrollees or providers indicating that this is not the case, we will investigate and follow-up with plans to ensure they are complying with our requirements. We note, as well, that we expect Part D plans to include multiple strengths and dosage forms, when available, for each drug included in each drug category or class on their formularies. This includes those dosage forms commonly used in long term care and home infusion settings.

Comment: One commenter encouraged CMS to conduct a study on Part D enrollees' access to home infusion drugs and their out-of-pocket expenditures.

Response: Access to home infusion drugs is important. We plan to continue to assess the adequacy of home infusion pharmacy access based on an evaluation of plans' home infusion pharmacy networks. We also plan to aggressively respond to beneficiary and provider complaints alleging compromised access. As we continue to implement the Part D benefit, we will consider other ways of monitoring access to home infusion drugs to ensure it is adequate.

C. Subpart F—Submission of Bids and Monthly Beneficiary Premiums: Plan Approval—Timing of Payments (§ 423.293(a))

We proposed a technical correction to § 423.293(a) (70 FR 4546) to reflect the statutory requirement that all the provisions of section 1854(d) of the Act apply in the same manner as they apply under Part C of Title XVIII of the Act. Section 1860D–13(c)(1) of the Act states that, with two exceptions not particularly relevant to this discussion, the provisions of ''section 1854(d) shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under part C, except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.'' Section 1854(d)(1) of the Act requires an organization to permit the payment of both basic and supplemental premiums on a monthly basis. This concept is reflected in the Part C regulations at § 422.262(e). In accordance with the statutory mandate, we have already required plans to permit beneficiaries to pay their premiums on a monthly basis. We proposed to make a technical correction to § 423.293(a) to cite both § 422.262(f) and § 422.262(e). We did not receive any comments on the proposed changes to § 423.293(a) and therefore adopt the changes as final without modification.

D. Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage: Payment Appeals (§ 423.350(b))

In the January 2005 final rule (70 FR 4550), we made a technical error in § 423.350(b). In this paragraph, we inadvertently used the phrase ''notice of the adverse determination'' when we said that the request for reconsideration for a payment determination must be filed within 15 days from the date of the notice of the adverse determination. The term ''notice of the adverse determination'' is not relevant here. We proposed to revise the regulation text to instead cite to the notice of final payment for risk adjustment, reinsurance, low-income cost sharing subsidies, or risk-sharing payments under §§ 423.343(b), 423.343(c), 423.343(d) or 423.336, respectively. We did not receive any comments on the proposed changes to § 423.350(b), and therefore, adopt the changes as final without modification.

E. Subpart I—Organization Compliance With State Law and Preemption by Federal Law—Waiver of Certain Requirements To Expand Choice (§ 423.410)

In accordance with section 1860D–12(c)(2)(B) of the Act, which describes the special waivers available for the 2006 and 2007 plan years, we proposed to revise § 423.410(d) to correct an error. We believe that the statute requires only a substantially complete (rather than a fully complete) application to have been submitted to the applicable state in order for an applicant to be granted the special waiver for 2006 and 2007. Therefore, we proposed to correct the regulatory language to require that an applicant submit a substantially completed application to the state in order for the applicant to be eligible for the § 423.410(d) waiver. We received no comments regarding our proposed change. Therefore, this final rule adopts the proposed revision to § 423.410(d) without change.

F. Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

1. Application of Part D Rules to Certain Part D Plans on and After January 1, 2006 (§ 423.458)

We proposed to revise § 423.458(d)(2)(ii) because we inadvertently omitted a reference to section 1894 of the Act in describing the statutory authority for the benefits offered by a Program of All Inclusive Care for the Elderly (PACE) organization. As published in the January 2005 final rule (70 FR 4552), § 423.458(d)(2)(ii) referenced only section 1934 of the Act when describing benefits provided by PACE organizations. In fact, PACE operates under both the Medicare and Medicaid statutes, and all descriptions to PACE benefits should refer to both sections 1894 and 1934 of the Act. We therefore proposed to revise § 423.458(d)(2)(ii) so that it refers to benefits offered by a PACE organization under both sections 1894 and 1934 of the Act. We received no comments on our proposed revision to § 423.458(d)(2)(ii) and are therefore adopting it as proposed.

2. Coordination of Benefits With Other Providers of Prescription Drug Coverage (§ 423.464)

a. Coordination of Benefits With Rural Health Clinics

In the January 2005 final rule (70 FR 4553), we made a technical error in § 423.464(f)(1)(vii) by inadvertently referring to rural health clinics as rural health centers. In fact, our intent was to reference facilities described in section 1861(aa)(2) of the Act, and the correct terminology for those facilities is rural health clinics. Accordingly, we proposed to correct the reference to these entities in § 423.464(f)(1)(vii) by removing the phrase rural health centers and adding in its place rural health clinics. We did not receive any public comments on our proposed correction to § 423.464(f)(1)(vii) and are therefore adopting the correction as proposed.

b. Coordination of Benefits With Part D Plans and Other Payers

We proposed to codify in § 423.464(f) guidance we have already issued to Part D sponsors addressing coordination of benefits requirements in cases that involve another Part D plan that is not the correct Part D plan of record or another payer that has incorrectly paid as primary for a covered Part D drug for an enrolled beneficiary. In accordance with sections 1860D–24(a)(1) and (b) of the Act, § 423.464(a) of the regulations extends the coordination of benefits requirements in section 1860D–23 of the Act applicable to Part D plans vis-à-vis State Pharmaceutical Assistance Programs (SPAPs) to other entities providing prescription drug coverage. We proposed to clarify § 423.464(f)(1) to state that included among the entities providing other prescription drug coverage with which Part D plans must coordinate are other Part D plans. Although Part D plans are already obligated to coordinate with group health plans, as provided in § 423.464(f)(1)(ii), we believed this revision formalizes our implicit recognition of other Part D plans as other entities providing prescription drug coverage with which a beneficiary's correct Part D plan of record must coordinate.

We also proposed to amend § 423.464(f) by adding a fifth paragraph that clarifies that Part D plans coordinate benefits with other Part D plans through the reconciliation process we have developed for 2006, which involves making payments to other Part D plans on the basis of the covered plan-paid and low-income cost-sharing subsidy amounts reported to them by CMS with respect to transferred enrollees. Payments made by the Part D plans as part of this reconciliation process would be made without regard to the plan's formulary or drug utilization review edits.

In addition, we proposed modifying § 423.464(f) by adding a sixth paragraph that would require Part D sponsors to coordinate benefits on a timely basis with other third parties and use CMS-developed reconciliation processes,

when established, in situations in which a payer other than the correct Part D plan of record pays for covered Part D drug costs as a primary payer. Except as otherwise provided below, the final rule adopts the revisions to § 423.464(f) set forth in our proposed rule.

Comment: Many commenters supported our proposed clarification and codification of previously issued guidance on Part D plan sponsor coordination of benefits with other payers. Several commenters, in expressing their support, noted the importance of the reconciliation processes in avoiding pharmacy reversal and claims re-adjudication. One commenter agreed with the proposed codification, but requested that the provision specifically address the reconciliation of inaccurate cost-sharing amounts withheld from pharmacy payments by Part D plan sponsors.

Response: We are pleased with the extent of the support expressed for the proposed changes. However, we believe the coordination of benefits (COB) provisions at section 1860D–24 of the Act do not permit expanding § 423.464 to address the reconciliation of inaccurate cost sharing withheld from pharmacy payments. The reconciliation process provision is specific to other entities providing prescription drug coverage and the inclusion of pharmacies would be inconsistent with section 1860D–24(b) of the Act. Paragraph (5) of this section of the Act extends the COB requirements to ''other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision'' of drugs; it does not apply to providers holding accounts receivables resulting from incorrect cost sharing or otherwise.

Further, the requested extension of the reconciliation process to include pharmacies cannot be construed as a logical extension of the proposed rule and therefore its inclusion would violate the requirements of the Administrative Procedures Act concerning adequate public notice. Although we are not extending the provision as requested, existing CMS policy requires Part D plan sponsors to pay for covered Part D drugs provided during the retroactive enrollment periods. We have clarified in our policy issuances that this requirement includes both out-of-network pharmacies holding receivable balances for covered Part D drug costs, and network pharmacies holding receivable balances for covered Part D drug claims incurred during a beneficiary's period of retroactive Part D enrollment.

Comment: Another commenter agreed with our proposed clarification, but recommended that CMS require that reconciliation processes with non-Part D sponsors include the submission of claims-level data to the Part D plan sponsors. The commenter notes that claims-level data is required for the accurate calculation of beneficiary true out-of-pocket costs, prescription drug event data reporting, and payment reconciliation with CMS.

Response: While we appreciate the importance of claims-level data to reconciliation with non-Part D payers, we do not have the authority to regulate the activities of non-Part D payers. Also, we do not believe it would be appropriate to include the detail recommended by the commenter when it concerns as-yet-to-be developed CMS reconciliation processes.

Comment: Two commenters expressed concern that the proposed provision does not address the payment reconciliation process or adjustments for claims Part D plans receive after the coverage year. The commenters noted that this non-point-of-sale claims volume is not insignificant and therefore recommended that CMS extend the periods of time for submission of claims and data reporting so that these claims may be included in the payment reconciliation process.

Response: The established deadlines for submission of claims and data reporting are necessary in order to ensure a timely payment reconciliation process. However, we understand and appreciate the concern that some claims will not be available for submission until after these deadlines, and therefore, will not be included in the payment reconciliation process. Per § 423.346, we have discretion to reopen and revise initial or reconsidered final Part D payment determinations. One of the grounds for finding good cause to reopen a final payment determination is the furnishing of new and material evidence that was not readily available at the time the final determination was made. Thus, in cases where claims data becomes available after the submission deadlines which would have a material impact on the final Part D payments, we will determine whether a reopening of the final Part D payments is appropriate.

G. Subpart K—Application Procedures and Contracts With Part D Plan Sponsors

1. General Provisions (§ 423.504)—Submission of Bids

In § 423.504, we inadvertently made reference to § 423.265(a)(1) rather than § 423.265. Section 423.265(a) gives only the most narrow and rudimentary of information concerning the bidding process, our intent was to cite in its entirety the much broader list found under § 423.265 (Submission of bids and related information). Accordingly, we proposed to correct the reference in § 423.504(a) to cite all of § 423.265 (72 FR 29412). We received no comments regarding our proposed correction. Therefore, the final rule adopts the revision to § 423.504 set forth in our proposed rule.

2. Contract Provisions (§ 423.505)

We proposed to correct the citation for the False Claims Act in § 423.505. The correct reference to the False Claims Act is 31 U.S.C. 3729 *et seq.* Accordingly, we proposed to correct the reference found under § 423.505 (h)(1) by replacing 32 U.S.C. 3729 *et seq.* with 31 U.S.C. 3729 *et seq.* (72 FR 29412). We received no comments regarding our proposed correction. Therefore, the final rule adopts the revision to § 423.505 (h)(1) set forth in our proposed rule.

3. Failure To Comply With the Dissemination of Information Requirements Grounds for Contract Termination (§ 423.509(a)(9))

In § 423.509(a)(9), we indicate that CMS may terminate a plan's contract if the plan substantially fails to comply with the Part D marketing requirements (70 FR 4559). This provision cites the marketing requirements at § 423.128, which is an incorrect citation. Section 423.128 deals with the dissemination of Part D plan information, not with plans' marketing requirements, per se. Therefore, we proposed to revise the regulation text, consistent with our original intent, to reflect that a plan contract may be terminated if a plan sponsor substantially fails to comply with the marketing requirements in § 423.50 or the dissemination of Part D plan information requirements in § 423.128. (72 FR 29412). We received no comments regarding our proposed correction. Therefore, the final rule adopts the revision to § 423.509(a)(9) as proposed without change.

H. Subpart M—Grievances, Coverage Determinations, and Appeals

1. Definitions (§ 423.560)

We proposed to make technical changes to the definitions of ''appointed representative'' and ''projected value,'' and to add language to the definition of appointed representative indicating that an enrollee's appointed representative may request a grievance on the enrollee's behalf. We also proposed to revise the definition of projected value

in § 423.560 to be consistent with the definition of projected value provided in the preamble of the January 2005 final rule (70 FR 4360) and in the regulation text at § 423.610(b).

Comment: We received a comment suggesting that we grant appointed representative status to long-term care (LTC) facility staff.

Response: We agree with the commenter that LTC caregivers should be able to represent resident enrollees in the Part D appeals process. However, the decision to have a representative is left with the enrollee, and we neither encourage nor discourage representation. If a Part D enrollee chooses to appoint an LTC caregiver as his or her representative in the Part D appeals process, the current regulations allow the enrollee to do so.

Comment: Another commenter asked that the appointed representative policy operate consistent with State family and surrogate laws.

Response: We agree with the commenter's recommendation and believe that the regulations already address the commenter's suggestion. Section 423.560 defines appointed representative as any person properly appointed by an enrollee, or any person authorized to act as an enrollee's representative under a State or other applicable law. Thus, both individuals appointed by enrollees and individuals authorized under State or other applicable law may act on behalf of Part D enrollees in obtaining coverage determinations or in dealing with any of the levels of the appeals process, subject to the rules described in part 423, subpart M.

Comment: We received one comment recommending that we modify the definition of projected value in § 423.610(b) to comply with the definition in § 423.560 instead of revising the definition of projected value in § 423.560 to comply with the definition in § 423.610(b).

Response: We disagree with the commenter. As noted in the May 2007 proposed rule, the definition of projected value in § 423.560 is not consistent with the definitions of projected value in the January 2005 final rule (70 FR 4360) and in § 423.610(b) of the regulations. Both of those definitions limit projected value to benefits incurred within a plan year. Limiting projected value to benefits incurred within a plan year is consistent with sections of the regulation that limit exception approvals to a plan year and permit enrollees to switch plans at the beginning of each plan year. (See § 423.38 and § 423.578(c).)

2. Expediting Certain Coverage Determinations (§ 423.570)

We proposed to amend the regulation text of § 423.570(d)(3) by requiring a Part D sponsor to deliver written notice to an enrollee within 3 calendar days after it denies a request to expedite a coverage determination.

Comment: We received one comment suggesting that we require plans to deliver notice of a decision not to expedite a coverage determination to a dispensing pharmacy when an enrollee is a resident of a LTC facility.

Response: We disagree with the commenter. Section 423.570(d)(2) of the regulations requires plan sponsors to deliver oral notice of a decision not to expedite a coverage determination to the enrollee (or the enrollee's appointed representative) and the enrollee's prescribing physician. Section 423.570(d)(3) requires the plan sponsor to send an equivalent written notice, but it does not indicate if the notice must be sent to the enrollee (or the enrollee's appointed representative), the prescribing physician, or both. Our proposal simply corrects this omission. The commenter's recommendation to add a new party to the list of recipients would create a new regulatory requirement that is not directly related to our proposed clarification. However, it is worth noting that an employee of a pharmacy could receive this and other notices if he or she were an enrollee's appointed representative.

Comment: Another commenter recommended requiring plans to deliver notice of a decision not to expedite a coverage determination both to the enrollee and to his or her appointed representative, if one is on record.

Response: We do not agree with the commenter's suggestion. We require notices to be delivered to an enrollee or an enrollee's appointed representative, but not to both. If a representative is acting on behalf of an enrollee in the Part D appeals process, he or she is standing in the shoes of the enrollee and must inform the enrollee of the status of a coverage determination or appeal and the results of any actions taken on behalf of the enrollee. It could be confusing for an enrollee to receive a notice that is also sent to his or her appointed representative since the enrollee is relying on that person to resolve any issues related to his or her Part D appeal.

3. Expediting Certain Redeterminations (§ 423.584)

We proposed to revise the regulation text of § 423.584(b) to include the procedures for filing and withdrawing a request for an expedited redetermination. We did not receive any comments on the proposed change to § 423.584(b) and therefore adopt this change as final without modification.

4. Right to an ALJ Hearing (§ 423.610)

We proposed revising the regulation text of § 423.610(c)(2) by numbering the three requirements listed under § 423.610(c)(2) with (i), (ii), and (iii). We did not receive any comments on the proposed change to § 423.610(c)(2) and therefore adopt this change as final without modification.

I. Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

1. Premium Subsidy Amount (§ 423.780)

a. Low-Income Benchmark Premium Amount

Section 1860D–14 of the Act requires us to subsidize the monthly beneficiary premium and cost-sharing amounts incurred under Part D by Part D eligible individuals with income and resources below certain thresholds. Our rules mirror the statute's structure, which divides low-income subsidy eligible individuals into two different groups, based on income and resources: (1) Full subsidy eligible individuals (as defined at § 423.772); and (2) other low-income subsidy eligible individuals (as defined at § 423.772). The different groups are entitled to different amounts of premium assistance and reductions in cost sharing.

As stated in the May 2007 proposed rule, we became aware that certain sections of part 423 subpart P need to be corrected to accurately reflect the statutory language in section 1860D–14 of the Act. Specifically, in the January 2005 final rule (70 FR 4574) there is an error in § 423.780(b), which sets forth the methodology for determining the premium subsidy amount. In accordance with section 1860D–14(b)(1) of the Act, § 423.780(b)(1) of the regulation provides that the premium subsidy amount for a full low-income subsidy eligible individual is equal to the lesser of— (1) the portion of his or her plan's monthly beneficiary premium attributable to basic coverage; or (2) the greater of the low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP offering basic prescription drug coverage in the PDP region where the individual resides. The low-income benchmark premium amount, as defined in the statute at section 1860D–14 of the Act, specifically describes how to calculate the low-income subsidy for regions with only one PDP sponsor. At section

1860D–14(b)(2)(A)(i) of the Act, the statute indicates that ''the term 'low-income benchmark premium amount' means, with respect to a PDP region in which all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans.'' However, while § 423.780(b)(2)(i) accurately describes the low-income benchmark premium amount calculation for PDP regions with multiple PDP sponsors, it omits the methodology for determining the low-income benchmark premium amount in a PDP region with any number of MA–PD plans but only one PDP sponsor (although the preamble of the January 2005 final rule correctly describes this methodology). We proposed to correct this error in the current rule to comport with the statute and our intent as outlined in the preamble of the January 2005 final rule by adding a new subparagraph (A) to § 423.780(b)(2)(i) to correctly reflect the methodology for situations where there is only one PDP sponsor. We note that in 2006, all PDP regions included multiple PDP sponsors.

We also proposed revisions to § 423.780(b)(2)(i)(B). Our proposed change would make clear that in multiple-PDP sponsor regions, the MA–PD plans included in the calculation of the low income benchmark weighted average are coordinated care plans, as defined at § 422.4(a)(1)(iii). We did not receive any comments on the proposed changes § 423.780(b)(1) and (2)(i). Therefore, we are adopting the changes to § 423.780(b)(1) as final without modification. However, we are not finalizing the changes to § 423.780(b)(2)(i) in this final rule; rather, we have revised this provision in the Modification to the Weighting Methodology Used to Calculate the Low-income Benchmark Amount final rule that published in the April 3, 2008 **Federal Register** (73 FR 18176).

b. Premium Subsidy for Late Enrollment Penalty

We indicated in the May 2007 proposed rule that we needed to correct an omission in the regulation text at § 423.780(e) related to the subsidy of any late enrollment penalty imposed on other low-income subsidy individuals. In this paragraph, we omitted a provision from the statute at section 1860D–14(a)(2)(A) of the Act, which provides for a subsidy or any late enrollment penalty imposed on other low-income subsidy eligible individuals. Accordingly, we proposed to revise § 423.780(e) to accurately reflect the statute. We proposed that this subsidy would be based on a linear sliding scale, with a higher subsidy available to other low income subsidy eligible individuals with incomes at or below 135 percent of the Federal poverty line (FPL), and the lowest level subsidy available to other low income subsidy eligible individuals with incomes below 150 percent of the FPL.

The table below illustrates the penalty subsidy available to other low income subsidy individuals.

Income level	Percent of penalty subsidized during the first 60 months individual is subject to penalty	Percent of penalty subsidized after the first 60 months individual is subject to penalty
≤135% FPL	80	100
>135% and ≤140% FPL	60	75
>140% and ≤145% FPL	40	50
>145% and <150% FPL	20	25
≥150% FPL	0	0

Comment: Commenters supported the proposed changes to calculation of the low-income premium subsidies for other low income subsidy eligible individuals. However, they also indicated that other low-income subsidy beneficiaries subject to the late enrollment penalty are still burdened with paying 20 percent of such penalty for the first 60 months during which the penalty is imposed, and that this burden serves as a disincentive for low-income beneficiaries to enroll in Medicare Part D.

Response: While we recognize the concern of the commenters for the needs of low-income beneficiaries, section 1860D–14(a)(1)(A) of the Act requires late enrollment penalties for the low-income subsidy population. Therefore, we are adopting these proposed revisions in the final rule. Please note, however, that we have used the Secretary's authority under section 402(a)(1)(A) of the Social Security Amendments of 1967, 42 U.S.C. 1395b–1(a)(1)(A) (expressly made applicable to Part D in section 1860D–42(b) of the Act) to implement the Medicare payment demonstration entitled ''Elimination of 2006 Late Enrollment Penalty.'' Under this demonstration, as amended in 2007, we will not collect the late enrollment penalty from individuals who receive a low-income subsidy and enroll in the Medicare Prescription Drug Program in 2006, 2007, or 2008. As long as these individuals remain continuously enrolled in Medicare Part D, they will not be assessed a late enrollment penalty. This demonstration is of limited duration and is only applicable to low-income subsidy eligible individuals who enroll in Medicare Part D in 2006, 2007, or 2008. Following an evaluation of this Medicare payment demonstration, we will review the results of the evaluation and may consider recommending that Congress eliminate the late enrollment penalty for individuals who receive the low-income subsidy.

J. Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

1. Requirements for Qualified Retiree Prescription Drug Plans (§ 423.884)

a. Application Timing

Section 423.884(c) sets forth the application requirements for the retiree drug subsidy (RDS). Section 423.884(c)(5)(i) requires a plan sponsor to file an application for the subsidy by no later than 90 days before the beginning of its plan year, unless we grant the sponsor's request for an extension (for example, the deadline for 2007 calendar year plans under the regulation was October 2, 2006). As we stated in the proposed rule, we believe that an end-of-month deadline would be administratively simpler for both plan sponsors and CMS to track. Accordingly, we proposed to replace the 90-day requirement with the phrase ''by a date specified by CMS in published guidance'' to allow us the discretion to specify an end-of-month deadline in the future through guidance. We noted that

this would give us the flexibility to take into account operational systems changes in determining the RDS application deadline, while providing adequate advance notice to plan sponsors and their advisers. We did not receive any comments on the proposed change to § 423.884(c)(5)(i) and therefore adopt this change as final without modification.

b. Data Match

In accordance with section 1860D–22(a)(1), employer and union sponsors of qualified retiree prescription drug plans may receive the RDS only for their enrollees who are eligible for, but not enrolled in, a Part D plan. In order to properly administer this requirement, we compare the retiree enrollment data that a plan sponsor submits to us with CMS enrollment records to ensure that sponsors are only receiving retiree drug subsidies for qualifying covered retirees, as defined in § 423.882. In § 423.884(c)(7)(i), we specifically referenced the Medicare Beneficiary Database (MBD) as the system of record for this data match (70 FR 4578). While the MBD is currently the system we use to verify retirees' Part D eligibility and enrollment status, we also may use other systems of record for purposes of the data match. Accordingly, we proposed to modify § 423.884(c)(7)(i) by substituting a general reference to ''CMS database(s)'' for the ''Medicare Beneficiary Database (MBD).'' We did not receive any comments on the proposed change to § 423.884(c)(7)(i) and therefore are finalizing this change without modification.

c. Actuarial Equivalence

(1) Medicare Supplemental Adjustment

Section 1860D–22(a)(2)(A) of the Act requires that a plan sponsor claiming the RDS provide an attestation that its qualified retiree prescription drug plan is actuarially equivalent to Medicare standard prescription drug coverage. Section 423.884(d)(5) sets forth a two-prong test for determining the actuarial value of the defined standard prescription drug coverage under Part D against which the actuarial value of the retiree prescription coverage under the qualified retiree prescription drug plans is measured (70 FR 4578). The actuarial equivalence test includes a ''gross test'' and a ''net test.'' Section 423.884(d)(5)(iii)(B)(2) states that the net test includes a ''Medicare supplemental adjustment'' which allows a plan sponsor that provides supplemental coverage for its retirees that elect Part D coverage to reflect the impact of the supplemental coverage on the net value of defined standard prescription drug coverage under Part D. Supplemental coverage for this purpose means drug coverage over and above defined standard prescription drug coverage under Part D for those retirees that enroll in Part D coverage. As stated in the preamble to the May 2007 proposed rule, our intent, which we clarified in operational guidance to plan sponsors, was that a sponsor must actually provide employer or union-sponsored supplemental retiree drug coverage to its retirees who enroll in Part D in order to qualify for the Medicare supplemental adjustment. Therefore, we proposed to revise § 423.884(d)(5)(iii)(B)(2) to indicate that plan sponsors must actually provide supplemental drug coverage for their retirees that elect Part D in order to take advantage of the Medicare supplemental adjustment provided for in § 423.884(d)(5)(iii)(B)(2). We view this revision as merely incorporating previously issued guidance, and not as a new policy proposal. We did not receive any comments on the proposed change to § 423.884(d)(5)(iii)(B)(2) and therefore adopt this change as final without modification.

(2) Noncalendar Year Plans

Section 1860D–22(a)(2)(A) of the Act requires a plan sponsor claiming the RDS to provide an attestation that its qualified retiree prescription drug plan is actuarially equivalent to the Medicare defined standard prescription drug coverage. The actuarial equivalence test requires that the actuarial value of the plan sponsor's retiree drug coverage under its qualified retiree prescription drug plan be compared to the actuarial value of the Medicare defined standard prescription drug coverage had the sponsor's Part D eligible individuals taken that coverage.

Sections 423.884(d)(5)(iii)(C) and (D) state that for purposes of comparing the actuarial value of the retiree coverage under the sponsor's plan and the Medicare defined standard prescription drug coverage, the actuarial valuation of the latter is based on the initial coverage limit, cost sharing amounts, and annual out-of-pocket threshold in effect at the start of the plan year. However, the attestation must be submitted to us no later than 60 days after the publication of these coverage limits for the upcoming calendar year; otherwise, the valuation must be based on the initial coverage limit, cost sharing amounts, and annual out-of-pocket threshold for the upcoming plan year. The intent of this 60-day provision is to prevent actuaries from having to redo valuations for noncalendar year plans that were based on the current calendar year initial coverage limit, cost sharing amounts, and annual out-of-pocket threshold when, after doing their calculations but prior to submission of the RDS application, we publish the coverage limits for defined standard drug coverage for the upcoming calendar year.

As we stated in the proposed rule, plan sponsors' actuaries have indicated to us that they believe they should have the flexibility for non-calendar year plans to use the initial coverage limit, cost-sharing amounts, and annual out-of-pocket threshold for defined standard drug coverage for the upcoming plan year, provided it does not impact their ability to meet the application deadline. We agreed that actuaries should have this flexibility, and proposed to amend § 423.884(d)(5)(iii)(C) to permit a noncalendar year plan's actuary to use either the current or subsequent year's coverage limits for defined standard prescription drug coverage when the attestation is submitted within 60 days of the publication of the following year's cost limits. We also proposed to make corresponding changes to § 423.884(d)(5)(iii)(D). We did not receive any comments on the proposed change to §§ 423.884(d)(5)(iii)(C) and (D), and therefore are finalizing this change without modification.

(3) Benefit Options

Employment-based retiree health coverage often has different plan design features or benefit options that apply to specific groups of retirees. Section 423.882 defines a benefit option as a particular benefit design, category of benefits, or cost sharing arrangement offered within a group health plan. Section 423.884(d)(5)(iv) states that a plan with more than one benefit option must pass the gross test separately on a disaggregated basis for each option, but that it may pass the net test on an aggregated or disaggregated basis. As we stated in the proposed rule and in guidance published previous to that rule, our intent was that a plan sponsor should also have the option of aggregating a subset of the benefit options in a group health plan for the actuarial equivalence net test in addition to aggregating all of the options or evaluating each option individually. If the sponsor combines two or more benefit options, the sponsor may not claim the subsidy for those benefit options excluded from the net value calculation, even if those options meet the gross test (unless the excluded benefit options each individually meet the net test). We proposed to amend the final rule to reflect this clarification of

our intent, which reflects policy that has been applied consistently since the rule was published. We did not receive any comments on the proposed change to § 423.884(d)(5)(iv) and therefore are finalizing this change without modification.

(4) Submission of Actuarial Attestation Upon Material Change

Section 1860D–22(a)(2)(A) of the Act requires that a plan sponsor submit an actuarial attestation annually or at another time as the Secretary may require. Section 423.884(d)(6)(ii) requires submission of an attestation no later than 90 days before the implementation of a material change to the coverage. While the term ''material change'' can be construed broadly to include any change to the value of a sponsor's plan, we indicated in the proposed rule that ''[w]e would not require submission of an attestation under § 423.884(d)(6)(ii) where a plan sponsor still meets the actuarial equivalence test after the change, and there are no benefit options being added'' (72 FR 29416). We did not receive any comments on this clarification of our policy. However, as has always been the intent of the regulations, an attestation must be submitted only when coverage satisfies the actuarial equivalence standards in the regulations, and should not and must not be submitted when coverage fails to satisfy those standards. Therefore, in the text of the final regulation, we are articulating the clarification in the proposed regulation in a way that makes this distinction. Specifically, § 423.884(d)(6)(ii) in the final regulation states that an attestation must be provided no later than 90 days before the implementation of a material change to the sponsor's drug coverage, and that the term ''material change'' means the addition of a benefit option that does not have the impact of causing the actuarial value of the retiree prescription drug coverage to fail the actuarial equivalence standards set forth in the regulations. (Regardless of whether there has been such an impact, a plan sponsor, upon deleting a benefit option for RDS purposes, must provide an update to CMS of its list of individuals for whom it is claiming RDS. (See § 423.884(c)(6)). The final regulation also adds § 423.884(d)(7), which states that a sponsor must notify CMS, in a form and manner specified by CMS, no later than 90 days before the implementation of a change to the drug coverage that does have the impact of causing the actuarial value of the retiree prescription drug coverage to fail the actuarial equivalence standards set forth in the regulations.

K. Subpart S—Special Rules for States Eligibility

1. General Payment Provisions—Coordination With Medicare Prescription Drug Benefits (§ 423.906)

Section 1935(d) of the Act contains specific provisions regarding Medicaid coordination with Medicare prescription drug benefits. In the case of a full benefit dual eligible individual, Federal Financial Participation (FFP) in State Medicaid expenditures is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to these drugs. We proposed correcting § 423.906(b) and (c) to make clear that, in accordance with the statutory requirement in section 1935(d)(2) of the Act, only drugs specifically excluded from the definition of Part D drugs may be covered by medical assistance. The effect of these changes is to make clear that FFP is not available to States for coverage of drugs that would be Part D covered drugs except that they are not on a plan's formulary. We also proposed adding a definition of ''noncovered drugs'' to § 423.902. We did not receive comments regarding our proposed changes. Therefore, the final rule adopts the revisions to § 423.906(b) and (c) and § 423.902 set forth in the proposed rule.

2. States' Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.910)

Section 1935(b) of the Act, as amended by the MMA, requires States and the District of Columbia to be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals. The statute further defines full benefit dual eligible individuals to mean ''for a State for a month an individual who has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA–PD plan under part C of such title and is determined eligible by the State for medical assistance for full benefits under this title * * *'' In the January 2005 final rule, we explained the calculation of the monthly State phased-down contributions. The calculation of the monthly state contribution is dependent upon the State's reporting of the total number of full-benefit dual eligible individuals for the State in the applicable month. States are required, in accordance with the § 423.910(d), to submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State Medicaid program for each month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

In § 423.910(b)(1) of the Medicare Prescription Drug Benefit final rule, section 423.910(b)(1) specified that ''[f]or States that do not meet the quarterly reporting requirement for the monthly enrollment reporting.'' The text should have read ''For States that do not meet the monthly reporting requirement for the monthly enrollment reporting,'' since there is no State quarterly reporting requirement referred to in either the statute or regulation when calculating the phased-down State contribution. Accordingly, we proposed to revise the text to be consistent with the statute. We did not receive comments regarding our proposed changes. Therefore, the final rule adopts the proposed revisions to § 423.910(b)(1) without modification.

L. Out-of-Scope Comments

We received a number of comments that were beyond the scope of the clarifications in the proposed rule but, rather, addressed other policy areas or sought new clarifications that we did not propose to clarify in this final rule. Specifically, we received public comments recommending that we—

- Implement rules providing for consistency in utilization management requirements across Part D sponsors;
- Establish rules requiring a universal prescription drug card;
- Eliminate proposed rules removing the e-prescribing facsimile exemption;
- Address beneficiary related concerns with the coverage gap or Part D drug coverage in general;
- Codify the six classes of clinical concern;
- Add cancer treatments to the six classes of clinical concern;
- Change the cut-off date for the six classes of clinical concern to January 1, 2008;
- Limit expansion of the parameters for Agency Record Searches;
- Allow tiering exceptions for specialty tier drugs;
- Address lags in the transfer of information, particularly regarding beneficiary Medicaid eligibility, and Part D plan sponsor unwillingness to accept documentation of Medicaid as proof of a beneficiary's dual status;
- Address cases of retroactive Medicaid eligibility and Part D enrollment and direct Part D plan sponsors to not deny claims incurred

during the period of retroactive eligibility;

- Direct Part D sponsors to provide disclosure instructions for the filing of claims incurred during periods of retroactive Part D enrollment;
- Act on MedPAC recommendations on vaccine reimbursement;
- Withdraw the *Medicare Marketing Guidelines* or, at a minimum, eliminate or loosen current restrictions contained in *the Medicare Marketing Guidelines* on provider marketing activities—particularly when providers are acting independently of Part D plans or when there is no direct financial conflict of interest under the Federal anti-kickback statute.
- Expand the definition of a long-term care facility under § 423.100 to include assisted living facilities;
- Revise our policies to require Part D coverage of the professional services, supplies, and equipment associated with home infusion of Part D drugs;
- Direct that appeals overturned by an administrative law judge are effective for a period of 12 months, not just the remainder of the plan year.

Because these comments are beyond the scope of the proposed rule, we are not responding to them in this final rule.

III. Collection of Information Requirements

This document does not impose additional information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Analysis

A. Overall Impact

We examined the impacts of our May 2007 proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. We received only one comment with regard to our impact analysis concerning the definition of negotiated prices, which is not addressed in this final rule. As a result, we restate that impact analysis below.

With the exception of the statutory change addressing the payment of vaccine administration under Part D beginning in 2008 for covered Part D vaccines, the impact of the policy clarifications in this final rule were addressed as part of a prior final rule and do not require further analysis. Specifically, we performed a full regulatory impact analysis (RIA) for the January 2005 final rule (70 FR 4454) implementing the Part D provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003. Many of the provisions in this final rule are simply clarifications of provisions in the January 2005 final rule.

Executive Order 12866 (as amended by Executive Order 13258) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million or less to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

We estimate that the coverage of vaccine administration under Part D to have a net impact to the FY 2008 budget in the amount of $100 million and an impact for FY 2008 through 2017 in the amount of $340 million. Given this estimated net impact of vaccine administration coverage under Part D beginning in FY 2008, the final rule meets the threshold of being ''economically significant'' and is consequently a major rule. Therefore, the RFA requires us to conduct a regulatory flexibility analysis with regard to the implementation of vaccine administration coverage under Part D. Table I provides the costs associated with vaccine administration for FYs 2008 through 2017.

TABLE 1.—VACCINE ADMINISTRATION COSTS FOR FY 2008–FY 2017

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FYs 2008–2017
Vaccine Administration Costs (in millions) ...	$100	$80	$40	$20	$20	$20	$10	$10	$20	$20	$340

In the proposed rule we made a technical error when we listed the Small Business Administration's consideration of small business at $6 million and used an inappropriate census table. We have corrected these errors in this final rule. The corrected calculations did not have an impact on our analysis. The Small Business Administration (SBA) considers pharmacies with firm revenues of less than $6.5 million to be small businesses. The 2004 Business Census (the latest available detailed data) indicates that there were about 19,443 firms operating about 40,115 retail pharmacies and drug store establishments (NAICS code 44611). Of these firms, 17,835 had revenues under $6.5 million and operated a total of 17,835 establishments. Because more than 90 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards), we estimate that the inclusion of vaccine administration within the statutory definition of a Part D drug will have some effect on a substantial number of small retail pharmacies. However, we estimate that, overall, the revenue effect on the retail pharmacy industry, including small pharmacies, will be positive. Given the nature of immunization in the U.S. market and the nature of Part D coverage of vaccines, only two small business areas—retail pharmacy and physicians in private practice—merit analysis.

Given the real-time nature of the Part D benefit and the fact that—unlike physician offices—pharmacies are network providers that can bill Part D sponsors for vaccines and vaccine administration costs at the point of sale, we anticipate that Medicare beneficiaries will consider receiving Part D vaccine immunization in a pharmacy setting in those States that permit pharmacists to administer vaccinations (currently 46 of 50 States—

two more States since the publication of our May 2007 proposed rule). We expect this trend to continue, when, beginning in 2008, Part D plans' network pharmacies are able to seek reimbursement for the administration of Part D vaccines. While there may be some additional cost associated with pharmacists' time in administering vaccines, these costs should be more than offset by the reimbursement of vaccine administration costs. We note that network pharmacies can negotiate with Part D sponsors so that they do not administer vaccines if they believe that the costs of administering vaccines outweigh any potential benefits.

Almost all physicians in private practice (or the practices of which they are members) are small businesses because their annual revenues do not meet the Small Business Administration's threshold for ''small'' physician practices; therefore, they are small entities. Since we expect that a substantial number of Part D vaccines will continue to be administered in the physician office setting, we believe physicians will benefit from the inclusion of vaccine administration in the statutory definition of a Part D drug. Beginning in calendar year 2008, administering physicians will have a new source of reimbursement for Part D vaccine administration fees. As physicians will likely bill beneficiaries directly for Part D vaccines and its administration, we do not expect there will be any additional costs to the physicians in private practice as a result of this statutory change.

The other technical corrections and substantive clarifications in this final rule are not expected to affect small businesses in a significant manner, if at all. For example, although the clarification relating to the delivery of home infusion medications may result in a slight increase to the cost of delivering these medications for some Part D sponsors given potential increased costs for sponsors that do not currently have timely delivery provisions in their contracts with home infusion pharmacies, any such increase will be accounted for in plan sponsors' bids. However, we expect any such increase to be minimal and to affect only some sponsors. The final rule's requirements regarding timely delivery of home infusion pharmacies should have no cost impact on network home infusion pharmacies. In our ongoing communications with the home infusion industry, we have learned that these delivery timeframes are already an industry standard. Thus, incorporation of these new requirements does not place any new burdens on the pharmacy cost structure, as home infusion pharmacies should already be meeting these performance standards.

Section 1102(b) of the Act requires us to prepare a RIA 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 standards 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. Because prescription drugs, including Part D vaccines, are dispensed to Medicare outpatients in hospitals, the final rule's change to the definition of a Part D drug to include vaccine administration could have an effect on small rural hospitals that administer Part D vaccines. Since a number of rural hospitals administer vaccines on an outpatient basis, they too would likely benefit from the ability to collect a Part D vaccine administration fee. Rural hospitals should already have the systems in place to handle, store, and administer vaccines. While some rural hospital pharmacies may become Part D network pharmacies, we do not expect the majority will do so. Consequently, small rural hospitals should only benefit from Part D sponsors' coverage of Part D vaccine administration fees and should not incur new costs as a result of our final rule. Additionally, the other policy clarifications in our final rule are related to the Medicare Part D drug benefit and not to prescription drug coverage under Medicare Part A. Therefore, these additional proposals do not affect small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $127 million. Many of the final rule's provisions are either corrections to bring our regulations in line with statute or merely the formal proclamation of existing policies that are consistent with the statute and do not exceed the $127 million dollar threshold. For example, one clarification we made in our final rule to bring our regulations in line with statute prohibits States from covering Part D drugs for Medicaid recipients. This provision may save States the money they would have otherwise spent on these drugs, if they had chosen to cover the drugs at issue. Because the statute only allows States to cover excluded drugs, as opposed to noncovered Part D drugs, and we expect that most States complied with the statute, as opposed to the Part D regulation, we do not believe that this clarification will significantly affect States, local, or tribal governments.

As stated above, many of the final rule's provisions are either corrections to bring our regulations in line with statute or merely the formal proclamation of existing policies that are consistent with the statute. Although there may be added costs for Part D sponsors associated with the broadening of the definition of Part D drug to include ''[s]upplies required to deliver insulin by inhalation[,]'' sponsors are aware that new drugs and supplies come to market constantly and account for these potential formulary changes in their bids. Furthermore, only those sponsors that choose to cover inhaled insulin will be affected by the change to our final rule to broaden the definition of supplies associated with the delivery of insulin into the body encompassed within the definition of a Part D drug. We expect the costs to the private sector resulting from this change will be less than the $130 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The changes and technical clarifications in this final rule will not have a substantial effect on State or local governments. For example, our clarification in the final rule concerning timing of State reporting for the purposes of calculating State phase-down contributions is not expected to affect State governments, since monthly reporting is consistent with the statute. In addition, although there is a provision in this final rule clarification that relates to waivers of State plan licensure, there are no anticipated Federalism implications because the clarification simply brings our regulations in line with existing statute.

B. Anticipated Effects on Health Plans and Pharmacy Benefit Managers (PBM)

Part D plans will incur costs in implementing the reimbursement of Part D vaccine administration fees, since this is a new Part D benefit established by Congress in the Tax Relief and Health Care Act of 2006. However, since Congress defined the Part D vaccine administration fee as a Part D drug cost, the impact of this statutory change will be no different than for any other new drug entering the market. Part D plans will need to factor Part D vaccine

administration into their benefit designs and resulting bids. We estimate the net cost of vaccine administration coverage for FY 2008 to be $100 million. This estimate takes into account the offset associated with beneficiary cost sharing and the Federal direct subsidy and risk-sharing.

We believe that our other provisions of our final rule merely reflect existing policy and have no cost impact on health plans and PBMs. For example, the final rule's changes associated with plan-to-plan reconciliation reflect current plan requirements. Even if this requirement were a new standard, we believe that all parties involved in the reconciliation will benefit, since the reconciliation process will be simpler than if pharmacies were required to reverse and re-adjudicate claims.

We also do not believe our broadening of the definition of medical supplies associated with insulin administration or our clarification relating to the timely delivery of home infusion medications place any additional cost burden on Part D plans. We had initially estimated the gross costs of inhaled insulin for Fiscal Year 2008 would be $10 million. Given this product's current status, we now believe it will be substantially lower in costs. As discussed elsewhere in this analysis, our requirement for the timely delivery of home infusion drugs is consistent with an existing standard with which sponsors should be familiar. Consequently, we do not believe it will increase sponsors' costs.

C. Alternatives Considered

We considered not issuing regulations to address the policy clarifications and technical changes we proposed in our May 2007 proposed rule. However, we believed that in order to ensure public awareness of our policies, as well as to avoid potential confusion regarding those policies, we should codify our clarifications as well as make certain technical corrections to the January 2005 final rule. In addition, we wished to codify a few new clarifications for Part D plans as a result of our experience in implementing Part D. Finally, we wanted to codify certain changes made by Congress to the statutory definition of a Part D drug since the publication of the January 2005 final rule.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/index.html*), in Table D1 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the increase in costs as a result of the changes presented in this final rule. All costs are classified as transfers by the Federal Government to Part D plans.

TABLE D1.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR POLICY AND TECHNICAL CHANGES TO THE MEDICARE PRESCRIPTION DRUG BENEFIT, FINAL RULE

Category	Transfers ($ millions)
Vaccine Administration, FYs 2008–2017:	
Undiscounted Annualized Monetized Transfers	340.
Annualized Monetized Transfers Using 7% Discount Rate	387.
Annualized Monetized Transfers Using 3% Discount Rate	360.
From Whom To Whom?	Federal Government To Part D Plans.

E. Conclusion

Given that we expect the cost of implementing vaccine administration under Part D will exceed the $100 million threshold in FY 2008, we conducted an economic impact analysis with regard to those entities potentially involved in administering Part D vaccines. As we stated previously, we expect that entities such as private physician practices and pharmacies will benefit from this change in FY 2008, whereas other entities, such as Part D sponsors, will experience no or little difference in their costs as a result of the implementation of this statutory change. We conducted a full analysis of the impact of this final rule's technical corrections and substantive clarifications for the final regulations implementing the Part D provisions of Medicare Prescription Drug Improvement and Modernization Act of 2003, which were published on January 28, 2005. For reasons cited previously, we believe that these additional clarifications either do not require further analysis or are in practice today and, as such, will not have an economically significant impact.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart B—Eligibility and Enrollment

■ 2. Section 423.50 is amended by revising paragraph (f)(1)(v) to read as follows:

§ 423.50 Approval of marketing materials and enrollment forms.

* * * * *

(f) * * *

(1) * * *

(v) Use providers, provider groups or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which the providers, provider groups or pharmacies contract.

* * * * *

■ 3. Section § 423.56 is amended by revising paragraph (b)(6) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

* * * * *

(b) * * *

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 403.205 of this chapter.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 4. Section 423.100 is amended by revising the definitions of ''contracted pharmacy network,'' and ''Part D drug'' to read as follows:

§ 423.100 Definitions.

* * * * *

Contracted pharmacy network means licensed pharmacies, including retail, mail-order, and institutional pharmacies under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

* * * * *

Part D drug means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act):

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.

(iii) Insulin described in section 1927(k)(2)(C) of the Act.

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.

(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

* * * * *

■ 5. Section 423.120 is amended by revising paragraphs (a)(2) and (a)(4) to read as follows:

§ 423.120 Access to covered Part D drugs.

(a) * * *

(2) *Applicability of some non retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Clinics toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

* * * * *

(4) *Access to home infusion pharmacies.* A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with CMS guidelines and instructions. A Part D plan must ensure that such network pharmacies, at a minimum—

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion;

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies;

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs; and

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

* * * * *

Subpart F—Submission of Bids and Monthly Beneficiary Premiums: Plan Approval

■ 6. Section 423.293 is amended by revising paragraph (a) to read as follows:

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rules.* Part D sponsors must—

(1) Charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage).

(2) Permit payment of monthly Part D premiums (if any) under the timing of payments established in § 422.262(e) of this chapter; and

(3) Permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

* * * * *

Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

■ 7. In § 423.350 paragraph (b)(1) is revised to read as follows:

§ 423.350 Payment appeals.

(b) * * *

(1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the final payment. For purposes of this paragraph, the date of final payment is one of the following:

(i) For risk adjustment, the date of the final reconciled payment under § 423.343(b) of this subpart.

(ii) For reinsurance, the date of the final reconciled payment under § 423.343(c) of this subpart; for low-income cost sharing subsidies, the date of the final reconciled payment under § 423.343(d) of this subpart.

(iii) For risk-sharing payments, the date of the final payments under § 423.336 of this subpart.

* * * * *

Subpart I—Organizational Compliance With State Law and Preemption by Federal Law

■ 8. Section 423.410 is amended by revising paragraph (d) to read as follows:

§ 423.410 Waiver of certain requirements to expand choice.

* * * * *

(d) Special waiver for plan years beginning before January 1, 2008. For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a substantially completed application for licensure to the State.

* * * * *

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

■ 9. Section 423.458 is amended by revising paragraph (d)(2)(ii) to read as follows:

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

* * * * *

(d) * * *

(2) * * *

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under sections 1894 and 1934 of the Act, with the benefits under Part D.

■ 10. Section 423.464 is amended by—

■ (A) Revising paragraphs (f)(1)(vii) and (f)(1)(viii).

■ (B) Adding new paragraphs (f)(1)(ix), (f)(5), and (f)(6).

The revision and additions read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(f) * * *

(1) * * *

(vii) *Rural health clinics*. Rural health clinics as defined under section 1861(aa)(2) of the Act.

(viii) Other Part D plans.

(ix) *Other prescription drug coverage*. Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

* * * * *

(5) *Plan-to-plan liability*. In the process of coordinating benefits between Part D plans when a Part D plan from which a beneficiary has transferred has incorrectly made payment for covered prescription drug costs incurred after the effective date of the Part D enrollee's enrollment in the new Part D plan of record, the new Part D plan of record must make the reconciling payments based on amounts reported to it by CMS without regard to the Part D plan's own formulary or drug utilization review edits.

(6) *Use of other reconciliation processes*. In the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, rather than requesting pharmacy claims reversal and re-adjudication.

Subpart K—Application Procedures and Contracts With Part D Sponsors

■ 11. Section 423.504 is amended by revising paragraph (a) to read as follows:

§ 423.504 General provisions.

(a) *General rule*. Subject to the provisions at § 423.265 of this part concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

* * * * *

■ 12. Section 423.505 is amended by revising paragraph (h)(1) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(h) * * *

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

* * * * *

■ 13. Section 423.509 is amended by revising paragraph (a)(9) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

(9) Substantially fails to comply with either of the following:

(i) Marketing requirements in § 423.50.

(ii) Information dissemination requirements of § 423.128 of this part.

* * * * *

Subpart M—Grievances, Coverage Determinations, and Appeals

■ 14. Section 423.560 is amended by revising the definitions of ''appointed representative'' and ''projected value'' to read as follows:

§ 423.560 Definitions.

* * * * *

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

* * * * *

Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

* * * * *

■ 15. Section 423.570 is amended by revising paragraph (d)(3) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(3) Subsequently deliver to the enrollee, within 3 calendar days, equivalent written notice.

* * * * *

■ 16. Section § 423.584 is amended by adding a new paragraph (b)(3) as to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(b) * * *

(3) The provisions set forth in § 423.582(b), (c), and (d) of this subpart also apply to expedited redeterminations.

* * * * *

■ 17. Section § 423.610 is amended by revising paragraph (c)(2) to read as follows:

§ 423.610 Right to an ALJ hearing.

* * * * *

(c) * * *

(2) *Multiple enrollees*. Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b) of this part; and

(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

Subpart P—Premiums and Cost Sharing Subsidies for Low-Income Individuals

■ 18. Section 423.780 is amended by revising paragraphs (b)(1) and (e) to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(b) * * *

(1) The premium subsidy amount is equal to the lesser of—

(i) Under the Part D plan selected by the beneficiary, the portion of the monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the portion of the MA monthly prescription drug beneficiary premium attributable to basic prescription drug coverage (for enrollees in MA–PD plans); or

(ii) The greater of the low-income benchmark premium amount (determined under paragraph (b)(2) of this section) for the PDP region in which the subsidy eligible individual resides or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region.

* * * * *

(e) *Premium subsidy for late enrollment penalty*.

(1) *Amount of premium subsidy for late enrollment penalty*. Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 of this part are entitled to an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

(2) *Other low-income subsidy eligible individuals sliding scale premium subsidy for late enrollment penalty*. Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale as follows:

(i) For individuals with income at or below 135 percent of the FPL applicable to the family size, a premium subsidy equal to 80 percent of the late enrollment for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

(ii) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 60 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 75 percent of their late enrollment penalty thereafter.

(iii) For individuals with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size, a premium subsidy equal to 40 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 50 percent of their late enrollment penalty thereafter.

(iv) For individuals with income greater than 145 percent but below 150 percent of the FPL applicable to the family size, a premium subsidy equal to 20 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 25 percent of their late enrollment penalty thereafter.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

■ 19. Section § 423.884 is amended by—

■ A. Revising paragraphs (c)(5)(i), (c)(7)(i).

■ B. Revising paragraphs (d)(5)(iii)(B)(*2*), (d)(5)(iii)(C), and (d)(5)(iii)(D).

■ C. Revising the last sentence of paragraph (d)(5)(iv).

■ D. Revising paragraph (d)(6)(ii).

■ E. Adding a new paragraph (d)(7).

The revisions and addition read as follows:

§ 423.884 Requirements for qualified retiree prescription drug plans.

* * * * *

(c) * * *

(5) * * *

(i) *General rule*. An application for a given plan year must be submitted prior to the beginning of the plan year by a date specified by CMS in published guidance, unless a request for an extension has been filed and approved under procedures set forth in such guidance.

* * * * *

(7) * * *

(i) Matches the names and identifying information for the individuals submitted as qualifying covered retirees with a CMS database(s) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

* * * * *

(d) * * *

(5) * * *

(iii) * * *

(B) * * *

(*2*) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage actually provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(*2*).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect either at the start of the plan year or that is announced for the upcoming calendar year. In order to use the coverage limits in effect at the beginning of the plan year, the attestation must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year; otherwise, the valuation is based on the upcoming year's initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D.

(D) Example: If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the sponsor has a choice of basing the attestation for the year April 1, 2007 through March 30, 2008 on either the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold amounts that apply to defined standard prescription drug coverage under Part D in CY 2007, or the amounts announced for CY 2008. However, in order to use the amounts applicable in CY 2007, the sponsor must submit the attestation within 60 days after the publication of the Part D coverage limits for CY 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the CY 2008 coverage limits would apply.

(iv) * * * For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options (or for a subset of the benefit options).

(6) * * *

(ii) Submission following material change. The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's retiree prescription drug plan. For purposes of this clause, the term ''material change'' means the addition of a benefit option that does not impact the actuarial value of the retiree prescription drug coverage under the sponsor's plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

(7) Notice of failure to continue to satisfy the actuarial equivalence standards. A sponsor must notify CMS,

in a form and manner specified by CMS, no later than 90 days before the implementation of a change to the drug coverage that impacts the actuarial value of the retiree prescription drug coverage under the sponsor's plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

* * * * *

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

■ 20. Section 423.902 is amended by adding the definition of ''noncovered drugs'' in alphabetical order to read as follows:

§ 423.902 Definitions.

* * * * *

Noncovered drugs are those drugs specifically excluded from the definition of Part D drug, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

* * * * *

■ 21. Section 423.906 is amended by revising paragraphs (b)(1), (b)(2), and (c) to read as follows:

§ 423.906 General payment provisions.

* * * * *

(b) * * *

(1) Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to Part D drugs.

* * * * *

(c) *Noncovered drugs.* States may elect to provide coverage for outpatient drugs other than Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

■ 22. Section 423.910 is amended by revising paragraph (b)(1) introductory text to read as follows:

§ 423.910 Requirements.

(b) * * *

(1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the monthly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 19, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: January 4, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on April 9, 2008.

[FR Doc. 08–1120 Filed 4–9–08; 11:45 am]

BILLING CODE 4120–01–P

Federal Register

Tuesday,
April 15, 2008

Part IV

Securities and Exchange Commission

17 CFR Part 239

Revisions to Form S–11 To Permit Historical Incorporation by Reference; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 239

[Release No. 33–8909; File No. S7–30–07]

RIN 3235–AK02

Revisions to Form S–11 To Permit Historical Incorporation by Reference

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: We are adopting amendments to Form S–11, a registration statement used by real estate entities to register offerings under the Securities Act of 1933. The amendments permit an entity that has filed an annual report for its most recently completed fiscal year and that is current in its reporting obligations under the Securities Exchange Act of 1934 to incorporate by reference into Form S–11 information from its previously filed Exchange Act reports and documents. The amendments are identical to amendments to Form S–1 and Form F–1 previously adopted by the Commission and effective as of December 1, 2005.

DATES: *Effective Date:* April 15, 2008.

FOR FURTHER INFORMATION CONTACT: Michael McTiernan at (202) 551–3852, Division of Corporation Finance, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–3010.

SUPPLEMENTARY INFORMATION: We are amending Form S–11 [1] under the Securities Act of 1933.[2]

I. Discussion

A. Background

Form S–11 is the form that real estate entities generally must use to register offerings under the Securities Act.[3] The form is used for the registration of securities issued by real estate investment trusts and securities issued by other issuers whose business is primarily that of acquiring and holding for investment real estate, interests in real estate, or interests in other issuers whose business is primarily that of acquiring and holding real estate or interests in real estate for investment.[4] Prior to these amendments, Form S–11 did not permit an issuer to satisfy the disclosure requirements of the form through incorporation by reference to the reports and other documents that the issuer previously had filed under the Securities Exchange Act of 1934.[5]

On June 29, 2005, we adopted amendments to Form S–1 [6] and Form F–1 [7] to permit companies filing those forms to incorporate by reference information from their previously filed Exchange Act reports and documents.[8] The purpose of the amendments was to integrate further the Exchange Act and the Securities Act.[9] The ability to incorporate by reference is conditioned, among other things, on the company having filed its annual report for the most recent fiscal year, being current in its reporting obligations under the Exchange Act, and making the incorporated Exchange Act reports and documents available and accessible on a Web site maintained by or for the registrant.[10] Blank check companies, shell companies and penny stock registrants are not permitted to use incorporation by reference. Successor registrants may incorporate by reference if their predecessors were eligible.[11]

In 2005, we did not adopt similar amendments to Form S–11. However, we believe that Form S–11 should be consistent with Form S–1 with respect to incorporation by reference. Both Form S–11 and Form S–1 are long-form registration statements intended for new and unseasoned issuers. The only substantive difference between the two forms is that Form S–11 contains certain additional disclosure requirements specific to real estate entities. We believe that integrating disclosure under the Exchange Act and Securities Act should extend equally to the disclosure obligations of real estate entities.

On December 10, 2007, we proposed amendments to Form S–11 to permit a reporting issuer that has filed an annual report for its most recently completed fiscal year and that is current in its reporting obligations under the Exchange Act to incorporate by reference into its Form S–11 information from its previously filed Exchange Act reports and documents.[12] We received six comment letters in response to the proposed amendments.[13] We are adopting amendments to Form S–11 substantially as proposed with certain modifications to reflect comments received.

B. Amendments to Form S–11

1. Historical Incorporation by Reference

(a) Eligibility

We are amending Form S–11 to permit a reporting issuer that has filed an annual report for its most recently completed fiscal year and that is current in its reporting obligations under the Exchange Act to incorporate by reference into its Form S–11 information from previously filed Exchange Act reports and documents. A successor registrant will be able to incorporate information by reference on the same terms if its predecessor was eligible to do so.[14] Consistent with Form S–1 and the provisions outlined in the Proposing Release, the following issuers will not be able to incorporate by reference into a Form S–11:

- Reporting issuers who are not current in their Exchange Act reports; [15]
- Issuers who are or were, or any of whose predecessors were during the past three years:
  - Blank check issuers;
  - Shell companies (other than business combination related shell companies); or
  - Issuers for offerings of penny stock.[16]

In addition, to enhance the availability to investors of incorporated information, the ability to incorporate by reference is conditioned on the issuer making its incorporated Exchange Act reports and other materials readily accessible on a Web site maintained by or for the issuer. By conditioning the

[1] 17 CFR 239.18.

[2] 15 U.S.C. 77a *et seq.*

[3] Real estate entities may also use Form S–3 [17 CFR 239.13] and Form S–4 [17 CFR 239.25] if they meet the applicable eligibility requirements of those forms. When no other form is available, these entities are required to file on Form S–11 rather than Form S–1.

[4] See General Instruction A of Form S–11.

[5] 15 U.S.C. 78a *et seq.*

[6] 17 CFR 239.11.

[7] 17 CFR 239.31.

[8] See *Securities Offering Reform*, Release No. 33–8591 (Jul. 19, 2005) [70 FR 44722].

[9] *Id.* at 237.

[10] See General Instruction VII of Form S–1 and General Instruction VI of Form F–1.

[11] *Id.*

[12] *Revisions to Form S–11 to Permit Historical Incorporation by Reference*, Release No. 33–8871 (Dec. 14, 2007) [72 FR 72274] (the ''Proposing Release'').

[13] All comment letters are publicly available at *http://www.sec.gov/comments/s7-30-07/s73007.shtml* or at our Public Reference Room at 100 F Street, NE, Washington, DC 20549.

[14] The succession would have to be either primarily for the purpose of changing the state or jurisdiction of incorporation of the issuer or forming a holding company and the assets and liabilities of the successor would have to be substantially the same as the predecessor at the time of the succession, or all of the predecessor issuers would have to be eligible at the time of the succession and the issuer must continue to be eligible.

[15] As with Forms S–1, F–1 and S–3, to be current, at the time of filing the registration statement, the issuer must have filed all materials required to be filed pursuant to Exchange Act Section 13, 14 or 15(d) [15 U.S.C. 78m, 78n, or 78o(d)] during the preceding 12 calendar months (or for such shorter period that the issuer was required to file such materials).

[16] See Securities Act Rule 419(a)(2) [17 CFR 230.419(a)(2)], Exchange Act Rule 3a51–1 [17 CFR 240.3a51–1] and Securities Act Rule 405 [17 CFR 230.405] for definitions of ''blank check company,'' ''penny stock'' and ''shell company,'' respectively.

ability to incorporate by reference on the ready accessibility of an issuer's incorporated Exchange Act reports and other materials on its Web site, we are providing investors the ability to obtain the information from those reports and materials at the same time that they would have been able to obtain the information if it was set forth directly in the registration statement. Issuers may satisfy this condition by including hyperlinks directly to the reports or other materials filed on EDGAR or on another third-party Web site where the reports or other materials are made available in the appropriate timeframe and access to the reports or other materials is free of charge to the user.

(b) Procedural Requirements

Under the amendments we are adopting today, the prospectus in the registration statement at effectiveness must identify all previously filed Exchange Act reports and materials, such as proxy and information statements, that are incorporated by reference. There will be no permitted incorporation by reference of Exchange Act reports and materials filed after the registration statement is effective—known as ''forward incorporation by reference.'' [17] Under the amendments, an issuer eligible to incorporate by reference its Exchange Act reports and other materials into its Form S–11 must include the following in the prospectus that is part of the registration statement:

- A list of the incorporated reports and materials;
- A statement that it will provide copies of any incorporated reports or materials on request;
- An indication that the reports and materials are available through the Securities and Exchange Commission's EDGAR system or public reference room;
- Identification of the issuer's Web site address where such incorporated reports and other materials can be accessed; and
- Required disclosures regarding material changes in, or updates to, the information that is incorporated by reference from an Exchange Act report or other material required to be filed.

2. Form S–11 and Rule 415 Under the Securities Act

We have historically permitted registrants offering securities on a continuous basis pursuant to Rule 415 [18] under the Securities Act to use Form S–11. However, unlike the cover page of Form S–1, the cover page of Form S–11 does not require a registrant to reflect whether it is relying on Rule 415 under the Securities Act. In response to the suggestion of a commenter, as described below, we have amended the cover page of Form S–11 to conform to the cover page of Form S–1 so as to require a registrant to reflect whether it has relied on Rule 415 under the Securities Act.[19] This amendment also will assist the staff in assessing compliance with the requirements for incorporation by reference, particularly as they apply in the continuous offering context.

C. Comments on Form S–11 Amendments

Commenters strongly supported the proposed amendments to allow issuers to incorporate by reference historical Exchange Act filings into Form S–11.[20] One commenter suggested that Form S–11 should also permit forward incorporation by reference for filings made after effectiveness of a registration statement.[21] We are not adopting this suggestion. The purpose of these amendments is to revise Form S–11 to conform to Form S–1 and Form F–1 with respect to incorporation by reference and those forms do not permit forward incorporation by reference.

Another commenter suggested that we revise the eligibility requirement that the registrant must have filed an annual report required under Section 13(a) or 15(d) of the Exchange Act for its most recently completed fiscal year.[22] Again, since Form S–1 and Form F–1 include this eligibility requirement, we have not adopted the commenter's suggestion to provide an alternative requirement in Form S–11. We do not believe that this eligibility requirement will prevent the use of incorporation by reference in the multi-year continuous offerings commonly registered on Form S–11 by non-traded real estate investment trusts (''REITs''). These registrants regularly file post-effective amendments to reflect property acquisitions. A post-effective amendment to a Form S–11 may be filed after the end of a registrant's fiscal year but prior to the filing of its Form 10–K, raising the question of whether the registrant may continue to incorporate by reference historical Exchange Act reports in such post-effective amendment. In the continuous offering context, we believe that eligibility to incorporate by reference should be measured immediately prior to the time of filing a Form S–11 registration statement, as specified in Instruction H of the form, and thereafter, each time that a post-effective amendment is filed for purposes of updating the information contained in the prospectus pursuant to Section 10(a)(3) of the Securities Act.[23] Thus a post-effective amendment filed for purposes other than a Section 10(a)(3) update, such as a post-effective amendment to reflect property acquisitions, could continue to incorporate by reference historical Exchange Act reports to the extent the previous post-effective amendment filed for purposes of Section 10(a)(3) or, if not applicable, the original registration statement, was eligible to do so.

Two commenters requested guidance on whether a prospectus supplement may be used to update the information incorporated by reference into the prospectus included in a Form S–11 registration statement.[24] Rule 411 [25] under the Securities Act prohibits incorporation by reference of information into a prospectus except as specifically permitted in the registration statement form. If the registrant meets the requirements set forth in Instruction H of Form S–11, as we are adopting Instruction H in this release, then the registrant may elect to incorporate by reference ''into the prospectus contained in the registration statement'' the information in the documents set forth in Item 29 of Form S–11, as we are adopting Item 29 in this release. For purposes of these form instructions, a revised or supplemented prospectus is ''contained in the registration statement'' when it is part of a post-effective amendment to the registration statement. This is consistent with our earlier statement that there will be no permitted incorporation by reference of Exchange Act reports and documents filed after the effective date of the registration statement.

Two commenters [26] requested guidance on whether a new non-traded

[17] As discussed below, incorporation by reference of historical Exchange Act reports and documents will be permitted in post-effective amendments to the registration statement, provided the issuer otherwise satisfies the eligibility and procedural requirements set forth in Form S–11.

[18] 17 CFR 230.415.

[19] See letter from Bimini Capital Management, Inc. (''Bimini'').

[20] See, for example, letters from Bimini, The Investment Program Association (''IPA''), Corporate Property Associates 17—Global Incorporated (''CPA''), Hines Real Estate Investment Trust, Inc. (''Hines'') and Grubb & Ellis Company (''Grubb'').

[21] See letter from Bimini.

[22] See letter from IPA.

[23] 15 U.S.C. 77j(a). Section 10(a)(3) of the Securities Act requires that when a prospectus is used more than nine months after the effective date of the registration statement, the information contained therein shall be as of a date not more than sixteen months prior to such use, so far as such information is known to the user of such prospectus or can be furnished by such user without unreasonable effort or expense.

[24] See letters from IPA and Hines.

[25] 17 CFR 230.411.

[26] See letters from IPA and Grubb.

REIT [27] would be a shell company and thus ineligible to incorporate by reference for at least three years. The determination of whether a particular registrant is a shell company depends on the facts and circumstances of that company as considered against the definition of the term ''shell company'' in Rule 405 and the principles underlying that definition as described in the release adopting that definition.[28] Under appropriate circumstances a non-traded REIT may not be deemed a shell company; however, the determination of whether certain registrants such as non-traded REITs are shell companies is outside the scope of these amendments. Furthermore, in adopting the definition of ''shell company'' in 2005, we declined to provide more specific or quantitative measurements, as we believed the definition in Rule 405 reflected the traditional understanding of the term ''shell company'' in the area of corporate finance.[29]

One commenter [30] suggested that we amend the disclosure requirements of Form S–11 to conform to the recent amendments to Regulation S–K [31] with respect to the disclosure requirements of smaller reporting companies.[32] Form S–11 includes some substantive disclosure requirements that are not contained in Regulation S–K.[33] Thus the recent amendments to Regulation S–K made in connection with the elimination of the small business registration forms do not impact these Form S–11 disclosure requirements. Since the purpose of these amendments is only to revise Form S–11 to conform to Form S–1 and Form F–1 with respect to incorporation by reference, we have not adopted the suggestion at this time. We may consider future amendments to Form S–11 to address any differences between Form S–11 disclosures and Regulation S–K disclosures.

One commenter [34] suggested that we amend an undertaking in Industry Guide 5 [35] related to disclosures made in connection with property acquisitions. Since the purpose of these amendments is only to revise Form S–11 to conform to Form S–1 and Form F–1 with respect to incorporation by reference, we have not adopted the suggestion at this time. We may consider future revisions to Industry Guide 5.

Finally, one commenter [36] requested we amend the cover page of Form S–11 to conform to Form S–1 and require a registrant to reflect its reliance on Rule 415 under the Securities Act. Registrants required to register offerings on Form S–11 are permitted to rely on Rule 415 to the extent permitted by the terms of the rule to the same extent as registrants registering on Form S–1. Accordingly, we have adopted the suggestion to revise the cover page of Form S–11 to require a registrant to reflect its reliance on Rule 415 under the Securities Act.

D. Effective Date

The amendments to Form S–11 shall take effect upon publication in the **Federal Register**. The Commission finds good cause to make the amendments effective prior to 30 days after publication to enable calendar fiscal year registrants eligible to incorporate by reference to satisfy their obligations to update the financial information contained in current prospectuses as required by Section 10(a)(3) of the Securities Act by incorporating their most recently filed Form 10–K. Calendar fiscal year registrants are required to satisfy these updating requirements by April 30, 2008. These registrants would need to make any incorporated reports or materials readily accessible on their Web site; investors, therefore, should be able to obtain the information from those reports or materials at the same time that they would have been able to obtain the information if it was set forth directly in the registration statement. In addition, because the amendments to Form S–11 relieve restrictions on companies to include information already on file with the Commission, we believe that it is appropriate that the effective date of the release be upon publication in the **Federal Register**.

II. Paperwork Reduction Act

A. Background

The amendments to Form S–11 contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995.[37] As discussed in the Proposing Release, we submitted a request for approval of these to the Office of Management and Budget in accordance with the Paperwork Reduction Act.[38] The title for this information is ''Form S–11'' (OMB Control No. 3235–0067).

Form S–11 was adopted pursuant to the Securities Act. This form sets forth the disclosure requirements for registration statements prepared by real estate entities to provide investors with the information they need to make informed investment decisions in registered offerings.

Our amendments to Form S–11 are intended to allow issuers that are required to use Form S–11 to incorporate by reference previously filed Exchange Act reports and documents. The amendments revise Form S–11 to conform to Form S–1 and Form F–1 with respect to incorporation by reference.

The hours and costs associated with preparing disclosure, filing forms, and retaining records constitute reporting and cost burdens imposed by the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid control number. The information collection requirements related to registration statements on Form S–11 are mandatory. There is no mandatory retention period for the information disclosed, and the information disclosed will be made publicly available on the EDGAR filing system.

B. Summary of Information Collection

The amendments will decrease existing disclosure requirements for eligible issuers by eliminating the need to repeat information in a Form S–11 when that information was previously disclosed in Exchange Act filings. Any reporting issuer that has filed an annual report for its most recently completed fiscal year and that is current in its

[27] Typically a non-traded REIT has only cash assets at the time of effectiveness of its initial Form S–11 registration statement. The initial public offering generally is a best-efforts continuous offering and the proceeds of the offering are used to purchase real estate or real estate related assets that are not identified in the registration statement at the time of effectiveness.

[28] *Use of Form S–8, Form 8–K, and Form 20–F by Shell Companies*, Release No. 33–8587 (Jul. 15, 2005) [70 FR 42234] (adopting 17 CFR 230.405 and other rules). The shell company rules adopted in that release were intended to protect investors by deterring fraud and abuse through the use of reporting shell companies, including through ''pump-and-dump'' schemes and schemes to avoid Securities Act registration and prospectus delivery requirements.

[29] See *id.* The term ''shell company'' means a registrant, other than an asset-backed issuer as defined in Item 1101(b) of Regulation AB, that has

No or nominal operations; and

—Either:

—no or nominal assets;

—assets consisting solely of cash and cash equivalents; or

—assets consisting of any amount of cash and cash equivalents and nominal other assets.

[30] See letter from Bimini.

[31] 17 CFR 229.10 to 17 CFR 229.915.

[32] See *Smaller Reporting Company Regulatory Relief and Simplification*, Release No. 33–8876 (Dec. 19, 2007) [73 FR 934]. The final rules were effective as of February 4, 2008.

[33] For example, Items 11–15 of Form S–11 include specific disclosure requirements regarding general information about the registrant, its investment policies and its properties that are not contained in Regulation S–K.

[34] See letter from Grubb.

[35] 17 CFR 229.801.

[36] See letter from Bimini.

[37] 44 U.S.C. 3501 *et seq.*

[38] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

reporting obligation will be permitted to incorporate information by reference into its registration statement on Form S–11.

C. Summary of Comments and Revisions to Amendments

Four of the commenters indicated that the amendments will increase the efficiency of the registration process and decrease costs borne by registrants.[39] None of the commenters specifically addressed our request for comment on the Paperwork Reduction Act analysis contained in the Proposing Release. We are nevertheless revising our Paperwork Reduction Act estimates in light of certain rounding adjustments made in our submission to OMB.

D. Revised Paperwork Reduction Act Burden Estimates

As discussed in Section II.C. above, we are revising the Paperwork Reduction Act burden estimates in the Proposing Release to reflect the rounding of those calculations, as reflected in the submission made to OMB.

For purposes of the Paperwork Reduction Act, we now expect the annual decrease in the paperwork burden for issuers eligible to incorporate by reference to comply with Form S–11 to be approximately 37,950 hours of in-house company personnel time and approximately $45,540,000 for the services of outside professionals.[40] These estimates include the time and the cost of preparing and reviewing disclosure, filing documents, and retaining records. These estimates were based on the following assumptions:

- Each year, approximately 100 registration statements on Form S–11, including post-effective amendments, will incorporate information by reference.[41]
- The estimated paperwork burden for a Form S–11 that does not incorporate information by reference is 1,977 hours, which consists of 494.25 internal hours and 1,482.75 professional hours.[42]
- The estimated paperwork burden for a Form S–11 that incorporates information by reference will be the same as the burden currently imposed by Form S–3,[43] which is 459 hours, which consists of 114.75 internal hours and 344.25 professional hours.
- The amount of time eliminated for each Form S–11 that incorporates information by reference will be 1,518 hours per form (1,977 hours for a Form S–11 that does not incorporate information by reference minus 459 hours for a Form S–11 that incorporates information by reference).
- We estimate that the annual decrease in compliance burden after adoption of the amendments will be 151,800 hours (100 registration statements multiplied by 1,518 hours per form).[44] This would include 37,950 hours of issuer personnel time (100 registration statements times 379.5[45] hours of issuer personnel time per registration statement) and 113,850 hours of professional time (100 registration statements times 1,138.5[46] hours of professional time per registration statement).
- The annual cost savings will be approximately $45,540,000 for the services of outside professionals.

III. Cost-Benefit Analysis

A. Summary of Amendments

We are adopting revisions to Form S–11 that will allow real estate entities to take advantage of incorporation by reference for their previously filed Exchange Act reports and documents. Form S–1 and Form F–1, which are similar long-form registration statements, currently permit this type of incorporation by reference. The amendments revise Form S–11 to permit incorporation by reference on the same terms as currently provided in Form S–1 and Form F–1. The purpose of the amendments is to integrate further the disclosure obligations of the Exchange Act and the Securities Act for real estate entities.

B. Benefits

We anticipate that the amendments will enable real estate entities to access the capital markets at a lower cost. The amendments will enable eligible issuers to use their Exchange Act filings to satisfy a portion of their Form S–11 disclosure requirements without having to incur costs to replicate information that they already have disclosed in previously filed Exchange Act reports and other documents. For purposes of our Paperwork Reduction Act analysis, we estimate that our amendments to Form S–11 will reduce the annual paperwork burden by approximately 37,950 hours for issuer personnel time at a cost of approximately $6,641,250[47] and by a cost of approximately $45,540,000 for the services of outside professionals. In addition, we believe that the reduction in the size of the prospectus as a result of incorporation by reference will also result in some cost savings and efficiencies in printing and delivering prospectuses.

The amendments are intended to result in regulatory simplification and efficiency by permitting incorporation by reference on Form S–11 and conforming the requirements of Form S–11 to the requirements of Form S–1 and Form F–1 in that respect. Incorporation by reference will allow eligible issuers to avoid duplicating disclosure in Form S–11 when the information has already been disclosed in Exchange Act reports. In addition, the revisions will simplify the disclosure regime for long-form registration statements by permitting incorporation by reference equally, regardless of industry. Although four of the commenters indicated that the amendments will increase the efficiency of the registration process and decrease costs borne by registrants,[48] none of the commenters specifically addressed our request for comment on the Cost-Benefits Analysis contained in the Proposing Release.

Two commenters requested guidance on whether a prospectus supplement may be used to update the information incorporated in a prospectus included in a Form S–11 registration statement.[49] As discussed above, we believe it is

[39] See letters from IPA, CPA, Hines and Grubb.

[40] Consistent with recent rulemakings and based on discussions with several private law firms, we estimate that the cost of outside professionals retained by the issuer is an average of $400 per hour.

[41] This estimate is based on prior filing history and future estimates. From September 1, 2006 to August 31, 2007, issuers that will be eligible to incorporate by reference under these amendments filed approximately 14 new registration statements on Form S–11 and 68 post-effective amendments to registration statements on Form S–11 (excluding post-effective amendments filed for the purpose of deregistering shares). A majority of these filings were made by non-traded REITs. With the elimination of small business registration forms, we estimate that the number of registration statements filed on Form S–11 will increase by 15. See Release No. 33–8876.

[42] Consistent with current OMB estimates, we assume that 25% of the total burden is borne by internal staff and 75% by professionals.

[43] 17 CFR 239.13.

[44] Generally, companies eligible to incorporate by reference on Form S–11 will have previously filed at least one Form S–11. The estimated decrease in the compliance burden discussed in this section reflects the reduced costs of preparing a subsequent Form S–11 as well as the reduced costs from utilizing incorporation by reference.

[45] Reflects the difference between the amount of internal time required to prepare a Form S–11 without incorporation by reference (494.25 hours) and the amount of internal time required to prepare a Form S–11 with incorporation by reference (114.75 hours).

[46] Reflects the difference between the amount of professional time required to prepare a Form S–11 without incorporation by reference (1,483 hours) and the amount of professional time required to prepare a Form S–11 with incorporation by reference (344.25 hours).

[47] Consistent with recent rulemaking releases, we estimate the value of work performed by the company internally at a cost of $175 per hour.

[48] See letters from IPA, CPA, Hines and Grubb.

[49] See letters from IPA and Hines.

appropriate to limit the use of incorporation by reference to revised or supplemented prospectuses included in post-effective amendments to the registration statement. We believe this limitation is consistent with our prior statements that forward incorporation by reference is not appropriate for long-form registration statements, such as Form S–11, while still reducing the overall filing burden associated with the form.

C. Costs

We expect that the amendments will result in some ongoing costs to issuers that elect to use incorporation by reference. These potential costs relate to the issuer's obligation to make the incorporated Exchange Act reports and documents available on its Web site and include creating and/or maintaining a Web site as well as actually posting the required filings on the Web site. However, we believe that a substantial majority of issuers eligible to use incorporation by reference already maintain Web sites and thus will not have to incur any additional costs to establish a new Web site for this purpose. In addition, we believe that many issuers eligible to use incorporation by reference already post their Exchange Act reports on their Web sites. Those that do not will incur incremental costs to post the required filings. Given that the amendments will not mandate use of incorporation by reference, issuers that are unwilling to bear the cost of complying with the Web site requirement can simply elect not to incorporate information by reference.

We also recognize that permitting incorporation by reference may impose an analytical burden on investors. For example, for offerings on Form S–11 today, much of the relevant information regarding an offering and the issuer is required to be contained in the registration statement. As a result of our amendments, offerings pursuant to Form S–11 could require an investor to assemble and assimilate information from various Exchange Act reports and the registration statement in order to compile all of the relevant information regarding an offering. Investors will have to compile the information integrated into the registration statement or delivered by means outside of the prospectus. We note, however, that Securities Act Forms S–3 and F–3 have long permitted incorporation by reference from the issuer's Exchange Act reports, as have Form S–1 and Form F–1 since December 2005, and we know of no indications that investors are unduly burdened when investing in offerings registered on these forms.

IV. Consideration of Promotion on Efficiency, Competition and Capital Formation

Section 2(b) of the Securities Act,[50] requires us, when engaged in rulemaking where we are required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition and capital formation. In response to our request for comment in the Proposing Release on the impact of the proposed amendments on efficiency, competition and capital formation, four of the commenters indicated that the amendments will increase the efficiency of the registration process and decrease costs borne by registrants.[51]

The amendments will amend Form S–11 to permit incorporation by reference on terms equivalent to that currently provided in Form S–1 and Form F–1. We believe the amendments will provide benefits, as discussed in further detail above, by reducing the costs of complying with the Form S–11 disclosure requirements by enabling eligible issuers to incorporate their Exchange Act filings. Eased filing burdens resulting from the amendments will promote efficiency in capital formation for real estate entities and may provide a competitive benefit to entities filing on Form S–11 by allowing them to incorporate their periodic reports by reference to the same extent as registrants filing on Form S–1 and Form F–1.

V. Final Regulatory Flexibility Act Analysis

This Final Regulatory Flexibility Analysis has been prepared in accordance with 5 U.S.C. 603. It relates to amendments to Form S–11.

A. Reasons for and Objectives of the Amendments

In 2005, the Commission adopted revisions to Form S–1 and Form F–1 to permit incorporation by reference from previously filed Exchange Act reports and other documents. Currently, real estate entities are not permitted to use Form S–1 to register offerings under the Securities Act. Consequently, these entities are unable to take advantage of the important benefit of incorporation by reference that is enjoyed by companies in all other industries that file registration statements on Form S–1. The ability to use a prospectus that does not need to include information provided in previous Exchange Act filings permits companies to streamline the preparation of registration statements and raise capital more efficiently. Companies that are not permitted to incorporate by reference have a greater burden in preparing registration statements in connection with their public offerings. We believe there is no reason to distinguish between real estate entities and other industries for purposes of incorporation by reference.

The purpose of the amendments is to further integrate the Exchange Act and Securities Act by amending Form S–11 to permit incorporation by reference of Exchange Act filings on terms equivalent to that currently provided in Form S–1 and Form F–1. The amendments will extend an important benefit to real estate entities.

B. Significant Issues Raised by Public Comment

In the Proposing Release, we requested comment on any aspect of the Initial Regulatory Flexibility Act Analysis, including the number of small entities that would be affected by the proposals, and both the qualitative and quantitative nature of the impact. While several commenters supported the proposal because of the cost savings to real estate entities, they did not provide any specific comments on the Initial Regulatory Flexibility Act Analysis.

C. Small Entities Subject to the Amendments

The Regulatory Flexibility Act defines ''small entity'' to mean ''small business,'' ''small organization,'' or ''small governmental jurisdiction.''[52] The Commission's rules define ''small business'' and ''small organization'' for purposes of the Regulatory Flexibility Act for each of the types of entities regulated by the Commission.[53] Roughly speaking, a ''small business'' and ''small organization,'' when used with reference to an issuer other than an investment company, means an issuer with total assets of $5 million or less on the last day of its most recent fiscal year. We estimate that there are approximately 1,100 issuers, other than investment companies, that may be considered reporting small entities.[54] The amendments will apply to all

[50] 15 U.S.C. 77b(b).

[51] See letters from IPA, CPA, Hines and Grubb.

[52] 5 U.S.C. 601(6).

[53] Rules 157 under the Securities Act [17 CFR 230.157], 0–10 under the Exchange Act [17 CFR 240.0–10] and 0–10 under the Investment Company Act [17 CFR 270.0–10] contain the applicable definitions.

[54] The estimated number of reporting small entities is based on 2007 data, including the Commission's EDGAR database and Thomson Financial's Worldscope database.

issuers required to file registration statements on Form S–11.

As previously noted, in the 12 months ended August 31, 2007, 82 registration statements on Form S–11 were filed, including new registration statements and post-effective amendments. We estimate that four of those were filed by small entities. We also estimate that approximately 15 registration statements were filed on Form SB–2 in the last fiscal year covering transactions by real estate entities that in the future will be required to register on Form S–11.[55] Thus, we estimate that 19 registration statements by small entities will be subject to the amendments.

D. Reporting, Recordkeeping and Other Compliance Requirements

The amendments are expected to impact all capital raising and selling security holder transactions that are registered under the Securities Act on Form S–11. Small entities required to register on Form S–11 will be able to take advantage of the ability to incorporate by reference previously filed Exchange Act reports and documents. We expect that permitting the incorporation by reference of previously filed Exchange Act reports and documents will reduce the aggregate costs incurred by small entities of preparing registration statements on Form S–11 by $9,914,438.[56]

We expect that small entities eligible to register on Form S–11 may need to incur some insignificant additional costs related to complying with the Web site requirements related to incorporation by reference, although issuers could avoid such costs by electing not to incorporate information by reference. They may also have already incurred this cost for other business reasons.

E. Agency Action To Minimize Effect on Small Entities

The Regulatory Flexibility Act directs us to consider significant alternatives that would accomplish the stated objective, while minimizing any significant adverse impact on small entities. In connection with the amendments, the Regulatory Flexibility Act requires us to consider the following alternatives:

1. Establishing different compliance or reporting requirements that take into account the resources of small entities;

2. The clarification, consolidation, or simplification of disclosure for small entities;

3. Use of performance standards rather than design standards; and

4. Exempting smaller entities from coverage of the disclosure requirements or any part thereof.

Our amendments will extend the benefit of incorporation by reference to small entities that are required to file registration statements on Form S–11. Establishing a different standard for small business entities would impose a greater compliance burden on small entities and would be inconsistent with the benefits provided for small entities that register on Form S–1 and Form F–1.

VI. Statutory Authority and Text of the Amendments

The amendments described in this release are adopted under the authority set forth in Sections 6, 7, 8, 10 and 19(a) of the Securities Act, as amended.

List of Subjects in 17 CFR Part 239

Reporting and recordkeeping requirements, Securities.

■ For the reasons set out in the preamble, the Commission amends title 17, chapter II, of the Code of Federal Regulations as follows:

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 1. The authority citation for part 239 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78*l*, 78m, 78n, 78o(d), 78u–5, 78w(a), 78*ll*, 77mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

■ 2. Amend Form S–11 (referenced in § 239.18) as follows:

■ a. Add General Instruction H;

■ b. Add to the cover page, above the check box related to ''Rule 462(b) under the Securities Act,'' a check box requiring the registrant to indicate whether it is relying on Rule 415 under the Securities Act;

■ c. In Part I, add Item 28A;

■ d. Redesignate Item 29 as Item 29A; and

■ e. Add new Item 29.

The additions read as follows:

Note— The text of Form S–11 does not, and this amendment will not, appear in the Code of Federal Regulations.

FORM S–11

FOR REGISTRATION UNDER THE SECURITIES ACT OF 1933 OF SECURITIES OF CERTAIN REAL ESTATE COMPANIES

General Instructions

* * * * *

H. Eligibility To Use Incorporation by Reference

If a registrant meets the following requirements immediately prior to the time of filing a registration statement on this Form, it may elect to provide information required by Items 3 through 28 of this Form in accordance with Item 28A and Item 29 of this Form:

1. The registrant is subject to the requirement to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934.

2. The registrant has filed all reports and other materials required to be filed by Section 13(a), 14, or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports and materials).

3. The registrant has filed an annual report required under Section 13(a) or Section 15(d) of the Exchange Act for its most recently completed fiscal year.

4. The registrant is not:

(a) And during the past three years neither the registrant nor any of its predecessors was:

(i) A blank check company as defined in Rule 419(a)(2) (§ 230.419(a)(2) of this chapter);

(ii) A shell company, other than a business combination related shell company, each as defined in Rule 405 (§ 230.405 of this chapter); or

(iii) A registrant for an offering of penny stock as defined in Rule 3a51–1 of the Exchange Act (§ 240.3a51–1 of this chapter).

(b) Registering an offering that effectuates a business combination transaction as defined in Rule 165(f)(1) (§ 230.165(f)(1) of this chapter).

5. If a registrant is a successor registrant it shall be deemed to have satisfied conditions 1, 2, 3, and 4(b) above if:

(a) Its predecessor and it, taken together, do so, provided that the succession was primarily for the purpose of changing the state of incorporation of the predecessor or forming a holding company and that the assets and liabilities of the successor at the time of succession were substantially the same as those of the predecessor; or

(b) All predecessors met the conditions at the time of succession and the registrant has continued to do so since the succession.

[55] See Release No. 33–8876.

[56] This estimate is based on our estimate that 19 registration statements by small entities will be subject to the amendments.

6. The registrant makes its periodic and current reports filed pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference pursuant to Item 28A or Item 29 of this Form readily available and accessible on a Web site maintained by or for the registrant and containing information about the registrant.

* * * * *

FORM S–11

* * * * *

If any of the Securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box: [ ]

* * * * *

PART I—INFORMATION REQUIRED IN PROSPECTUS

* * * * *

Item 28A. Material Changes

If the registrant elects to incorporate information by reference pursuant to General Instruction H, describe any and all material changes in the registrant's affairs which have occurred since the end of the latest fiscal year for which audited financial statements were included in the latest Form 10–K and which have not been described in a Form 10–Q or Form 8–K filed under the Exchange Act.

Item 29. Incorporation of Certain Information by Reference

If the registrant elects to incorporate information by reference pursuant to General Instruction H:

(a) It must specifically incorporate by reference into the prospectus contained in the registration statement the following documents by means of a statement to that effect in the prospectus listing all such documents:

(1) The registrant's latest annual report on Form 10–K filed pursuant to Section 13(a) or Section 15(d) of the Exchange Act which contains financial statements for the registrant's latest fiscal year for which a Form 10–K was required to have been filed; and

(2) All other reports filed pursuant to Section 13(a) or Section 15(d) of the Exchange Act or proxy or information statements filed pursuant to Section 14 of the Exchange Act since the end of the fiscal year covered by the annual report referred to in paragraph (a)(1) of this Item.

Note to Item 29(a). Attention is directed to Rule 439 (§ 230.439 of this chapter) regarding consent to use of material incorporated by reference.

(b)(1) The registrant must state:

(i) That it will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that have been incorporated by reference in the prospectus contained in the registration statement but not delivered with the prospectus;

(ii) That it will provide these reports or documents upon written or oral request;

(iii) That it will provide these reports or documents at no cost to the requester;

(iv) The name, address, telephone number, and e-mail address, if any, to which the request for these reports or documents must be made; and

(v) The registrant's Web site address, including the uniform resource locator (URL) where the incorporated reports and other documents may be accessed.

Note to Item 29(b)(1). If the registrant sends any of the information that is incorporated by reference in the prospectus contained in the registration statement to security holders, it also must send any exhibits that are specifically incorporated by reference in that information.

(2) The registrant must:

(i) Identify the reports and other information that it files with the SEC; and

(ii) State that the public may read and copy any materials it files with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. State that the public may obtain information on the operation of the Public Reference Room by calling the SEC at 1–800–SEC–0330. If the registrant is an electronic filer, state that the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC and state the address of that site (*http://www.sec.gov*).

* * * * *

Dated: April 10, 2008.

By the Commission.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–7967 Filed 4–14–08; 8:45 am]

BILLING CODE 8010–01–P

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Part V

The President

Proclamation 8237—National Crime Victims' Rights Week, 2008

Memorandum of April 10, 2008—Designation of the Committee on Technology of the National Science and Technology Council To Carry Out Certain Requirements of the America COMPETES Act

Federal Register
Vol. 73, No. 73
Tuesday, April 15, 2008

Presidential Documents

Title 3—

The President

Proclamation 8237 of April 11, 2008

National Crime Victims' Rights Week, 2008

By the President of the United States of America

A Proclamation

During National Crime Victims' Rights Week we highlight our dedication to protecting and strengthening the rights of crime victims and their families.

My Administration is committed to providing services and resources for victims of crime so that they can find justice, hope, and healing in their lives. To assist victims of domestic violence and their children, my Family Justice Center Initiative established comprehensive support centers in communities across the country. Through the Justice for All Act of 2004, we expanded DNA testing and enhanced the scope and enforceability of crime victims' rights. In 2006, I signed into law the Adam Walsh Child Protection and Safety Act to expand the National Sex Offender Registry, increase Federal penalties for crimes against children, and protect our children while on the Internet. I also support a Crime Victims' Rights Amendment to the Constitution. Through these and other efforts, we can better protect our citizens and our communities.

During National Crime Victims' Rights Week, we recognize the advocates, counselors, and others who assist victims in their time of need, and the law enforcement personnel who work to bring offenders to justice. To learn more about victims' rights, Americans can visit www.crimevictims.gov. By working together, we can help protect crime victims and build a society that respects the life and value of every person.

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 April 13 through April 19, 2008, as National Crime Victims' Rights Week. I encourage all Americans to promote

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of April, 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. 08–1137
Filed 4–14–08; 8:52 am]
Billing code 3195–01–P

Presidential Documents

Memorandum of April 10, 2008

Designation of the Committee on Technology of the National Science and Technology Council To Carry Out Certain Requirements of the America COMPETES Act

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

By the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, including section 1006(e) of the America COMPETES Act (Public Law 110–69) (the ''Act''), I hereby designate the Committee on Technology of the National Science and Technology Council to carry out the responsibilities assigned to the Council on Innovation and Competitiveness in section 1006 of the Act.

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

THE WHITE HOUSE,
Washington, April 10, 2008.

[FR Doc. 08–1138
Filed 4–14–08; 8:52 am]
Billing code 3170–W8–P–M

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