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WHEN: Tuesday, April 10, 2007
9:00 a.m.–Noon

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

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

THE WHITE HOUSE

Privacy and Civil Liberties Oversight Board

6 CFR Chapter X

[0311–AA00]

Freedom of Information Act Procedures

AGENCY: Privacy and Civil Liberties Oversight Board.

ACTION: Interim final rule.

SUMMARY: This interim final rule establishes procedures for the public to obtain information from the Privacy and Civil Liberties Oversight Board under the Freedom of Information Act.

DATES: This interim final rule is effective May 25, 2007. Written comments must be submitted by May 25, 2007.

ADDRESSES: Submit written comments to: FOIA Officer, Privacy and Civil Liberties Oversight Board, The White House, Washington, DC 20502. Comments may also be faxed to 202–456–1066 or e-mailed to *privacyboard@who.eop.gov.* Given the additional time required to process mail through security procedures, the Board recommends sending comments via fax or e-mail.

FOR FURTHER INFORMATION CONTACT: Seth Wood, 202–456–1240.

SUPPLEMENTARY INFORMATION: The Intelligence Reform and Terrorism Prevention Act of 2004, Public Law 108–458, § 1061 (2004) (IRTPA), created the Privacy and Civil Liberties Oversight Board (Board). IRTPA instructs the Board to ''ensure that concerns with respect to privacy and civil liberties are appropriately considered in the implementation of laws, regulations, and executive branch policies related to efforts to protect the Nation against terrorism.'' *Id.* § 1061(c)(1)(C). In carrying out this mandate, the Board exercises both an advisory and oversight responsibility. First, it ''advise[s] the President and the head of any department or agency of the executive branch to ensure that privacy and civil liberties are appropriately considered'' in the development and implementation of ''laws, regulations, and Executive Branch policies related to efforts to protect the Nation from terrorism'' *Id.* Second, it ''continually review[s] regulations, executive branch policies, and procedures * * * and other actions by the executive branch related to efforts to protect the Nation from terrorism to ensure that privacy and civil liberties are protected.'' *Id.* § (c)(2)(A). IRTPA places the Board within the Executive Office of the President.

The Board's membership consists of a Chairman, Vice Chairman, and three regular Members. The President appoints all Members, with the Chairman and Vice Chairman requiring Senate confirmation. *Id.* § 1061(e). IRTPA subjects the Board to the Freedom of Information Act, 5 U.S.C. 552 (FOIA). IRTPA § 106(i)(2). These interim-final regulations provide procedures for individuals to request records from the Board and inform the public regarding how the Board will process such requests. Members of the public may comment on these interim-final regulations forty-five days following their publication.

List of Subjects in 6 CFR Part 1000

Administrative practice and procedure, Confidential business information, Reporting and recordkeeping requirements.

■ For the reasons set forth in this preamble and under the authority of the Intelligence Reform and Terrorism Prevention Act of 2004, the Privacy and Civil Liberties Oversight Board establishes 6 CFR Chapter X, consisting of part 1000.

Chapter X—Privacy and Civil Liberties Oversight Board

PART 1000—DISCLOSURE OF RECORDS AND INFORMATION

Freedom of Information Act

Sec.

1000.1 Definitions.
1000.2 Purpose.
1000.3 Authority and functions of Board.
1000.4 Other information.
1000.5 Public reference.
1000.6 How to request records.
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1000.10 Charges for search, review, and reproduction.
1000.11 Annual report.

Authority: Public Law 108–408; 5 U.S.C. 552 *et seq.*

Freedom of Information Act

§ 1000.1 Definitions.

Agency means Agency as defined in 5 U.S.C. 552(f)(1). The Privacy and Civil Liberties Oversight Board shall not be considered as an agency for any other purpose, except as referred to in this Regulation, and for Freedom of Information Act (FOIA) purposes.

Board or *PCLOB* means the Privacy and Civil Liberties Oversight Board.

Calendar Days means all days, including Saturday, Sunday, or Federal holidays.

Commercial Use Request refers to a request from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requestor or the person on whose behalf the request is made.

Compelling need means that a failure to obtain requested Records on an expedited basis under this paragraph could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or with respect to a request made by a person primarily engaged in disseminating information, an urgency to inform the public concerning actual or alleged Federal Government activity.

Computer search means the actual direct cost of providing the service. This will include the cost of operating the central processing unit for that portion of operating time that is directly attributable to Searching for potentially responsive records to a FOIA request and the portion of the salary of the operators/programmers attributable to the search.

Days means ''work days'' not including Saturday, Sunday, Federal holidays, or other days the Board is closed.

Direct costs means those expenditures that the Board actually incurs in searching for and duplicating (and in the case of commercial requestors, reviewing) documents to respond to a FOIA request. Direct costs include, for

example, the salary of the employee performing work (the basic rate of pay for the employee plus 16 percent of that rate to cover benefits) and the cost of operating duplicating machinery. Not included in direct costs are overhead expenses such as costs of space and heating or lighting the facility in which the Records are stored.

Duplication means the making of a copy of a document, or of the information contained in it, necessary to respond to a FOIA request. Such copies can take the form of paper, microform, audiovisual materials, or electronic Records (e.g., magnetic tape or disk), among others.

Educational institution refers to a preschool, a public or private elementary or secondary school, an institution of graduate higher education, an institution of undergraduate higher education, an institution of professional education, or an institution of vocational education that operates a program or programs of scholarly research.

FOIA means the Freedom of Information Act (5 U.S.C. 552).

Head of the agency means the Chairman of the Privacy and Civil Liberties Oversight Board or the Chairman's designee.

Non-commercial scientific institution refers to an institution that is not operated on a commercial basis, and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry.

Record means a record as defined in 5 U.S.C. 552(f)(2). A Record must exist and be in the Board's custody and control at the time of the request to be considered subject to this part and FOIA.

Representative of the news media refers to any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. The term ''news'' means information that is about current events or that would be of current interest to the public. As traditional methods of news delivery evolve (e.g., electronic dissemination of newspapers through telecommunications services and Web sites), such media would be included in this category. In the case of freelance journalists, they may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization, even though they are not actually employed by it.

Review means the process of examining documents located in response to a request that is for a commercial use to determine whether any portion of any document located is exempt from release or otherwise permitted to be withheld. It also includes processing any documents for disclosure (doing all that is necessary to excise them and otherwise prepare them for release). Review does not include time spent resolving general legal or policy issues regarding the application of exemptions.

Search means the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from Records maintained in electronic form or format.

§ 1000.2 Purpose.

These regulations describe how the Board implements the requirements of the Freedom of Information Act, 5 U.S.C. 552 *et seq.,* and the procedures by which records may be obtained from the Board. Official records of the Board made available pursuant to FOIA shall be furnished to members of the public only pursuant to statute and as prescribed in these regulations.

§ 1000.3 Authority and functions of Board.

The Board advises the President and other senior Executive Branch officials to ensure that concerns with respect to privacy and civil liberties are appropriately considered in the implementation of all laws, regulations, and Executive Branch policies related to efforts to protect the Nation against terrorism. This includes advising on whether adequate guidelines, supervision, and oversight exist to protect these important legal rights of all Americans. The Board was established by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. No. 108–458).

§ 1000.4 Other information.

Additional information regarding the Board, including its members, organization, public statements, and relevant legislation, may be located on its Web site: *http://www.privacyboard.gov.*

§ 1000.5 Public reference.

(a) The Board will make available for public inspection a copy of all material required to be made public by 5 U.S.C. 552(a)(2), including all documents published by the Board in the **Federal Register** and currently in effect. This material will also be available on the Board's Web site, *http://www.privacyboard.gov.*

(b) In order to view documents maintained pursuant to § 1000.5(a), members of the public should contact the Board at (202) 456–1240 or by e-mail at *privacyboard@who.eop.gov.*

(c) The FOIA Officer shall also maintain a file open to the public, which shall contain copies of all grants or denials of appeals by the Board.

(d) The public may contact the Board's Chief FOIA Officer and the Public Liaison by writing to the address listed in § 1000.6(a) or by calling (202) 456–1240.

§ 1000.6 How to request records.

(a) A request for records pursuant to FOIA must be submitted in writing. An individual may submit a request via mail: FOIA Officer, Privacy and Civil Liberties Oversight Board, The White House, Washington, DC 20502; or via fax: (202) 456–1066. To ensure prompt receipt, the Board recommends sending a request via fax, as security procedures may delay requests sent through the mail. The words ''FOIA REQUEST'' should be clearly marked on the envelope or cover page, as well as on the actual request. The request must contain a means of contacting the requestor via mail and via telephone. The Board does not accept FOIA requests by e-mail.

(b) Each request must reasonably describe the record(s) sought, including when known: The organization or individual originating the Record; subject matter; type of record; location; and any other pertinent information which would assist in promptly locating the Record. Requests shall also contain a description of their purpose so that a determination may be made regarding the appropriate fee structure that should be applied to the request. See § 1000.10(i). Requests that do not meet these requirements will not be considered a proper request.

(c) When a request is not considered reasonably descriptive, or requires the production of voluminous records, or places an extraordinary burden on the FOIA Officer or other members of the Board staff that would seriously interfere with its normal functioning, the Board shall provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the Board an alternative time frame for processing the request or a modified request. Refusal by the person reasonably to modify the request or arrange such an alternative time frame shall be considered as a factor in determining whether exceptional circumstances exist for purposes of 5 U.S.C. 552(a)(6)(C).

§ 1000.7 Initial determination.

References to the FOIA Officer shall, unless otherwise stated, include the FOIA Officer's designee. The FOIA Officer shall have the authority to approve or deny requests received pursuant to these regulations. The decision of the FOIA Officer shall be final, subject only to administrative appeal as provided in § 1000.9.

§ 1000.8 Response to FOIA request.

(a) When a requested record has been identified and is available, the FOIA Officer shall notify the person making the request as to where and when the record is available for inspection or the copies will be available. The notification shall also advise the person making the request of any fees pursuant to § 1000.10.

(b) The FOIA Officer shall approve or deny, in whole or in part, a request for Records as soon as reasonably possible. Such a response will be given in writing and will occur within 20 days after the Officer receives the request. The FOIA Officer may grant or deny a portion of a request if it appears that other, separate elements of the request will require additional time to complete. Pursuant to 5 U.S.C. 552(a)(6)(B), the FOIA Officer may extend these time limits by written notice to the person making such request. Such written notice shall set forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. Such a notice shall not specify a date that would result in an extension for more than 10 days, except as provided in § 1000.6(c). Additional time may be required because:

(1) It is necessary to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request;

(2) It is necessary to consult with another organization having a substantial interest in the determination of the request or among two or more components of the organization having substantial subject matter interest therein; or

(3) For other reasons discussed in 5 U.S.C. 552(a)(6)(B).

(c) If the request is denied, the written notification to the person making the request shall include the names of the individuals who participated in the determination, the reasons for the denial, and a notice that an appeal may be lodged with the head of the agency within 30 calendar days of receipt of the denial or partial denial.

(d) The FOIA officer may grant expedited consideration of a FOIA request or appeal if the requestor shows a compelling need for such expedited consideration. The requestor must submit such a request in writing. A demonstration of a compelling need by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief. The FOIA officer will respond to such a request within 10 days of receipt of the request.

§ 1000.9 Administrative appeal.

Appeals shall be set forth in writing within 30 calendar days of receipt of a denial and addressed to the head of the agency via mail or fax pursuant to the contact information listed in § 1000.6(a). The words ''FOIA APPEAL'' must be clearly marked on the envelope or cover page, as well as the actual appeal. The appeal shall include a statement explaining the basis for the appeal. Determinations of appeals will be set forth in writing and signed by the head of the agency, or his designee, within 20 days of receipt of the appeal. If, on appeal, the denial is in whole or in part upheld, the written determination will also contain a notification of the provisions for judicial review, where a challenge may be filed, and the names of the persons who participated in the determination.

§ 1000.10 Charges for search, review, and reproduction.

(a) The Board will charge fees that recoup the full allowable direct costs it incurs. This may also include costs incurred by another organization to search for, review, and produce potentially responsive records. Moreover, it shall use the most efficient and least costly methods to comply with requests for records made under FOIA.

(b) With regard to manual searches for records, the Board will charge at the salary rate(s) (i.e., basic pay plus 16 percent) of the employee(s) making the search.

(c) In calculating charges for computer searches for records, the Board will charge at the actual direct cost of providing the service. This will include the cost of operating the central processing unit for that portion of operating time that is directly attributable to searching for records potentially responsive to a FOIA request and the portion of the salary of the operators/programmers attributable to the search.

(d) Only requestors who are seeking documents for commercial use may be charged for time spent reviewing records to determine whether they are exempt from mandatory disclosure. Charges may be assessed only for the initial review—that is, the review undertaken the first time the Board analyzes the applicability of a specific exemption to a particular record or portion of a record. Records or portions of records withheld in full under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The Board may assess the costs for such a subsequent review.

(e) Records will be duplicated at a rate of $.15 per page, except that the Board may adjust that rate from time to time by notice published in the **Federal Register**. For copies prepared by computer, such as tapes or printouts, the Board shall charge the actual cost, including operator time, of production of the tape or printout. For other methods of reproduction or duplication, the Board will charge the actual direct costs of producing the document(s). If the Board estimates that duplication charges are likely to exceed $25, it shall notify the requestor of the estimated amount of fees, unless the requestor has indicated in advance his willingness to pay fees as high as those anticipated. Such a notice shall offer a requestor the opportunity to confer with PCLOB personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(f) Remittances shall be in the form either of a personal check or bank draft drawn on a bank in the United States, or a postal money order. Remittances shall be made payable to the order of the Treasury of the United States and mailed to the FOIA Officer, Privacy and Civil Liberties Oversight Board, The White House, Washington, DC 20502.

(g) A receipt for fees paid will be given upon request. Refund of fees paid for services actually rendered will not be made.

(h) With the exception of requestors seeking documents for a Commercial Use, the Board will provide the first 100 pages of duplication and the first two hours of search time without charge.

(1) For purposes of these restrictions on assessment of fees, the word ''pages'' refers to 8½″ x 11″ or 11″ x 14″ paper copies. Thus, requestors are not entitled to 100 microfiche or 100 computer disks, for example. By contrast, a microfiche containing the equivalent of 100 pages or 100 pages of computer printout does meet the terms of the restriction.

(2) Similarly, the term ''Search time'' in this context applies to a manual search. To apply this term to searches made by computer, the Board will determine the hourly cost of operating the central processing unit and the

operator's hourly salary plus 16 percent. When the cost of search (including the operator time and the cost of operating the computer to process a request) equals the equivalent dollar amount of two hours of the salary of the person performing the search, the Board will begin assessing charges for computer searches.

(i) The Board divides FOIA requestors into four categories: Commercial use requestors; educational and non-commercial scientific institutions; representatives of the news media; and all other requestors. The specific levels of fees for each of these categories are:

(1) *Commercial use requestors.* When the Board receives a request for documents for commercial use, it will assess charges that recover the full direct costs of searching for, reviewing for release, and duplicating the record sought. Requestors must reasonably describe the records sought. Commercial use requestors are entitled neither to two hours of free search time nor to 100 free pages of reproduction of documents. The Board may recover the cost of searching for and Reviewing Records even if there is ultimately no disclosure of Records.

(2) *Educational and non-commercial scientific institution requestors.* The Board shall provide documents to requestors in this category for the cost of reproduction alone, excluding charges for the first 100 pages. To be eligible for inclusion in this category, requestors must show that the request is being made as authorized by and under the auspices of a qualifying institution and that the records are not sought for a commercial use, but are sought in furtherance of scholarly (if the request is from an Educational Institution) or scientific (if the request is from a non-commercial scientific institution) research. Requestors must reasonably describe the records sought.

(3) *Requestors who are representatives of the news media.* The Board will provide documents to requestors in this category for the cost of reproduction alone, excluding charges for the first 100 pages. To be eligible for inclusion in this category, a requestor must satisfy the definition of representatives of the news media in § 1000.1, and his or her request must not be made for a commercial use. In reference to this class of requestor, a request for Records supporting the news dissemination function of the requestor shall not be considered to be a request that is for a commercial use. Requestors must reasonably describe the Records sought.

(4) *All other requestors.* The Board shall charge requestors who do not fit into any of the categories above fees that recover the full reasonable Direct Cost of Searching for and reproducing Records that are responsive to the request, except that the first 100 pages of reproduction and the first two hours of Search time shall be furnished without charge. Requestors must reasonably describe the Records sought.

(j) The Board may assess interest charges on an unpaid bill starting on the 31st Calendar Day following the day on which the billing was sent. The fact that the fee has been received within the thirty Calendar Day grace period, even if the fee has not been processed, will suffice to stay the accrual of interest. Interest will be at the rate prescribed in section 3717 of title 31 of the United States Code and will accrue from the date of the billing.

(k) The Board may assess charges for time spent searching, even if it fails to locate the Records or if Records located are determined to be exempt from disclosure. If the Board estimates that Search charges are likely to exceed $25, it shall notify the requestor of the estimated amount of fees, unless the requestor has indicated in advance his willingness to pay fees as high as those anticipated.

(l) A requestor may not file multiple requests, each seeking portions of a document or documents, solely in order to avoid payment of fees. When the Board reasonably believes that a requestor, or a group of requestors acting in concert, has submitted requests that constitute a single request, involving clearly related matters, it may aggregate those requests and charge accordingly.

(m)(1) The Board may not require a requestor to make payment before work is commenced or continued on a request, unless:

(i) The Board estimates or determines that allowable charges that a requestor may be required to pay are likely to exceed $250; or

(ii) A requestor has previously failed to pay a fee charged in a timely fashion (i.e., within 30 Days of the date of the billing).

(2) When the Board acts under paragraph (m)(1)(i) or (ii) of this section, the administrative time limits prescribed in FOIA, 5 U.S.C. § 552(a)(6) will begin only after the Board has received fee payments described in paragraphs (m)(1)(i) and (ii) of this section.

(n) Fees otherwise chargeable in connection with a request for disclosure of a record shall be waived or reduced where it is determined that disclosure is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government and is not primarily in the commercial interest of the requestor.

§ 1000.11 Annual report.

The FOIA Officer or the FOIA Officer's designee shall annually, on or before February 1, submit a FOIA report addressing the preceding fiscal year to the Attorney General. The report shall include those matters required by 5 U.S.C. 552(e)(1). The Board will make the annual report available to the public pursuant to 5 U.S.C. 552(e)(2).

Mark A. Robbins,

Executive Director, Privacy and Civil Liberties Oversight Board.

[FR Doc. E7–5812 Filed 4–9–07; 8:45 am]

BILLING CODE 3195–W7–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 946

[Docket No. AMS–FV–06–0182; FV06–946–1 FR]

Irish Potatoes Grown in Washington; Modification of Administrative Rules Governing Committee Representation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule modifies the administrative rules governing committee representation under the Washington potato marketing order. The marketing order regulates the handling of Irish potatoes grown in Washington, and is administered locally by the State of Washington Potato Committee (Committee). This rule reestablishes districts within the production area, reestablishes the Committee with fewer members, and reapportions members among districts. These changes will result in more efficient administration of the program while providing for more effective representation of the Washington fresh potato industry on the Committee.

DATES: *Effective Date:* July 1, 2007.

FOR FURTHER INFORMATION CONTACT: Teresa Hutchinson or Gary Olson, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or e-mail: *Teresa.Hutchinson@usda.gov* or *GaryD.Olson@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Jay Guerber,

Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or e-mail: *Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Order No. 946, as amended (7 CFR part 946), regulating the handling of Irish potatoes grown in Washington, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This proposal will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule modifies the administrative rules governing committee representation under the Washington potato marketing order. This rule reestablishes districts within the production area, reestablishes the Committee with fewer members, and reapportions members among the new districts. Specifically, this rule reestablishes the order's five districts as three districts; decreases Committee membership from fifteen members and fifteen alternate members to nine members and nine alternate members; and reapportions the members such that one handler member and alternate member, and two producer members and their respective alternate members are elected from each of the three reestablished districts. These changes will result in more efficient administration of the program while providing for more effective representation of the fresh potato industry on the Committee. The Committee unanimously recommended these changes at a meeting held on June 6, 2006, with a request that they be made effective by July 1, 2007.

The order provides in § 946.22 that USDA, upon recommendation of the Committee, may reestablish districts, may reapportion members among districts, may change the number of members and alternate members, and may change the composition by changing the ratio of members, including their alternates. In recommending any such changes, the order requires that the Committee consider the following: (1) Shifts in acreage within districts and within the production area during recent years; (2) the importance of new production in its relation to existing districts; (3) the equitable relationship between Committee apportionment and districts; and (4) other relevant factors.

Prior to this rule change, the Committee had fifteen members, with membership apportioned among five districts. Sections 946.31 and 946.103 previously defined the districts as follows: District No. 1—The counties of Ferry, Stevens, Pend Oreille, Spokane, Whitman, and Lincoln, plus the East Irrigation District of the Columbia Basin Project, plus the area of Grant County not included in either the Quincy or South Irrigation Districts which lies east of township vertical line R27E, plus the area of Adams County not included in either of the South or Quincy Irrigation Districts.

District No. 2—The counties of Kittitas, Douglas, Chelan, and Okanogan, plus the Quincy Irrigation District of the Columbia Basin Project, plus the area of Grant County not included in the East or South Irrigation Districts which lies west of township line R28E.

District No. 3—The counties of Benton, Klickitat, and Yakima.

District No. 4—The counties of Walla Walla, Columbia, Garfield, and Asotin, plus the South Irrigation District of the Columbia Basin Project, plus the area of Franklin County not included in the South District.

District No. 5—All of the remaining counties in the State of Washington not included in Districts No. 1, 2, 3, and 4 of this section.

Further, §§ 946.25 and 946.104 currently provide in part that each of the five districts are represented as follows:

District No. 1: Three producer members and one handler member; District No. 2: Two producer members and one handler member; District No. 3: Two producer members and one handler member; District No. 4: Two producer members and one handler member; District No. 5: One producer member and one handler member.

The Committee's districts were last reestablished on July 1, 1975, largely due to changes in the production area brought about by the Columbia Basin Project (CBP). The CBP is a large scale irrigation project administered by the Bureau of Reclamation, U.S. Department of Interior. The CBP is comprised of three irrigation districts centered in Grant County, Washington.

The Committee's districts were originally established using county boundaries, whereas the 1975 redistricting process reestablished the districts by utilizing existing county and township lines, as well as the three irrigation districts formed under the CBP. As a consequence, the Committee utilized the CBP irrigation district boundaries in redistricting. At the time, the boundaries of the three irrigation districts were well known to producers in the area. However, as more producers installed wells to irrigate their potatoes, the CBP irrigation district boundaries became less relevant.

Also, the Committee reports that it is having difficulty recruiting members. This recruitment issue is largely due to a decreasing number of qualified individuals willing to take the time away from their families and farms to serve on the Committee.

Finally, the Washington State Potato Commission (Commission), an agency of the State of Washington, has recently reestablished its production area into three districts. The Committee recommended reestablishing the order's districts to align with the Commission's new districts.

After comparing current acreage and production statistics, as well as the current number of fresh potato producers in each of the order's five districts to statistics for the Commission's three new districts, the Committee found that reestablishment of its districts from five to three would not only be feasible, but could enhance the Committee's administration of the order. In considering the trend towards less industry participation on the Committee, as well as the decreasing relative size of the fresh potato producer population (the 5 year average fresh production is 13% of the total Washington potato production), the

Committee also determined that it could more effectively serve the industry if it were to reestablish with as few as nine members.

Prior to this rule, the Committee was comprised of ten producer members and five handler members and their respective alternates. The Committee felt that this ratio—two producer members to each handler member—should also be used in reestablishing and reapportioning the Committee. Based on statistical information available from USDA, the Committee therefore determined that the reestablished Committee should be comprised of nine members—six producer members and three handler members—with two producer members and respective alternates, and one handler member and respective alternate representing each of the three new districts.

In determining how to appropriately divide the production area into three districts, as well as the correct apportionment of nine members in three new districts, the Committee reviewed the relative differences in fresh production and acreage estimates in Washington's various potato producing counties. Using data from the USDA's National Agriculture Statistics Service (NASS), the Committee's research indicated that the new District No. 1 will have 41 percent of the fresh potato producers, 36 percent of the fresh potato production, and 32 percent of the fresh potato acreage in the order's production area. The new District No. 2 will have 31 percent of the producers, 43 percent of the production, and 36 percent of the acreage. Finally, the new District No. 3 will have 28 percent of the producers, 21 percent of the production, and 32 percent of the acreage.

Although these statistics show that the number of fresh potato farms and the related production figures are not evenly divided among the new districts, acreage figures are nearly equal. Additionally, the Committee reports that there are widely variable yields among the various table-stock potato varieties produced in Washington's diverse production areas. In equitably apportioning the nine members among the three districts, the Committee chose not to provide districts that predominately produce a lower yielding variety of potato with less representation on the Committee. As previously noted, the Committee's recommendation therefore includes provision that two producer members and one handler member, as well as their respective alternates, represent each district.

The new districts provide consistency in the Washington potato industry. All of Grant County is located in the reestablished District No. 1 instead of being divided between Districts No. 1, 2 and 4, as was previously the case. The new District No. 1 consists of the counties of Douglas, Chelan, Okanogan, Grant, Adams, Ferry, Stevens, Pend Oreille, Spokane, Whitman, and Lincoln. The new District No. 2 consists of the counties of Kittitas, Yakima, Klickitat, Benton, Franklin, Walla Walla, Columbia, Garfield, and Asotin. Finally, the new District No. 3 consists of all the remaining counties in the State of Washington not included in Districts No. 1 and 2 (essentially all of the counties west of the Cascade Mountains).

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 45 handlers of Washington potatoes subject to regulation under the order and approximately 267 potato producers in the regulated area. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $6,500,000, and small agricultural producers are defined as those having annual receipts of less than $750,000.

During the 2005–2006 marketing year, 10,516,095 hundredweight of Washington potatoes were inspected under the order and sold into the fresh market. Based on an estimated average f.o.b. price of $7.80 per hundredweight, the Committee estimates that 43 handlers, or about 96 percent, had annual receipts of less than $6,500,000.

In addition, based on information provided by NASS, the average producer price for Washington potatoes for the 2005 marketing year (the most recent period that final statistics are available) was $5.60 per hundredweight. The average annual producer revenue for each of the 267 Washington potato producers is therefore calculated to be approximately $220,562. In view of the foregoing, the majority of the handlers and producers of Washington potatoes may be classified as small entities.

This final rule modifies §§ 946.103 and 946.104 of the order's administrative rules and regulations by reestablishing the order's districts from the current five districts to three districts, reestablishing the Committee with nine members rather than fifteen members, and reapportioning the membership such that each district is represented by two producers and one handler and their respective alternates. This final rule is effective July 1, 2007. Authority for reestablishing the districts, as well as reestablishing and reapportioning the Committee is provided in § 946.22 of the order.

The Committee believes that these changes will not negatively impact handlers and producers in terms of cost. Costs for Committee meetings should actually decrease because of the reduction in the number of members and their respective alternates traveling to meetings. Such savings could ultimately be passed on to handlers and producers in the form of reduced assessments. The benefits for this rule are not expected to be disproportionately greater or less for small handlers or producers than for larger entities.

The Committee discussed various alternative reductions in Committee size and how to reapportion fewer members among the districts. Ultimately, the Committee determined that reducing its size to nine members would best mitigate the problems associated with recruitment of qualified members.

Since this final rule modifies the administrative rules governing committee representation by reestablishing districts, reestablishing the Committee, and reapportioning members among districts, additional reporting or recordkeeping requirements will not be imposed on either small or large potato handlers. The information collection requirements contained in this rule have been previously approved by the Office of Management and Budget under OMB No. 0581–0178, Vegetable and Specialty Crops. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen

access to Government information and services, and for other purposes.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this final rule.

In addition, the Committee's meeting was widely publicized throughout the Washington potato industry and all interested persons were invited to attend and participate in Committee deliberations on all issues. Like all Committee meetings, the February 9, 2006, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on January 16, 2007 (72 FR 1685). Copies of the rule were sent to all Committee members and were made available for all attendees at the February 7, 2007, Committee meeting. Finally, the rule was made available through the Internet by USDA and the Office of the Federal Register. A 60-day comment period ending March 19, 2007, was provided to allow interested persons to respond to the proposal. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/fv/moab.html.* Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because the Committee needs adequate time to conduct nominations and a mail vote to elect new Committee members and alternates prior to the fiscal period beginning on July 1, 2007. Further, Committee members and alternates are aware of this rule, which was recommended at a public meeting. Also, a 60-day comment period was provided for in the proposed rule.

List of Subjects in 7 CFR Part 946

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 946 is amended as follows:

PART 946—IRISH POTATOES GROWN IN WASHINGTON

■ 1. The authority citation for 7 CFR part 946 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 946.103 is revised to read as follows:

§ 946.103 Reestablishment of districts.

Pursuant to § 946.22, on and after July 1, 2007, the following districts are reestablished:

(a) District No. 1—the counties of Douglas, Chelan, Okanogan, Grant, Adams, Ferry, Stevens, Pend Oreille, Spokane, Whitman, and Lincoln.

(b) District No. 2—the counties of Kittitas, Yakima, Klickitat, Benton, Franklin, Walla Walla, Columbia, Garfield, and Asotin.

(c) District No. 3—all of the remaining counties in the State of Washington, not included in Districts No. 1 and No. 2 of this paragraph.

■ 3. Section 946.104 is revised to read as follows:

§ 946.104 Reestablishment and reapportionment of committee.

(a) Pursuant to § 946.22, on and after July 1, 2007, the State of Washington Potato Committee consisting of nine members, of whom six shall be producers and three shall be handlers, is hereby reestablished. For each member of the committee there shall be an alternate who shall have the same qualifications as the member.

(b) Pursuant to § 946.22, on and after July 1, 2007, membership representation of the State of Washington Potato Committee shall be reapportioned among the districts of the production area so as to provide that each of the three districts as defined in § 946.103 are represented by two producer members and one handler member and their respective alternates.

Dated: April 5, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. 07–1794 Filed 4–6–07; 12:20 pm]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 105 and 115

[Docket No. 02–107–2]

RIN 0579–AC29

Viruses, Serums, Toxins, and Analogous Products; Suspension, Revocation, or Termination of Biological Licenses or Permits; Inspections

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations to specify the actions to be taken by veterinary biologics licensees and permittees upon receipt of notice from the Animal and Plant Health Inspection Service (APHIS) to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product. After receiving notice from APHIS, licensees and permittees must notify each wholesaler, dealer, jobber, consignee, or other recipient known to have any such product in their possession to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of such product. In addition, licensees and permittees must provide a complete accounting of the remaining inventory of affected serials or subserials of such product in the current possession of known wholesalers, dealers, jobbers, consignees, or other known recipients and provide written documentation concerning the required notification(s) as directed by the Administrator of APHIS. These changes are necessary in order to clarify the regulations, provide for the most expeditious means of disseminating stop distribution and sale notices, and to mitigate the risk that any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product may cause harm to animals, the public health, or to the environment.

DATES: *Effective Date:* May 10, 2007.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

Parts 105 and 115 of the Virus-Serum-Toxin Act regulations (9 CFR parts 105 and 115, referred to below as the regulations) provide, respectively, for the suspension, revocation, or termination of biological licenses or permits and for the inspection of veterinary biologics establishments and veterinary biological products. These regulations also contain provisions that address the actions to be taken by the manufacturer or importer, and any jobbers, wholesalers, dealers, or other persons known to have veterinary biologics in their possession, upon their receipt of notice from the Animal and Plant Health Inspection Service (APHIS) to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product.

Section 105.3 of the regulations provides, in relevant part, that APHIS may notify a licensee or permittee to stop the preparation, sale, barter, exchange, shipment, or importation of any veterinary biological product if at any time it appears that such product may be dangerous in the treatment of domestic animals or unsatisfactory according to applicable Standard Requirements.

Similarly, § 115.2 provides, in relevant part, that if as a result of any inspection it appears that any veterinary biological product is worthless, contaminated, dangerous, or harmful, the Secretary will give notice of that finding to the manufacturer or importer and to any jobbers, wholesalers, dealers, or other persons known to have any of such product in their possession. After receiving such notice, no person may sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product in or from any State, Territory, or the District of Columbia.

Typically, before stop distribution and sale notifications provided for by §§ 105.3 and 115.2 can be given, APHIS must obtain from the licensees and permittees (manufacturers or importers) the names and addresses of the wholesalers, dealers, jobbers, consignees, or other persons known to have any of such unsatisfactory product in their possession. Any delay in obtaining the names and addresses of persons in possession of biological products subject to a stop distribution and sale notification increases the risk that such product may cause harm to animals, the public health, or to the environment. We believe that it is prudent to use the most expeditious means available to notify wholesalers, dealers, jobbers, foreign consignees, or other persons concerning the stop distribution and sale action.

On April 9, 2003, we published in the **Federal Register** (68 FR 17327–17330, Docket No. 02–107–1) a proposal to amend the regulations to require veterinary biologics licensees and permittees (instead of APHIS) to: (1) Notify wholesalers, dealers, jobbers, or other persons concerning APHIS-directed stop distribution and sale notifications pertaining to worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product; (2) account for any remaining quantity of such product in the current possession of persons involved in the distribution or sale of said product; and (3) to provide written documentation concerning the required notifications as directed by the Administrator of APHIS.

We solicited comments concerning our proposal for 60 days ending June 9, 2003. We received one comment by that date, from a trade association representing veterinary biologics manufacturers. We carefully considered this comment before we reached a decision concerning our proposal. The comment is discussed below.

The commenter stated that the proposed rule could be subject to multiple interpretations and would require licensees and permittees to be accountable for activities beyond their ability to control, and requested clarification regarding the proposed provisions that would require licensees and permittees to account for the quantity for each serial or subserial of unsatisfactory product at each location in the distribution channel (i.e., the provisions of proposed §§ 105.3(c)(3) and 115.2(b)(3)). The commenter inquired as to whether this meant accounting only for the quantity of product shipped from the manufacturer directly to primary (presumably, known) distributors (wholesalers, etc.) or, in addition, accounting for product shipped from primary distributors to secondary and/or tertiary recipients who may not be known to the manufacturer or importer.

In proposed §§ 105.3(c)(2) and 115.2(b)(2), we specified that stop sale notifications should be issued to all wholesalers, jobbers, dealers, foreign consignees, or other persons known to have the product in their possession. However, we agree that the wording of proposed §§ 105.3(c)(3) and 115.2(b)(3) could be interpreted as requiring licensees and permittees to account for product in the possession of persons that are not known to the manufacturer or importer. To clarify those provisions, we have amended §§ 105.3(c)(3) and 115.2(b)(3) in this final rule to refer to accounting for the quantity of product at each location known to the manufacturer or importer. As amended, §§ 105.3(c)(3) and 115.2(b)(3) now read: ''Account for the remaining quantity of each serial(s) or subserial(s) of any such veterinary biological product at each location in the distribution channel known to the manufacturer or importer.''

The commenter also inquired as to the meaning of ''immediately'' as used in §§ 105.3(c)(2) and 115.2(b)(2) of the proposed rule, and identified several situations where ''rapid notification'' may not be in the best interest of the consumer or manufacturer.

The purpose of the typical stop distribution and sale action is to mitigate the possibility that any worthless, dangerous, harmful, or unsatisfactory veterinary biological product may cause harm to animals, the public health, or to the environment. We realize that a hasty decision may not be in the best interest of the health of animals or the manufacturer, and would exercise great caution before issuing a stop distribution and sale notification. However, we believe that stop distribution and sale notifications should be carried out as expeditiously as possible once the determination has been made that suspension of distribution and sale of the product is the best means to limit harm to animals, the public health, or the environment. To clarify the meaning of ''immediately,'' we have amended §§ 105.3(c)(2) and 115.2(b)(2) in this final rule to read as follows: ''Immediately, but no later than 2 days, send stop distribution and sale notifications to any wholesalers, jobbers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All such notifications shall be documented in writing by the licensee or permittee.''

The commenter agreed with the estimate of burden in the proposed rule's Paperwork Reduction Act section of 1.7666 hours per response for respondents affected by stop distribution and sale notifications, provided that such notifications are only applicable to ''parties that are a single business transaction away from the licensee or permittee'' (i.e., known to the manufacturer or importer). However, the commenter opined that

1.7666 hours per response may be an underestimate for firms that market directly to veterinarians, or if such notifications must ''include all participants in each distribution chain,'' (i.e., known and unknown participants).

Regarding the commenter's concern that notification must include all participants in each distribution chain, APHIS has amended §§ 105.3(c)(3) and 115.2(b)(3) in this final rule to specify that licensees and permittees are only required to notify wholesalers, jobbers, dealers, foreign consignees, or other persons known to be in possession of product subject to the stop distribution and sale action. In addition, APHIS believes that available technological tools such as electronic mail, facsimile, and the telephone help lower the burden of notification in all cases, including for those who market directly to veterinarians. Given these facts, APHIS believes that the estimated burden of 1.7666 hours per response stated in the proposed rule is not unreasonable.

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

Executive Order 12866 and Regulatory Flexibility Act

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

We are amending §§ 105.3 and 115.2 of our regulations under the Virus-Serum-Toxin Act concerning actions that veterinary biologics licensees and permittees must take after receiving notice from APHIS to stop distribution and sale of a serial(s) or subserial(s) of veterinary biological product that is found to be unsatisfactory according to applicable standard requirements, or if it appears that such product is worthless, contaminated, dangerous, or harmful. Licensees and permittees are required to notify wholesalers, jobbers, dealers, foreign consignees, or other persons known to be in possession of such product immediately, but no later than 2 days after being contacted by APHIS, to stop further distribution and sale of such serial(s) or subserial(s) pending further instructions. This final rule also requires veterinary biologics licensees and permittees to document, in writing, their communications with wholesalers, jobbers, dealers, foreign consignees, or other persons concerning such stop distribution and sale notifications; determine the remaining inventory of such product in the current possession of such wholesalers, jobbers, dealers, consignees, or other persons; and, as directed by the Administrator, submit reports of all such notifications to APHIS.

The primary effect of this rule will be to provide for the most expeditious means of disseminating information concerning stop distribution and sale notices pertaining to veterinary biological product found unsatisfactory according to applicable standard requirements, and to mitigate the risk that such unsatisfactory veterinary biological product may cause harm to animals, the public health, or the environment. The rule also clarifies the regulations with regard to whom licensees and permittees should contact concerning stop distribution and sale notification, and what information APHIS may require to be reported concerning such notification.

There are approximately 125 veterinary biologics establishments, including permittees, that may be affected by this rule. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

It is anticipated that no undue recordkeeping burden will be added to licensees and permittees since §§ 116.2 and 116.5 of the regulations currently require the maintenance of detailed disposition records and the submission of reports concerning each biological product that is prepared and/or shipped. We further anticipate that the only economic effects that may result from this amendment to the regulations would be related to the costs incurred by licensees and permittees in connection with the notification process itself. This final rule does not specify the means by which licensees and permittees are required to give notification, only that notification be given immediately, but no later than 2 days of receipt of the stop distribution and sale notification from APHIS. We expect that licensees and permittees would use electronic mail, telephone, and facsimile to notify wholesalers, jobbers, dealers, consignees, or other persons known to be in possession of the product. These methods are inexpensive, so the actual costs of transmitting notifications required by this amendment would be minimal. The amendment will benefit manufacturers of veterinary biologics by clarifying the actions they must take should they receive notification from APHIS concerning a serial(s) or subserial(s) of biological product found to be unsatisfactory according to applicable standard requirements.

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

Executive Order 12372

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

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0318.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

9 CFR Part 105

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

9 CFR Part 115

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 105 and 115 as follows:

PART 105—SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS

■ 1. The authority citation for part 105 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 105.3 is amended by adding a new paragraph (c) and an OMB control number citation to read as follows:

§ 105.3 Notices re: worthless, contaminated, dangerous, or harmful biological products.

* * * * *

(c) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product under the provisions of paragraph (a) or (b) of this section, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any veterinary biological product pending further instructions from APHIS.

(2) Immediately, but no later than 2 days, send stop distribution and sale notifications to any wholesalers, jobbers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be documented in writing by the licensee or permittee.

(3) Account for the remaining quantity of each serial(s) or subserial(s) of any such veterinary biological product at each location in the distribution channel known to the manufacturer (licensee) or importer (permittee).

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to § 116.5 of this subchapter.

(Approved by the Office of Management and Budget under control number 0579–0318.)

PART 115—INSPECTIONS

■ 3. The authority citation for part 115 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 115.2 is revised to read as follows:

§ 115.2 Inspections of biological products.

(a) Any biological product, the container of which bears a United States veterinary license number or a United States veterinary permit number or other mark required by these regulations, may be inspected at any time or place. If, as a result of such inspection, it appears that any such product is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice to stop distribution and sale to the manufacturer (licensee) or importer (permittee) and may proceed against such product pursuant to the provisions of part 118 of this subchapter.

(b) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product by the Secretary, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any such veterinary biological product pending further instructions from APHIS.

(2) Immediately, but no later than 2 days, send stop distribution and sale notifications to any jobbers, wholesalers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be documented in writing by the licensee or permittee.

(3) Account for the remaining quantity of each serial(s) or subserial(s) of any such veterinary biological product at each location in the distribution channel known to the manufacturer (licensee) or importer (permittee).

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to § 116.5 of this subchapter.

(c) Unless and until the Secretary shall otherwise direct, no persons so notified shall thereafter sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product in or from any State, Territory, or the District of Columbia. However, failure to receive such notice shall not excuse any person from compliance with the Virus-Serum-Toxin Act. (Approved by the Office of Management and Budget under control number 0579–0318).

Done in Washington, DC, this 4th day of April 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–6700 Filed 4–9–07; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 4

[Docket ID OCC–2007–0007]

FEDERAL RESERVE SYSTEM

12 CFR Parts 208 and 211

[Docket No. R–1279]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 337 and 347

RIN 3064–AD17

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 563

[Docket ID OTS–2007–0006]

Expanded Examination Cycle for Certain Small Insured Depository Institutions and U.S. Branches and Agencies of Foreign Banks

AGENCIES: Office of the Comptroller of the Currency (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); and Office of Thrift Supervision (OTS), Treasury.

ACTION: Interim rules with request for comment.

SUMMARY: The OCC, Board, FDIC, and OTS (collectively, the Agencies) are jointly issuing and requesting public comment on these interim rules to implement the Financial Services Regulatory Relief Act of 2006 (FSRRA) and related legislation (collectively the Examination Amendments). The Examination Amendments permit insured depository institutions (institutions) that have up to $500 million in total assets, and that meet certain other criteria, to qualify for an 18-month (rather than 12-month) on-site examination cycle. Prior to enactment of FSRRA, only institutions with less than $250 million in total assets were eligible for an 18-month on-site examination

cycle. The OCC, Board, and FDIC are making parallel changes to their regulations governing the on-site examination cycle for U.S. branches and agencies of foreign banks (foreign bank offices), consistent with the International Banking Act of 1978 (IBA). In addition to implementing the changes in the Examination Amendments, the Agencies are clarifying when a small insured depository institution is considered ''well managed'' for purposes of qualifying for an 18-month examination cycle.

DATES: These interim rules are effective on April 10, 2007. Comments on the rules must be received by May 10, 2007.

ADDRESSES: *Comments should be directed to:*

OCC: You may submit comments by any of the following methods:

• *Federal eRulemaking Portal—''Regulations.gov'':* Go to *http://www.regulations.gov,* select ''Comptroller of the Currency'' from the agency drop-down menu, then click ''Submit.'' In the ''Docket ID'' column, select ''OCC–2007–0007'' to submit or view public comments and to view supporting and related materials for this interim rule. The ''User Tips'' link at the top of the Regulations.gov home page provides information on using Regulations.gov, including instructions for submitting or viewing public comments, viewing other supporting and related materials, and viewing the docket after the close of the comment period.

• *Mail:* Office of the Comptroller of the Currency, 250 E Street, SW., Mail Stop 1–5, Washington, DC 20219.

• *Hand Delivery/Courier:* 250 E Street, SW., *Attn:* Public Information Room, Mail Stop 1–5, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2007–0007'' in your comment. In general, OCC will enter all comments received into the docket and publish them on Regulations.gov without change, including any business or personal information that you provide such as name and address information, e-mail addresses, or phone numbers. Comments, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials by any of the following methods:

• *Viewing Comments Electronically:* Go to *http://www.regulations.gov,* select Comptroller of the Currency from the agency drop-down menu, then click ''Submit.'' In the ''Docket ID'' column, select ''OCC–2007–0007'' to view public comments for this interim final rule.

• *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC's Public Information Room, 250 E Street, SW., Washington, DC. You can make an appointment to inspect comments by calling (202) 874–5043.

• *Docket:* You may also view or request available background documents and project summaries using the methods described above.

Board: You may submit comments, identified by Docket No. R–1279, by any of the following methods:

• *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *E-mail: regs.comments@federalreserve.gov.* Include the docket number in the subject line of the message.

• *FAX:* 202–452–3819 or 202–452–3102.

• *Mail:* Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FDIC: You may submit comments by any of the following methods:

• *Agency Web Site: http://www.fdic.gov/regulations/laws/federal.* Follow instructions for submitting comments on the Agency Web Site.

• *E-mail: Comments@FDIC.gov.* Include ''Expanded Examination Cycle'' in the subject line of the message.

• *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

• *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m. (EST).

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Public Inspection:* All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal* including any personal information provided. Comments may be inspected and photocopied in the FDIC Public Information Center, 3501 North Fairfax Drive, Room E–1002, Arlington, VA 22226, between 9 a.m. and 5 p.m. (EST) on business days. Paper copies of public comments may be ordered from the Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

OTS: You may submit comments, identified by OTS–2007–0006, by any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* select ''Office of Thrift Supervision'' from the agency drop-down menu, then click submit. Select Docket ID ''OTS–2007–0006'' to submit or view public comments and to view supporting and related materials for this interim rule. The ''User Tips'' link at the top of the page provides information on using Regulations.gov, including instructions for submitting or viewing public comments, viewing other supporting and related materials, and viewing the docket after the close of the comment period.

• *Mail:* Regulation Comments, Chief Counsel's Office, Office Of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, *Attention:* OTS–2007–0006.

• *Hand Delivery/Courier:* Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9 a.m. to 4 p.m. on business days, *Attention:* Regulation Comments, Chief Counsel's Office, OTS–2007–0006.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be entered into the docket and posted on Regulations.gov without change, including any personal information provided. Comments, including attachments and other supporting materials received are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Viewing Comments Electronically: Go to *http://www.regulations.gov*, select ''Office of Thrift Supervision'' from the agency drop-down menu, then click ''Submit.'' Select Docket ID ''OTS–2007–0006'' to view public comments for this notice of proposed rulemaking.

View Comments On-Site: You may inspect comments in 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) 906–6518. (Prior notice identifying the materials you will be requesting will assist us in serving you.) We schedule appointments on business days between 10 a.m. and 4 p.m. In most cases, appointments will be available the next business day following the date we receive a request.

FOR FURTHER INFORMATION CONTACT:

OCC: Mitchell Plave, Counsel, Legislative and Regulatory Activities Division, (202) 874–5090; Stuart E. Feldstein, Assistant Director, Legislative and Regulatory Activities, (202) 874–5090; Fred Finke, Mid-size/Community Bank Supervision, (202) 874–4468; Patricia Roberts, Operational Risk Policy Analyst, (202) 874–5637.

Board: Barbara Bouchard, Deputy Associate Director, (202) 452–3072, Mary Frances Monroe, Manager, (202) 452–5231, or Stanley Rediger, Supervisory Financial Analyst, (202) 452–2629, Division of Banking Supervision and Regulation; or Pamela G. Nardolilli, Senior Counsel, (202) 452–3289, for the revisions to Regulation H, or Jon Stoloff, Senior Counsel, (202) 452–3269, for the revisions to Regulation K, Legal Division. For users of Telecommunication Device for the Deaf (TDD) only, contact (202) 263–4869.

FDIC: Melinda West, Senior Examination Specialist, (202) 898–7221; Patricia A. Colohan, Senior Examination Specialist, (202) 898–7283; Division of Supervision and Consumer Protection; Rodney D. Ray, Counsel, (202) 898–3556, for the revisions to 12 CFR Part 347; Kimberly A. Stock, Attorney, (202) 898–3815, for the revisions to 12 CFR Part 337; Legal Division.

OTS: Robyn H. Dennis, Director, Operation Risk, (202) 906–5751, Examinations and Supervision Policy; or Barbara Shycoff, Special Counsel, Regulations and Legislation, (202) 906–6947, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

Background

Section 10(d) of the Federal Deposit Insurance Act (the FDI Act) [1] generally requires that the appropriate federal banking agency for an insured depository institution conduct a full-scope, on-site examination of the institution at least once during each 12-month period. Prior to enactment of FSRRA, section 10(d) also authorized the appropriate federal banking agency to lengthen the on-site examination cycle for an institution to 18 months if the institution (1) had total assets of less than $250 million; (2) was well capitalized (as defined in the prompt corrective action statute at 12 U.S.C. 1831o); (3) was found, at its most recent examination, to be well managed and to have a composite condition of outstanding or good; [2] (4) had not undergone a change in control during the previous 12-month period in which a full-scope, on-site examination otherwise would have been required; and (5) was not subject to a formal enforcement proceeding or order by its appropriate federal banking agency or the FDIC. The Board, the FDIC and the OTS, as the appropriate federal banking agencies for state-chartered insured banks and savings associations, are permitted to conduct on-site examinations of such institutions on alternating 12-month or 18-month schedules with the institution's State supervisor, if the Board, FDIC, or OTS, as appropriate, determines that the alternating examination conducted by the State carries out the purposes of section 10(d) of the FDI Act and the Home Owners' Loan Act.

In addition, section 7(c)(1)(C) of the IBA provides that a U.S. branch or agency of a foreign bank shall be subject to on-site examination by its appropriate federal banking agency as frequently as a national or state bank would be subject to such an examination by the agency. The agencies previously adopted regulations to implement the examination cycle requirements of section 10(d) of the FDI Act and section 7(c)(1)(C) of the IBA, including the extended 18-month examination cycle available to qualifying small institutions and foreign bank offices.[3]

Section 605 of FSRRA, which became effective on October 13, 2006, amended section 10(d) of the FDI Act to raise, from $250 million to $500 million, the total asset threshold below which an insured depository institution may qualify for an 18-month (rather than a 12-month) on-site examination cycle.[4] Public Law No. 109–473, which became effective on January 11, 2007, also amended section 10(d)(10) of the FDI Act to authorize the appropriate agency, if it determines the action would be consistent with principles of safety and soundness, to allow an insured depository institution that falls within this expanded total asset threshold to qualify for an 18-month examination cycle if the institution received a composite rating of outstanding *or* good at its most recent examination.[5]

The Examination Amendments will allow the Agencies to better focus their supervisory resources on those institutions that may present capital, managerial, or other issues of supervisory concern, while concomitantly reducing the regulatory burden on small, well capitalized and well managed institutions. The Agencies will continue to use off-site monitoring tools to identify potential problems in smaller, well capitalized and well managed institutions that present low levels of risk. Moreover, neither the statute nor the Agencies' regulations limit, and the Agencies therefore retain, the authority to examine an insured depository institution or foreign bank office more frequently than would be required by the FDI Act or IBA.

Description of the Interim Rules

The Agencies are adopting interim rules to implement the Examination Amendments. In particular, the Agencies are amending their respective rules to raise, from $250 million to $500 million, the total asset threshold below which an insured depository institution that meets the qualifying criteria in section 10(d) and the Agencies' rules may qualify for an 18-month on-site examination cycle. In addition, as authorized by the Examination Amendments, the Agencies have determined that it is consistent with safety and soundness to permit institutions with between $250 million and $500 million in total assets that received a composite rating of 1 or 2 under the Uniform Financial Institutions Rating System (commonly referred to as CAMELS),[6] and that meet

[1] Section 10(d) of the FDI Act was added by section 111 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA) and is codified at 12 U.S.C. 1820(d).

[2] Under section 10(d) of the FDI Act, before enactment of the Examination Amendments, the Agencies had the authority to extend the 18-month examination cycle to institutions with composite CAMELS ratings of 2 and assets of up to $250 million. Section 10(d) required that the Agencies determine that extending the 18-month cycle in this manner would be consistent with safety and soundness. *See* 12 U.S.C. 1820(d)(10). The Agencies exercised this discretion in 1997 and extended the 18-month examination cycle to 2-rated institutions with assets of $250 million or less. *See* 62 FR 6449, February 12, 1997 (interim rule); *see also* 63 FR 16377, April 2, 1998 (final rule).

[3] *See* 12 CFR 4.6 and 4.7 (OCC), 12 CFR 208.64 and 211.26 (Board), 12 CFR 337.12 and 347.211 (FDIC), and 12 CFR 563.171 (OTS).

[4] Pub. L. No. 109–351, 120 Stat. 1966 (2006).

[5] 120 Stat. 3561 (2007).

[6] CAMELS is an acronym that is drawn from the first letters of the individual components of the rating system: Capital adequacy, Asset quality,

the other qualifying criteria set forth in section 10(d) and the Agencies' rules, to qualify for an 18-month examination cycle. In this regard, data indicate that between 1985 and 2000, insured depository institutions with a composite CAMELS rating of 1 or 2 were more than three times less likely to fail over the next five-year period than institutions with a lower composite CAMELS rating. Furthermore, the Agencies note that, in order to qualify for an 18-month examination cycle, any insured depository institution with total assets of less than $500 million—including one with a composite rating of 2—must meet the other capital, managerial and supervisory criteria set forth in section 10(d). These provisions, combined with the Agencies' off-site monitoring activities and ability to examine an institution more frequently as necessary or appropriate, have permitted the Agencies to effectively supervise and protect the safety and soundness of institutions with total assets of $250 million or less since 1997.

Consistent with section 7(c)(1)(C) of the IBA, the OCC, Board and FDIC also are making conforming changes to their regulations governing the on-site examination cycle for the U.S. branches and agencies of foreign banks. The Agencies' amended rules permit a foreign bank office with total assets of less than $500 million to qualify for an 18-month examination cycle if the office received a composite ROCA rating of 1 or 2 at its most recent examination.[7]

The Agencies estimate that these interim rules will increase the number of insured depository institutions that may qualify for an extended 18-month examination cycle by approximately 1,089 institutions, for a total of 6,670 insured depository institutions. Approximately 126 foreign branches and agencies would be eligible for the extended examination cycle based on the interim rules, for an increase of 31 offices.[8]

In connection with these changes, the Agencies also have modified their rules to specify, consistent with current practice, that a small institution meets the statutory ''well managed'' criteria for an 18-month cycle if the institution, besides having a CAMELS composite rating of 1 or 2, also received a rating of 1 or 2 for the management component of the CAMELS rating at its most recent examination. The Agencies believe this amendment will provide additional transparency to their rules and clarify for institutions how the ''well managed'' requirement in section 10(d) is interpreted and applied by the Agencies.[9] This interpretation is consistent with definitions of ''well managed'' that the Agencies currently apply in other circumstances.[10]

The FDI Act and the IBA set the outside limits within which an on-site safety and soundness examination of an institution or foreign bank office must commence, and permit the appropriate Agency for an institution or foreign bank to conduct an on-site examination more frequently than required. The Agencies' rules continue to expressly recognize that the appropriate Agency may examine an institution or foreign bank office as frequently as the Agency deems necessary.

Effective Date/Request for Comment

The Agencies are issuing these interim rules without advance notice and comment and the 30-day delayed effective date ordinarily prescribed by the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* (''APA''). The interim rules implement the provisions of section 605 of the FSRRA, which became effective on October 13, 2006, and Public Law No. 109-473, which became effective on January 11, 2007. The interim rules adopt without change the statutory increase in the asset ceiling for 18-month examination of CAMELS–1 rated institutions and the statutory availability of the 18-month examination cycle for CAMELS–2 institutions. The interim rules also explain how the Agencies apply the ''well managed'' requirement in the underlying statute and thus, provide greater clarity to institutions consistent with the agencies' current practices. For these reasons, the Agencies find there is good cause to issue the rules without advance notice and comment. 5 U.S.C. 553(b)(3)(A), (B). The rules explain how the Agencies generally exercise the discretion given them by the statute to examine qualifying institutions less frequently than once every 12 months. The Agencies retain the discretion to examine individual institutions more frequently; the interim rules do not bind the Agencies to examine qualifying institutions on an 18-month basis, nor do they create a right for institutions to be examined on an 18-month cycle. With respect to the delayed effective date, the Agencies conclude that, because the rules recognize an exemption, the interim rules are exempt from the APA's delayed effective date requirement. 5 U.S.C. 553(d)(1). The Agencies are nevertheless interested in the views of the public and request comment on all aspects of these interim rules.

Regulatory Flexibility Act

The interim rules do not impose any new obligations, restrictions or burdens on banking organizations, including small banking organizations, and, indeed, reduce regulatory burden associated with on-site examinations for qualifying small institutions and foreign bank offices. For these reasons, the Agencies certify that the interim rules will not have a significant impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act. 5 U.S.C. 601 *et seq.* The objective and legal basis for the interim rules are discussed in the **SUPPLEMENTARY INFORMATION**.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[11] the Agencies have determined that no collections of information pursuant to the Paperwork Reduction Act are contained in these interim rules.

OCC and OTS Executive Order 12866 Statement

The OCC and OTS have each independently determined that the interim rules with request for comment are not significant regulatory actions under Executive Order 12866.

OCC and OTS Unfunded Mandates Act of 1995 Statement

Section 202 of the Unfunded Mandates Reform Act of 1995[12] requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded

Management, Earnings, Liquidity, and Sensitivity to market risk.

[7] The four components of the ROCA supervisory rating system for foreign bank offices are: Risk management, Operational controls, Compliance, and Asset quality.

[8] Data are as of June 30, 2006, and reflect the number of institutions and foreign bank offices with total assets of less than $500 million.

[9] The Agencies' rules relating to the examination cycle for foreign bank offices already permit the appropriate Agency to consider, among other things, whether the office received a ''3'' or lower rating for any of the individual ROCA components (including risk management) in determining whether the office should qualify for an 18-month exam cycle. *See* 12 CFR 4.7(b)(2)(i) (OCC), 211.26(c)(2)(ii) (Board), and 347.211(b)(2)(i) (FDIC).

[10] *See, e.g.*, 12 CFR 362.17(c)(1) (FDIC); 12 CFR 5.34(d)(3) (OCC); 12 CFR 225.2(5) and 12 CFR 208.11(h) (Board); OTS Examination Handbook, Sec. 060 (2004) (OTS).

[11] 44 U.S.C. 3506; 5 CFR part 1320, Appendix A.1.

[12] Pub. L. 104–4, 109 Stat. 48 (March 22, 1995) (Unfunded Mandates Act).

Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. Because the OCC and the OTS have each independently determined that the interim rules will not result in expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $100 million in any one year, the OCC and the OTS have not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered. Nevertheless, as discussed in the preamble, the interim rules will have the effect of reducing regulatory burden on certain institutions and foreign bank offices.

Plain Language

Section 722 of the Gramm-Leach-Bliley Act (12 U.S.C. 4809) requires the Agencies to use ''plain language'' in all proposed and final rules published after January 1, 2000. The Agencies believe the interim rules are presented in a clear and straightforward manner and solicit comments on ways to make the rules easier to understand.

List of Subjects

12 CFR Part 4

Administrative practice and procedure, Availability and release of information, Confidential business information, Contracting outreach program, Freedom of information, National banks, Organization and functions (government agencies), Reporting and recordkeeping requirements, Women and minority businesses.

12 CFR Part 208

Accounting, Agriculture, Banks, Banking, Confidential business information, Crime, Currency, Federal Reserve System, Flood insurance, Mortgages, Reporting and recordkeeping requirements, Safety and soundness, Securities.

12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

12 CFR Part 337

Banks, banking, Reporting and recordkeeping requirements, Securities.

12 CFR Part 347

Authority delegations (Government agencies), Bank deposit insurance, Banks, banking, Credit, Foreign banking, Investments, Reporting and recordkeeping requirements, United States investments abroad.

12 CFR Part 563

Accounting, Advertising, Crime, Currency, Investments, Reporting and recordkeeping requirements, Savings associations, Securities, Surety bonds.

Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

■ For the reasons set forth in the joint preamble, part 4 of chapter I of title 12 of the Code of Federal Regulations is amended as follows:

PART 4—ORGANIZATION AND FUNCTIONS, AVAILABILITY AND RELEASE OF INFORMATION, CONTRACTING OUTREACH PROGRAM, POST-EMPLOYMENT RESTRICTIONS FOR SENIOR EXAMINERS

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

Authority: 12 U.S.C. 93a. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552; E.O. 12600 (3 CFR, 1987 Comp., p. 235). Subpart C also issued under 5 U.S.C. 301, 552; 12 U.S.C. 161, 481, 482, 484(a), 1442, 1817(a)(3), 1818(u) and(v), 1820(d)(6), 1820(k), 1821(c), 1821(o), 1821(t), 1831m, 1831p-1, 1831o, 1867, 1951 *et seq.*, 2901 *et seq.*, 3101 *et seq.*, 3401 *et seq.*; 15 U.S.C. 77uu(b), 78q(c)(3); 18 U.S.C. 641, 1905, 1906; 29 U.S.C. 1204; 31 U.S.C. 9701; 42 U.S.C. 3601; 44 U.S.C. 3506, 3510. Subpart D also issued under 12 U.S.C. 1833e.

■ 2. In Subpart A, § 4.6(b) is revised to read as follows:

§ 4.6 Frequency of examination of national banks.

* * * * *

(b) *18-month rule for certain small institutions.* The OCC may conduct a full-scope, on-site examination of a national bank at least once during each 18-month period, rather than each 12-month period as provided in paragraph (a) of this section, if the following conditions are satisfied:

(1) The bank has total assets of less than $500 million;

(2) The bank is well capitalized as defined in part 6 of this chapter;

(3) At the most recent examination, the OCC:

(i) Assigned the bank a rating of 1 or 2 for management as part of the bank's rating under the Uniform Financial Institutions Rating System; and

(ii) Assigned the bank a composite rating of 1 or 2 under the Uniform Financial Institutions Rating System;

(4) The bank currently is not subject to a formal enforcement proceeding or order by the FDIC, OCC or the Federal Reserve System; and

(5) No person acquired control of the bank during the preceding 12-month period in which a full-scope, on-site examination would have been required but for this section.

* * * * *

■ 3. In § 4.7, paragraph (b)(1) introductory text is republished and paragraph (b)(1)(i) is revised to read as follows:

§ 4.7 Frequency of examination of Federal agencies and branches.

* * * * *

(b) *18-month rule for certain small institutions.* (1) *Mandatory standards.* The OCC may conduct a full-scope, on-site examination at least once during each 18-month period, rather than each 12-month period as provided in paragraph (a) of this section, if the Federal branch or agency:

(i) Has total assets of less than $500 million;

* * * * *

Federal Reserve System

12 CFR Chapter II

Authority and Issuance

■ For the reasons set forth in the joint preamble, the Board amends 12 CFR parts 208 and 211 of chapter II of title 12 of the Code of Federal Regulations as follows:

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM (REGULATION H)

■ 1. The authority citation for part 208 continues to read as follows:

Authority: 12 U.S.C. 24, 36, 92(a), 93(a), 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1818, 1820(d)(9), 1823(j), 1828(o), 1831, 1831(o), 1831p–1, 1831r–1, 1831(w), 1831(x), 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, and 3906–3909; 15 U.S.C. 78b, 781(b), 781(g), 781(i), 78o–4(c)(5), 78q, 78q–1 and 78w; 1681S, 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104a, 4104b, 4106 and 4128.

■ 2. Section 208.64(b) is revised to read as follows:

§ 208.64 Frequency of examination.

* * * * *

(b) *18-month rule for certain small institutions.* The Federal Reserve may conduct a full-scope, on-site examination of an insured member bank at least once during each 18-month period, rather than each 12-month period as provided in paragraph (a) of this section, if the following conditions are satisfied:

(1) The bank has total assets of less than $500 million;

(2) The bank is well capitalized as defined in subpart D of this part (§ 208.43);

(3) At the most recent examination conducted by either the Federal Reserve or applicable State banking agency, the Federal Reserve—

(i) Assigned the bank a rating of 1 or 2 for management as part of the bank's rating under the Uniform Financial Institutions Rating System (commonly referred to as CAMELS); and

(ii) Assigned the bank a composite CAMELS rating of 1 or 2 under the Uniform Financial Institutions Rating System;

(4) The bank currently is not subject to a formal enforcement proceeding or order by the Federal Reserve or the FDIC; and

(5) No person acquired control of the bank during the preceding 12-month period in which a full-scope examination would have been required but for this paragraph (b).

* * * * *

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

■ 1. The authority citation for part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.*, 1818, 1835a, 1841 *et seq.*, 3101 *et seq.*, and 3901 *et seq.*

■ 2. In § 211.26 paragraph (c)(2)(i) introductory text is republished and paragraph (c)(2)(i)(A) is revised to read as follows:

§ 211.26 Examinations of offices and affiliates of foreign banks.

* * * * *

(c) *Frequency of on-site examination*

* * *

(2) *18-month cycle for certain small institutions*—(i) *Mandatory standards.* The Board may conduct a full-scope, on-site examination at least once during each 18-month period, rather than each 12-month period as required in paragraph (c)(1) of this section, if the branch or agency:

(A) Has total assets of less than $500 million;

* * * * *

Federal Deposit Insurance Corporation

12 CFR Chapter III

Authority and Issuance

■ For the reasons set forth in the joint preamble, the Board of Directors of the FDIC amends parts 337 and 347 of chapter III of title 12 of the Code of Federal Regulations as follows:

PART 337—UNSAFE AND UNSOUND BANK PRACTICES

■ 1. The authority citation for part 337 is revised to read as follows:

Authority: 12 U.S.C. 375a(4), 375b, 1816, 1818(a), 1818(b), 1819, 1820(d)(10), 1821(f), 1828(j)(2), 1831.

■ 2. Section 337.12(b) is revised to read as follows:

§ 337.12 Frequency of examination.

* * * * *

(b) *18-month rule for certain small institutions.* The FDIC may conduct a full-scope, on-site examination of an insured state nonmember bank at least once during each 18-month period, rather than each 12-month period as provided in paragraph (a) of this section, if the following conditions are satisfied:

(1) The bank has total assets of less than $500 million;

(2) The bank is well capitalized as defined in § 325.103(b)(1) of this chapter;

(3) At the most recent FDIC or applicable State banking agency examination, the FDIC—

(i) Assigned the bank a rating of 1 or 2 for management as part of the bank's composite rating under the Uniform Financial Institutions Rating System (commonly referred to as CAMELS); and

(ii) Assigned the bank a composite rating of 1 or 2 under the Uniform Financial Institutions Rating System (copies of which are available at the addresses specified in § 309.4 of this chapter);

(4) The bank currently is not subject to a formal enforcement proceeding or order by the FDIC, OCC or the Federal Reserve and

(5) No person acquired control of the bank during the preceding 12-month period in which a full-scope, on-site examination would have been required but for this section.

* * * * *

PART 347—INTERNATIONAL BANKING

■ 1. The authority citation for part 347 continues to read as follows:

Authority: 12 U.S.C. 1813, 1815, 1817, 1819, 1820, 1828, 3103, 3104, 3105, 3108, 3109; Title IX, Pub. L. 98–181, 97 Stat. 1153.

■ 2. In § 347.211, paragraph (b)(1) introductory text is republished and paragraph (b)(1)(i) is revised to read as follows:

§ 347.211 Examination of branches of foreign banks.

* * * * *

(b) *18-month cycle for certain small institutions.* (1) *Mandatory standards.* The FDIC may conduct a full-scope, on-site examination at least once during each 18-month period, rather than each 12-month period as provided in paragraph (a) of this section, if the insured branch:

(i) Has total assets of less than $500 million;

* * * * *

Office of Thrift Supervision

12 CFR Chapter V

Authority and Issuance

■ For the reasons set forth in the joint preamble, the OTS amends part 563 of Chapter V of title 12 of the Code of Federal Regulations as follows:

PART 563—SAVINGS ASSOCIATIONS—OPERATIONS

■ 1. The authority citation for part 563 continues to read as follows:

Authority: 12 U.S.C. 375b, 1462, 1462a, 1463, 1464, 1467a, 1468, 1817, 1820, 1828, 1831o, 3806; 31 U.S.C. 5318; 42 U.S.C. 4106.

■ 2. Section 563.171(b) is revised to read as follows:

§ 563.171 Frequency of safety and soundness examination.

* * * * *

(b) *18-month rule for certain small institutions.* The OTS may conduct a full-scope, on-site examination of a savings association at least once during each 18-month period, rather than each 12-month period as provided in paragraph (a) of this section, if the following conditions are satisfied:

(1) The savings association has total assets of less than $500 million;

(2) The savings association is well capitalized as defined in § 565.4 of this chapter;

(3) At its most recent examination, the OTS—

(i) Assigned the savings association a rating of 1 or 2 for management as part of the savings association's composite rating under the Uniform Financial Institutions Rating System (commonly referred to as CAMELS), and

(ii) Determined that the savings association was in outstanding or good condition, that is, it received a composite rating, as defined in § 516.5(c) of this chapter, of 1 or 2;

(4) The savings association currently is not subject to a formal enforcement proceeding or order by the OTS or the FDIC; and

(5) No person acquired control of the savings association during the preceding 12-month period in which a full-scope, on-site examination would have been required but for this section.

* * * * *

Dated: March 29, 2007.

John C. Dugan,

Comptroller of the Currency, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, April 3, 2007.

Jennifer J. Johnson,

Secretary of the Board.

Dated at Washington, DC, this 20th day of March, 2007.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated: April 2, 2007.

By the Office of Thrift Supervision.

John M. Reich,

Director.

[FR Doc. 07–1716 Filed 4–9–07; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P; 6720–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2006–24826; Airspace Docket No. 06–ANM–3]

Establishment of Class E Airspace; Nucla, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the northwest boundary description of a final rule that was published in the **Federal Register** on February 23, 2007 (72 FR 8100) Federal Register Docket No. FAA–2006–24826, Airspace Docket No. 06–ANM–3.

DATES: *Effective Date:* 0901 UTC, May 10, 2007. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Ed Haeseker, Federal Aviation Administration, Western Service Area, System Support Group, 1601 Lind Avenue, SW., Renton, WA 98057; telephone: (425) 917–6714.

SUPPLEMENTARY INFORMATION:

History

Federal Register Docket FAA–2006–24826, Airspace Docket No. 06–ANM–3, published on February 23, 2007 (72 FR 8100), establishes Class E Airspace at Hopkins Field, Nucla, CO, effective May 10, 2007. An error was discovered in the northwest geographic boundary of the Class E airspace. This action corrects this error.

Correction to Final Rule

■ Accordingly, pursuant to the authority delegated to me, the legal description as published in the **Federal Register** February 23, 2007 (72 FR 8100), Federal Register Docket No. FAA–2006–24826, Airspace Docket No. 06–ANM–3, and incorporated by reference in 14 CFR 71.1, is corrected as follows:

PART 71—[AMENDED]

§ 71.1 [Amended]

* * * * *

ANM CO E5 Nucla, CO [Corrected]

Hopkins Field, CO

(Lat. 38°14′20″ N., long. 108°33′48″ W.)

That airspace extending upward from 700 feet above the surface within a 6.0-mile radius of Hopkins Field and within 4 miles each side of the 317° bearing from Hopkins Field extending from the 6.0-mile radius of Hopkins Field northwest to 12.0 miles from Hopkins Field; that airspace extending upward from 1,200 feet above the surface beginning at lat. 38°45′00″ N., long. 109°00′00″ W.; to lat. 38°30′00″ N., long. 108°30′00″ W.; to CONES VOR/DME; to DOVE CREEK VORTAC; to lat. 38°30′00″ N., long. 109°10′00″ W.; to point of beginning.

* * * * *

Issued in Seattle, Washington, on March 30, 2007.

Steven M. Osterdahl,

Director of Operations, En Route and Oceanic, Western Service Area.

[FR Doc. E7–6649 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9322]

RIN 1545–BG26

Anti-Avoidance and Anti-Loss Reimportation Rules Applicable Following a Loss on Disposition of Stock of Consolidated Subsidiaries

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations under section 1502 of the Internal Revenue Code (Code). These regulations provide guidance to corporations filing consolidated returns. These regulations apply an anti-avoidance rule and revise an anti-loss reimportation rule that applies following a disposition of stock of a subsidiary at a loss. The text of the temporary regulations also serves as the text of the proposed regulations (REG–156420–06) set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective April 10, 2007.

Applicability Date: For dates of applicability, see §§ 1.1502–32T(k) and 1.1502–35T(j)(2).

FOR FURTHER INFORMATION CONTACT: Theresa Abell, (202) 622–7700 or Phoebe Bennett, (202) 622–7770 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Section 1.1502–35 currently addresses loss duplication. The rule generally applies whenever there is a disposition of loss shares of subsidiary stock or a subsidiary is deconsolidated. The regulation includes several specific anti-abuse rules, including a rule intended to prevent a group from getting the benefit of a loss on the stock of one of its subsidiaries and then reimporting the same economic loss back to into the group (or its successor) in order to claim a duplicative benefit from the one loss.

The current anti-loss reimportation rule generally disallows reimported losses that duplicate a loss recognized and allowed with respect to the disposition of subsidiary stock. The term ''subsidiary'' is defined in § 1.1502–1(c) to mean a corporation that is a member of a consolidated group but is not the common parent of the group. Taxpayers have attempted to avoid the anti-loss reimportation rule by first deconsolidating a subsidiary and then selling loss shares of the subsidiary's stock. The loss on the stock is one that was reflected in the subsidiary's attributes at the time of the deconsolidation and is thus one that the anti-loss reimportation rule is intended to address. But because the sale occurs after the subsidiary ceases to be a member of the group, taxpayers take the position that the loss recognized is not with respect to ''subsidiary'' stock and therefore is not subject to the anti-loss reimportation rule. Thus, after obtaining the tax benefit of its economic loss (on the disposition of the stock), the group would be free to reimport the loss and then (directly or through a successor group) claim a second tax benefit for its one economic loss.

The IRS and Treasury Department believe that the duplication of a group

loss distorts group income, and is therefore inappropriate, regardless of whether or not a duplicative recognition of the loss occurs while the subsidiary is a member. In either case, the group would obtain more than a single tax benefit for one economic loss. The IRS and Treasury Department recognize that such transactions remain subject to, and reimportation will be prevented by, other principles of law, such as the Step-Transaction Doctrine and other anti-avoidance rules of law. However, the IRS and Treasury Department have concluded that tax administration would be better served by revising the current anti-loss reimportation rule to address these situations more directly.

Accordingly, these final and temporary regulations revise the anti-loss reimportation rule to clarify that losses reflected in the basis of subsidiary stock at the time of deconsolidation may not be recognized and reimported into the group, regardless of whether the stock losses are recognized when the subsidiary is a member of the group. To discourage further structuring to avoid its purposes, the loss reimportation rule is also revised to replace the list of events that cause the application of the rule with a list of criteria that identify reimportation transactions that will be treated as subject to the rule.

In addition, the temporary regulations add a general anti-avoidance rule under § 1.1502–35T(g)(6), which provides that appropriate adjustments will be made if a taxpayer acts with a view to avoid the purposes of § 1.1502–35. The temporary regulations also remove § 1.1502–35(h) (continued applicability of other rules of law) because it unnecessarily duplicates § 1.1502–80(a), which provides that other rules of law apply to members of consolidated groups unless otherwise provided in the regulations.

The temporary regulations that revise the anti-loss reimportation rule apply to reimportation events that occur on or after *April 10, 2007 if they occur with respect to stock of a subsidiary sold on or after March 7, 2002, or with respect to stock of a subsidiary or former subsidiary sold on or after April 10, 2007.* The temporary regulations provide a general anti-avoidance rule that applies on or after April 10, 2007.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12666. Therefore, a regulatory assessment is not required. These temporary regulations address situations in which taxpayers inappropriately attempt to recognize duplicative tax losses by attempting to avoid the application of the anti-loss reimportation rule. For this reason, it has been determined pursuant to 5 U.S.C. 553(b)(B) that prior notice and public procedure are impracticable and contrary to the public interest. For the same reason, it has been determined pursuant to 5 U.S.C. 553(d)(3) that good cause exists to make these temporary regulations effective upon the date of publication. For applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6) refer to the Special Analyses section of the preamble to the cross-reference notice of the proposed rulemaking published in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Phoebe Bennett, Office of the Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *.

Sections 1.1502–32T and 1.1502–35T also issued under 26 U.S.C. 1502 * * *.

■ **Par. 2.** Section 1.1502–32 is amended by revising paragraph (b)(3)(iii)(D) and adding paragraph (k) to read as follows:

§ 1.1502–32 Investment adjustments.

* * * * *

(b) * * *

(3) * * *

(iii)* * *

(D) [Reserved]. For further guidance, see § 1.1502–32T(b)(3)(iii)(D).

* * * * *

(k) [Reserved]. For further guidance, see § 1.1502–32T(k).

■ **Par. 3.** Section 1.1502–32T is amended by revising paragraphs (a) through (b)(4)(iii) and adding paragraph (k) to read as follows:

§ 1.1502–32T Investment adjustments (temporary).

(a) through (b)(3)(iii)(C) [Reserved]. For further guidance, see § 1.1502–32(a) through (b)(3)(iii)(C).

(D) *Loss disallowed under § 1.1502–35T(g)(3)(ii).* Any loss or deduction the use of which is disallowed pursuant to § 1.1502–35T(g)(3)(ii) (other than duplicating items that are carried back to a consolidated return year of the group), and with respect to which no waiver described in paragraph (b)(4) of this section is filed, is treated as a noncapital, nondeductible expense incurred during the taxable year that such loss would otherwise be absorbed.

(b)(3)(iv) through (b)(4)(iii) [Reserved]. For further guidance, see § 1.1502–32(b)(3)(iv) through (b)(4)(iii).

* * * * *

(k) *Effective date*—(1) *Applicability date.* Paragraph (b)(3)(iii)(D) of this section applies to any original consolidated Federal income tax return due (without extensions) after April 10, 2007.

(2) *Expiration date.* The applicability of paragraphs (b)(3)(iii)(D) and (k) of this section will expire on April 9, 2010.

■ **Par. 4.** Section 1.1502–35 is amended by:

■ 1. Revising paragraphs (g)(3) and (h).

■ 2. Adding new paragraph (g)(6).

■ 3. Revising paragraph (j).

The revisions and additions read as follows:

§ 1.1502–35 Transfers of subsidiary stock and deconsolidations of subsidiaries.

* * * * *

(g) * * *

(3) [Reserved]. For further guidance, see § 1.1502–35T(g)(3).

* * * * *

(6) [Reserved]. For further guidance, see § 1.1502–35T(g)(6).

(h) [Reserved]. For further guidance, see § 1.1502–35T(h).

* * * * *

(j) *Effective dates*—(1) *In general.* This section applies with respect to stock transfers, deconsolidations of subsidiaries, determinations of worthlessness, and stock dispositions on or after March 10, 2006. For rules applicable before March 10, 2006, see § 1.1502–35T(j) as contained in 26 CFR part 1 in effect on January 1, 2006.

(2) [Reserved]. For further guidance, see § 1.1502–35T(j)(2).

* * * * *

■ **Par. 5.** Section 1.1502–35T is amended by revising paragraphs (c)(4)(ii) through (j) to read as follows:

§ 1.1502–35T Transfers of subsidiary stock and deconsolidations of subsidiaries (temporary).

* * * * *

(c)(4)(ii) through (g)(2) [Reserved]. For further guidance, see § 1.1502–35(c)(4)(ii) through (g)(2).

(3) *Anti-loss reimportation rule*—(i) *Conditions for application.* This paragraph (g)(3) applies when—

(A) A member of a group (the selling group) recognized and was allowed a loss with respect to a share of stock of S, a subsidiary or former subsidiary of the selling group;

(B) That stock loss was duplicated (in whole or in part) in S's attributes (duplicating items) at the earlier of the time that the loss was recognized or that S ceased to be a member; and

(C) Within ten years of the date that S ceased to be a member, there is a reimportation event. For this purpose, a reimportation event is any event after which a duplicating item is a reimported item. A reimported item is any duplicating item that is reflected in the attributes of any member of the selling group, including S, or, if not reflected in the attributes, would be properly taken into account by any member of the selling group (for example as the result of a carryback) (a reimported item).

(ii) *Effect of application.* Immediately before the time that a reimported item (or any portion of a reimported item) would be properly taken into account (but for the application of this paragraph (g)(3)), such item (or such portion of the item) is reduced to zero and no deduction or loss is allowed, directly or indirectly, with respect to that item.

(iii) *Operating rules.* For purposes of this paragraph (g)(3)—

(A) The terms member, subsidiary, and group include their predecessors and successors to the extent necessary to effectuate the purposes of this section;

(B) The determination of whether a loss is duplicative is made under the principles of paragraph (d)(4) of this section; and

(C) The reduction of a reimported item (other than duplicating items that are carried back to a consolidated return year of the selling group) is a noncapital, nondeductible expense within the meaning of § 1.1502–32(b)(3)(iii).

(g)(4) through (g)(5) [Reserved]. For further guidance, see § 1.1502–35(g)(4) through (g)(5).

(6) *General anti-avoidance rule applicable on or after April 10, 2007.* If a taxpayer acts with a view to avoid the purposes of this section, appropriate adjustments will be made to carry out the purposes of this section.

(h) *Application of other rules of law.* See § 1.1502–80(a) regarding the general applicability of other rules of law.

(i) [Reserved]. For further guidance, see § 1.1502–35(i).

(j)(1) [Reserved]. For further guidance, see § 1.1502–35(j)(1).

(2) *Transactions after April 10, 2007*—(i) *Effective date.* Paragraph (g)(3) of this section applies to reimported items if the related stock loss is recognized on or after April 10, 2007. Paragraph (g)(3) (other than paragraph (g)(3)(i)(A)) of this section also applies with respect to the duplication of subsidiary stock loss recognized in dispositions (described in § 1.1502–35(g)(3)(i)(A), as contained in 26 CFR part 1, revised as of January 1, 2007) on or after March 7, 2002, if the reimportation event with respect to that loss occurs on or after April 10, 2007. For rules applicable to losses reimported before April 10, 2007, see § 1.1502–35(g)(3), as contained in 26 CFR part 1 in effect on January 1, 2007. Paragraphs (g)(6) and (h) of this section apply on or after April 10, 2007. For rules applicable prior to April 10, 2007, see § 1.1502–35 as contained in 26 CFR part 1 in effect on January 1, 2007.

(ii) *Expiration date.* The applicability of paragraphs (g)(3), (g)(6), and (h) of this section will expire on April 9, 2010.

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Linda M. Kroening,

Acting Deputy Commissioner for Services and Enforcement.

Approved: March 29, 2007.

Eric Solomon,

Assistant Secretary of the Treasury.

[FR Doc. E7–6541 Filed 4–9–07; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 04011–2010–4114–02; I.D. 040407D]

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast (NE) Multispecies Fishery; Modification of the Yellowtail Flounder Landing Limit for the U.S./Canada Management Area

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

ACTION: Temporary rule; landing limit.

SUMMARY: NMFS announces that the Administrator, Northeast (NE) Region, NMFS (Regional Administrator), is increasing the Georges Bank (GB) yellowtail flounder trip limit to 25,000 lb (11,340 kg) for NE multispecies days-at-sea (DAS) vessels fishing in the U.S./Canada Management Area. This action is authorized by the regulations implementing Amendment 13 to the NE Multispecies Fishery Management Plan and is intended to prevent under-harvesting of the Total Allowable Catch (TAC) for GB yellowtail flounder while ensuring that the TAC will not be exceeded during the 2006 fishing year. This action is being taken to provide additional opportunities for vessels to fully harvest the GB yellowtail flounder TAC under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Effective April 5, 2007, through April 30, 2007.

FOR FURTHER INFORMATION CONTACT: Tobey Curtis, Fishery Management Specialist, (978) 281–9273, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION: Regulations governing the GB yellowtail flounder landing limit within the U.S./Canada Management Area are found at § 648.85(a)(3)(iv)(C) and (D). The regulations authorize vessels issued a valid limited access NE multispecies permit and fishing under a NE multispecies DAS to fish in the U.S./Canada Management Area, as defined at § 648.85(a)(1), under specific conditions. The TAC for GB yellowtail flounder for the 2006 fishing year (May 1, 2006 - April 30, 2007) is 2,070 mt. The regulations at § 648.85(a)(3)(iv)(D) authorize the Regional Administrator to increase or decrease the trip limits in the U.S./Canada Management Area to prevent over-harvesting or under-harvesting the TAC allocation. On March 8, 2007, the 10,000–lb (4,536–kg) trip limit for GB yellowtail flounder was reduced to 5,000 lb (2,268 kg) in the Eastern U.S./Canada Area to prevent over-harvesting the TAC (72 FR 10426), and the requirement to only use a haddock separator trawl in the Eastern U.S./Canada Area was removed. Currently, NE multispecies vessels fishing in the Eastern U.S./Canada Area under a NE multispecies day-at-sea (DAS) with trawl gear must use either a haddock separator trawl or a flounder trawl net, as specified at § 648.85(a)(3)(iii). Based upon the most

recent Vessel Monitoring System (VMS) reports and other available information, the Regional Administrator has determined that the current rate of harvest will result in the under-harvest of the GB yellowtail flounder TAC during the 2006 fishing year. Based on this information, the Regional Administrator is increasing the current 10,000–lb (4,536–kg) trip limit in the Western U.S./Canada Area, and the 5,000–lb (2,268–kg) trip limit in the Eastern U.S./Canada Area to 25,000 lb (11,340 kg) in both areas, effective April 5, 2007, through April 30, 2007. Accordingly, there is a 25,000–lb (11,340–kg) trip limit on the amount of GB yellowtail flounder that can be harvested or landed for the remainder of the fishing year for vessels subject to these regulations. GB yellowtail flounder landings will be closely monitored through VMS and other available information. Should 100 percent of the TAC allocation for GB yellowtail flounder be projected to be harvested, the Eastern U.S./Canada Area will close to all groundfish DAS vessels, and all vessels will be prohibited from harvesting, possessing, or landing yellowtail flounder from the U.S./Canada Management Area for the remainder of the fishing year. Additionally, the Eastern GB cod TAC will also be closely monitored, and should 100 percent of its TAC allocation be projected to be harvested, groundfish DAS vessels will be prohibited from entering the Eastern U.S./Canada Area for the remainder of the fishing year, as required by the regulations at § 648.85(a)(3)(iv).

Classification

This action is authorized by 50 CFR part 648 and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator (AA) finds good cause to waive prior notice and opportunity for public comment for this action, because notice and comment would be impracticable and contrary to the public interest. The regulations at § 648.85(a)(3)(iv)(D) grant the Regional Administrator the authority to adjust the GB yellowtail flounder trip limits to prevent over-harvesting or under-harvesting the TAC allocation. Given that approximately 20 percent of the GB yellowtail flounder TAC remains unharvested and the 2006 fishing year ends on April 30, 2007, the time necessary to provide for prior notice, opportunity for public comment, or delayed effectiveness would prevent the agency from ensuring that the 2006 TAC for GB yellowtail flounder will be fully harvested. If implementation of this action is delayed, the NE multispecies fishery could be prevented from fully harvesting the TAC for GB yellowtail flounder during the 2006 fishing year. Under-harvesting the GB yellowtail TAC would result in increased economic impacts to the industry and social impacts beyond those analyzed for Amendment 13, as the full potential revenue from the available GB yellowtail flounder TAC in the U.S./Canada Management Area would not be realized. This action also relieves a restriction placed on the NE multispecies fishing industry by liberalizing the trip limits for GB yellowtail flounder.

For the reasons specified above and because this action relieves a restriction, the AA finds good cause, pursuant to 5 U.S.C. 553(d)(3), to waive the entire 30-day delayed effectiveness period for this action. A delay in the effectiveness of the trip limit modification in this rule would prevent the agency from meeting its management obligation and ensuring the opportunity for the 2006 TAC for GB yellowtail flounder specified for the U.S./Canada Management Area to be harvested at a level that approaches optimum yield. Any such delay could lead to the negative impacts to the fishing industry described above.

The rate of harvest of the GB yellowtail flounder TAC in the U.S./Canada Management Area is updated weekly on the internet at *http://www.nero.noaa.gov*. Accordingly, the public is able to obtain information that would provide at least some advanced notice of a potential action to provide additional opportunities to the NE multispecies industry to fully harvest the TAC for GB yellowtail flounder during the 2006 fishing year. Further, the potential for this action was considered and open to public comment during the development of Amendment 13 and Framework 42. Therefore, any negative effect the waiving of public comment and delayed effectiveness may have on the public is mitigated by these factors.

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

Dated: April 5, 2007.

James P. Burgess

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

[FR Doc. 07–1764 Filed 4–5–07; 1:36 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 061228342–7068–02; I.D. 122206A]

RIN 0648–AT66

Fisheries of the Northeastern United States; Atlantic Herring Fishery; 2007–2009 Specifications

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

ACTION: Final rule.

SUMMARY: NMFS announces final specifications for the 2007–2009 fishing years for the Atlantic herring (herring) fishery. The intent of this final rule is to conserve and manage the herring resource and provide for a sustainable fishery.

DATES: Effective May 10, 2007, through December 31, 2009.

ADDRESSES: Copies of supporting documents, including the Environmental Assessment, Regulatory Impact Review, Initial Regulatory Flexibility Analysis (EA/RIR/IRFA), and Essential Fish Habitat Assessment are available from Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. The EA/RIR/IRFA is also accessible via the Internet at *http://www.nero.gov*. NMFS prepared a Final Final Regulatory Flexibility Analysis (FRFA), a summary of which is contained in the Classification section of the preamble of this final rule. Copies of the FRFA and the Small Entity Compliance Guide are available from Patricia A. Kurkul, Regional Administrator, Northeast Region, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930–2298.

FOR FURTHER INFORMATION CONTACT: Eric Jay Dolin, Fishery Policy Analyst, 978–281–9259, e-mail at *eric.dolin@noaa.gov*, fax at 978–281–9135.

SUPPLEMENTARY INFORMATION:

Background

Proposed 2007–2009 specifications were published on January 10, 2007 (72 FR 1206), with public comment accepted through February 9, 2007. These final specifications are unchanged from those that were proposed. A complete discussion of the

development of the specifications appears in the preamble to the proposed rule and is not repeated here.

2007–2009 Final Initial Specifications

The following specifications are established by this action: Allowable biological catch (ABC), optimum yield (OY), domestic annual harvest (DAH), domestic annual processing (DAP), total foreign processing (JVPt), joint venture processing (JVP), internal waters processing (IWP), U.S. at-sea processing (USAP), border transfer (BT), total allowable level of foreign fishing (TALFF), and total allowable catch (TAC) for each management area and subarea.

TABLE 1. SPECIFICATIONS AND AREA TACS FOR THE 2007–2009 ATLANTIC HERRING FISHERY

Specification	2007 Allocation (mt)	2008–2009 Allocation (mt)
ABC	194,000	194,000
OY	145,000	145,000
DAH	145,000	145,000
DAP	141,000	141,000
JVPt	0	0
JVP	0	0
IWP	0	0
USAP	20,000 (Areas 2 and 3 only)	20,000 (Areas 2 and 3 only)
BT	4,000	4,000
TALFF	0	0
Reserve	0	0
TAC - Area 1A	50,000 [48,500 fishery; 1,500 RSA] (January 1 - May 31, landings cannot exceed 5,000)	45,000 [43,650 fishery; 1,350 RSA] (January 1 - May 31, landings cannot exceed 5,000)
TAC - Area 1B	10,000 [9,700 fishery; 300 RSA]	10,000 [9,700 fishery; 300 RSA]
TAC - Area 2	30,000 [29,100 fishery; 900 RSA] (No Reserve)	30,000 [29,100 fishery; 900 RSA] (No Reserve)
TAC - Area 3	55,000 [53,350 fishery; 1,650 RSA]	60,000 [58,200 fishery; 1,800 RSA]
Research Set Aside	3 percent from each area TAC (2008 and 2009 FY only)	3 percent from each area TAC (2008 and 2009 FY only)

Comments and Responses

There were 460 comments received. Commenters included the American Pelagic Association; Cape Seafoods; Center for Oceanic Research and Education; Conservation Law Foundation; Garden State Seafood Association; Bumblebee Seafoods/ Stinson Seafood; Maine Department of Marine Resources; Mid-Atlantic Fishery Management Council; Northern Pelagic Group, LLC; Ocean Conservancy; and 451 individuals and vessel owners.

Comment 1: Three organizations and 448 individuals support the proposed rule, especially NMFS's decision to reduce the Area 1A TAC to 45,000 mt in 2008 and 2009.

Response: This action is unchanged from the proposed rule.

Comment 2: Two organizations and three vessel owners opposed the Council's recommendation to reduce the Area 1A TAC to 50,000 mt for 2007–2009, and strongly opposed NMFS's further reduction of the Area 1A TAC to 45,000 mt for 2008 and 2009. They argue that the Council's recommendation was unnecessarily restrictive, in light of the stock's status. They further argue that NMFS should not have relied on the Plan Development Team's (PDT's) risk assessment in making its decision to further reduce the Area 1A TAC to 45,000 mt because it was not peer-reviewed, and was overly conservative. They disagreed that the Councils' and NMFS's concern about the retrospective pattern in the stock assessment is an appropriate reason to reduce the Area 1A TAC. They argued that the 29,000–mt buffer between ABC and OY was intended to account for the retrospective pattern and that it is, therefore, scientifically inappropriate to further reduce the Area 1A TAC. The commenters argue that the Council's specifications document pointed out that trawl survey results are highly variable, and that no trends are apparent from the most recent years of the survey across all strata. The commenters state that encounter rates are increasing, rather than declining, and a broader size distribution is evident; and that both of these trends indicate a healthy resource. One organization stated that it is misleading for NMFS to state that there

is considerable overlap between the inshore stock component and Area 1A.

One organization supported the reduction of the Area 1A TAC to 50,000 mt, but not to 45,000 mt in 2008 and 2009. They argue that the retrospective pattern described by the Transboundary Resource Assessment Committee (TRAC) applies to the stock as a whole, and not individual stock components, and that the 29,000–mt buffer between ABC and OY addresses the issue. They stated that the reduction in the Area 1A TAC to 45,000 mt and commensurate increase in the Area 3 TAC does not account for the retrospective pattern, because it maintains OY at the same level. They also argued that only the NMFS fall survey shows a decline in abundance and biomass, and the other surveys are either increasing or variable and stable. They noted that the PDT suggested that encounter rates may be a better indicator of stock status for herring, and that the Northeast Fisheries Science Center (NEFSC) fall surveys are not showing a decline in the encounter rates, and the Massachusetts inshore survey is showing an increase in encounter rates.

One organization opposed the reduction of Area 1A TAC, but provided no additional rationale. One vessel owner argued that the industry was not allowed to participate in the Advisory Panel's decisionmaking during the specifications-setting process.

Response: The herring stock is in good shape. However, both the Council and NMFS agree that, while the overall stock is healthy, there is a clear need to be precautionary with the inshore component of the stock. This is directly related to the establishment of the Area 1A TAC because, contrary to some comments, there is substantial overlap between the inshore stock component and Area 1A. The inshore component, at different times of year, is distributed throughout Areas 1A, 1B, and 2. Based on the stock mixing ratios employed in the specifications document (and in the FMP), it is reasonable to state that there is a considerable amount of overlap between the inshore stock component and Area 1A. The specifications document estimates that, in the summer, 50 percent of the catch from Area 1A comes from the inshore component. In the winter, 100 percent of the catch in Area 1A, and 20 percent of the catch in Area 2, is assumed to come from the inshore component of the resource. Removals from Area 1B are assumed to be composed of 30 percent of the inshore component at all times of the year.

Several aspects of the specifications analyses provided a strong basis for NMFS to enact the Area 1A TACs specified in this action. Three elements in particular contributed to NMFS's determination that the 2008–2009 TACs should be set lower than recommended by the Council.

The Council's Scientific and Statistical Committee (SSC) met in 2003 to consider the status of the herring stock and found, among other things, that ''no severe declines in the stock complex should be expected by maintaining current levels of catches over the short-term; however, the current concentration of harvest in the inshore Gulf of Maine is of concern and may be excessive.'' Thus, NMFS concluded that the issue is not whether there is a need for more caution when establishing the Area 1A TAC, but rather, how much caution is necessary.

Both the Council and NMFS agreed that the available data and concerns warranted a significant reduction in the Area 1A TAC over the next 3 years. NMFS, however, concluded that the Council's proposal, to set the Area 1A TAC at 50,000 mt, did not go far enough to protect the stock in Area 1A.

NMFS also concluded that the retrospective pattern in the stock assessment, which overestimates biomass and underestimates fishing mortality in the terminal year of the assessment, argues for caution. NMFS concluded that for the stock as a whole, the buffer of 29,000 mt between ABC (maximum OY) and OY specified in this action would help ensure that adequate spawning stock biomass (SSB) is available to produce strong recruitment in the future. However, the retrospective pattern indicates that, as more data are collected and analyzed, the stock, including the inshore stock component, will be found to be not as robust as current data imply.

Finally, the PDT's risk assessment provides a useful tool for evaluating TAC alternatives. The risk assessment is a tool that the Council asked the PDT to provide, and it was presented and debated by the PDT members, the Herring Advisory Panel (AP), and the Herring Committee, as well as the Council. According to the risk assessment, setting the Area 1A TAC at 45,000 mt for 2008–2009 will provide a slightly improved chance of producing exploitation rates that are more consistent with Fmsy for the stock component, within a range of realistic stock mixing ratios. Therefore, NMFS finds that the SSC advice, the retrospective pattern in the stock assessment, and the conclusions of the PDT's risk assessment combine to make a sound case for specifying the Area 1A TAC at 45,000 mt in fishing years 2008 and 2009.

The commenters correctly characterize the variability of the trawl survey data and encounter rates. While NMFS acknowledges these points, it does not conclude that they overcome the concerns noted above. More specifically, although some of the encounter rates do not indicate a decline in stock status, they are just one of the indicators that the Council and NMFS needs to rely on in determining the appropriate levels for the various TACs. As mentioned above, taken together, the SSCs advice, the significant retrospective pattern in the stock assessment, and the PDT's risk assessment, even in the face of some positive or stable encounter rates, justify the precautionary approach being taken in this rule.

NMFS does not share the commenters' concerns about the use of the PDT's risk assessment. PDTs are established by the Council specifically to offer technical advice that will assist in making sound fishery management decisions. The current process for obtaining the PDT's advice does not include an additional formal peer review of that advice. A certain amount of informal peer review is built into the PDT process by virtue of its membership and the debates that take place at PDT meetings, the Council's committee meetings, and Council meetings. An additional layer of informal peer review takes place within NMFS, when the specifications package, including the PDT's products, are reviewed by NMFS staff.

The perception that the industry was not allowed to participate in the AP's deliberations is not accurate. Not only is the AP comprised of industry members, but all of its meetings were public meetings, for which public notice was provided. At those meetings a variety of industry members contributed their thoughts and ideas to the process, although not all of their suggestions were ultimately adopted.

Comment 3: Two organizations argued that the reduction of the Area 1A TAC to 45,000 mt is not justified. They also argued that the PDT analysis was presented to the Council at the last minute and that participants in the fishery did not have adequate opportunity to review and comment on it. One commenter argued that the use of this new analysis appears contrary to the recent Congressional reauthorization of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), which specifies in section 302(g) that, ''The Secretary and each Council may

establish a peer review process for that Council for scientific information used to advise the Council about the conservation and management of the fishery.'' Finally, this commenter argued that the assumption in the specifications that the New Brunswick (NB) weir fishery will catch 20,000 mt annually is an overestimate and, therefore, it serves to provide an additional level of caution in the specifications.

Response: The justification for setting the Area 1A TAC at 45,000 mt and the concerns about the PDT's risk assessment are addressed in the response to Comment 2. NMFS notes that the Council process provided several opportunities for public comment, including comment on the risk assessment.

The new Magnuson-Stevens Act requirement is not retroactively applicable to the process the Council followed to develop these herring specifications.

The Council adopted the estimate that the NB weir fishery will land 20,000 mt annually after public debate. Though in recent years landings by this fishery have not attained 20,000 mt, the Council and NMFS concluded it is a reasonable estimate. Historical catches in the NB weir fishery were much higher than those in recent years, and exceeded 20,000 mt in many years prior to 1995. Landings of herring in the NB weir fishery average 22,475 mt for 1978–2005, despite the fact that the 2005 landings are currently estimated to have been about 13,000 mt.

Comment 4: Five vessel owners pointed out that there is no stock assessment for the inshore component and, therefore, the target and threshold fishing mortality rates for the inshore stock component remain uncertain. Because of this, the owners argue that reducing the Area 1A TAC based on a concern that the Council's recommendations for 2008 and 2009 would be only marginally successful at producing an exploitation rate consistent with F_{msy} is not justified, because the F_{msy} for the inshore component remains uncertain. Furthermore, these owners pointed out that, although the TRAC assessment estimated that the inshore component of the stock represents 18 percent of the total stock biomass, the TRAC assessment does not provide guidance on the TAC allocations by management area or the mixing rates between stock components. The owners find the use of the 18 percent value to be problematic, and cast doubt on the usefulness of the PDT's risk assessment because it is not peer-reviewed. The risk assessment should not, they contend, be used as a justification for draconian cuts.

Response: The commenters are correct that the stock assessment does not provide specific fishing mortality target and threshold rates for the inshore stock component or the specification of management area TACs. However, NMFS concluded that it is appropriate to use the risk assessment and the TRAC estimate that the inshore stock component represents 18 percent of the total biomass, for reasons outlined in detail in the response to Comment 2. The stock mixing ratios used in the risk assessment are, as the specifications document points out, supported by the best available scientific information.

Comment 5: Five organizations argued that the proposed reallocation of 5,000 mt from Area 1A to Area 3 should, instead, be a reallocation of the same amount into a reserve for Area 2. The rationale offered is that a higher percentage of the Area 2 TAC has been taken in recent years than of the Area 3 TAC. The establishment of such a reserve would, the commenters argue, increase the amount of herring available to the Atlantic mackerel fishery, which has an incidental catch of herring. This would reduce the likelihood of a closure of the herring fishery in Area 2. The commenters believe that a herring closure would de facto close the mackerel fishery in that area because vessels would not fish in the area for mackerel if they could not also retain more than 2,000 lb (907.2 kg) of herring.

Response: There are two reasons for transferring the 5,000 mt from Area 1A to Area 3. First, since Area 3 fish are assumed to come entirely from the offshore component of the stock, the addition of 5,000 mt to that Area's TAC will not impact the status of the inshore component. Second, this reallocation will increase opportunities for the fleet to fish for herring in Area 3 and, therefore, support one of the FMP's goals, which is to provide for the orderly development of the offshore herring fishery. In contrast, because of mixing of the subcomponents of the stock, a shift of 5,000 mt from Area 1A to Area 2 would still allow the fishery to harvest from the inshore stock component.

On a practical level, the Area 2 TAC has never been fully harvested. In 2006, roughly 22,000 mt of herring was landed from this area, while in the 4 prior years, landings from the area ranged from 11,000 mt to 16,000 mt. In light of this history, the 30,000 mt allocated to Area 2 would appear unlikely to constrain the mackerel fishery. The Council has the option of reviewing information relating to the herring stock and fishery in 2007 and revising the Area 2 TAC for 2008–2009, if warranted.

Comment 6: Two organizations urged that a portion of the DAH be set-aside for use in value-added food grade products, and that such an allocation would be consistent with the allocation of 20,000 mt for USAP. These commenters also urged NMFS to establish three different fishing seasons within Area 1A, and to apportion the TAC among those seasons to extend the fishing season in Area 1A, achieve OY, and more effectively protect pre-spawning herring.

Response: These suggestions would require amendment of the Herring FMP, which defines the allocations that must be recommended by the Council and enacted by NMFS, and are therefore outside the scope, purpose, and authority of this action. Such changes may be pursued through the Council process.

Comment 7: Two organizations argued that the Council's decision to review the new survey data during 2007 and determine whether adjustments should be made to the specifications for the 2008 and 2009 fishing years was sufficiently precautionary and should be allowed to proceed. One organization believed that NMFS's revision of the allocations for 2008–2009 precluded the Council from conducting a review of the fishery during the 3–year specification period.

Response: NMFS's decision to reduce the Area 1A TAC to 45,000 mt for the 2008 and 2009 fishing years has no bearing on the review process that the Council stated that it plans to conduct during 2007. That review is expected to take place, and the Council is at liberty to recommend changes to the specifications for 2008 and/or 2009 based on its review, if warranted.

Comment 8: Five vessel owners supported the implementation of the status quo specifications for the herring fishery, which would set OY at 150,000 mt, the Area 1A TAC at 60,000 mt, and the Area 3 TAC at 50,000 mt. They argue that the recent landings levels of around 100,000 mt are sustainable. They note that the TRAC report supports this view, and that the PDT analysis indicates that all of the alternatives, including the status quo, are projected to result in removals of the inshore component that are less than the historical (1995–2006) removals within a reasonable range of stock mixing assumptions.

Response: The commenters are correct in noting that the TRAC concluded that removals at current levels (around 100,000 mt per year for the past 15 years) are sustainable. They are also

correct that the PDT's risk assessment indicated that setting the TACs at the status quo level was projected to result in removals from the inshore stock component that are less than historical removals for the period 1995–2005, during the winter (January-March; August-December). However, the PDT's risk assessment was not as clear cut for the summer period (April-July), where it showed that the status quo TACs would generate removals that would be at or below historical removals in about 50 percent of the possible scenarios. Both the Council's recommended TACs and the TACs established by this action would be more risk-averse than the status quo during the summer period, when a large amount of the Area 1A catch is taken.

The commenters failed to note that there was a second part to the PDT's risk assessment, which evaluated the success of proposed TAC alternatives in achieving an exploitation rate that equates to F_{msy} for the herring stock. As noted in the response to Comment 2, this aspect of the risk assessment was one of the reasons that both the Council and NMFS concluded that it was appropriate to make a significant reduction in the Area 1A TAC to reduce the risk of overfishing the inshore stock component.

Comment 9: One organization argued that, based on the TRAC results and reasonable assumptions about stock component mixing rates, the Area 1A TAC should be set between 35,000–42,000 mt. Furthermore, this organization does not support the addition of 5,000 mt to the Area 3 TAC, and argues that, at most, the Area 3 TAC should be 55,000 mt. The commenter argues that, because the natural mortality rate used by the TRAC in its assessment model is not accurate and might significantly underestimate natural mortality, NMFS has not accurately estimated the amount of herring that can be safely removed from the ecosystem and that, as a result, NMFS should be more precautionary in setting the herring specifications.

Response: The PDT stated that if it may be possible to apply a fishing mortality rate to an average biomass for the inshore stock component (assuming that it comprises 18 percent of total biomass), and estimate a TAC specifically for the inshore stock component. Using this approach would likely result in a TAC for the inshore stock component of about 35,000 mt - 42,000 mt. However, the PDT also stated that a TAC for the inshore stock component does not equate to a TAC for Area 1A, as fish from both the inshore and offshore component are caught in Areas 1A, 1B, and 2.

Regarding the commenter's contention that the natural mortality rate used in the TRAC assessment is not accurate, the TRAC investigated values for natural mortality other than 0.2, but deemed that 0.2 was the appropriate value to use in the stock assessment. The peer-reviewed TRAC results constitute the best available scientific information on this point.

NMFS notes that Fmsy for the stock was estimated at 0.31 by the TRAC. The analysis of the stockwide F associated with the specifications estimates F's of 0.18 in 2007; 0.197 in 2008, and 0.221 in 2009. NMFS concludes that these fishing mortality estimates are sufficiently precautionary.

Comment 10: Five vessel owners argued that the perceived declines in the inshore component, based on the incorporation of recent data (2004 and 2005) from the NMFS trawl survey, appears to be a rush to judgment. They pointed out that, in 2006, herring fishermen reported very high inshore biomass and that, based on a personal communication with NEFSC staff, the fall 2006 survey results indicate a rebound to previous levels.

Response: The PDT noted the impact that recent data has on overall trends for the inshore component; however it also placed that data within its proper context, stating that, ''While data specific to the inshore component of the stock is limited and the Herring PDT cannot make a status determination based on bottom trawl indices alone, a change in the direction of the trend line is an important consideration.'' The Council's 2007 review will consider any upated survey data and, if the results indicate a change in the apparent trend of recent years, then it could result in recommendations for TAC adjustments in 2008–2009. While NMFS took recent trawl survey information into account in taking this action, there were several factors that led NMFS to specify the Area 1A TAC at 45,000 mt for 2008–2009, as discussed in the response to Comment 2.

Comment 11: Five vessel owners argued that the 10,000–15,000 mt reduction of the Area 1A TAC will have greater economic impacts than the revenue loss estimates of $136,350–204,500 per vessel for purse seine vessels. They contend that it is incorrect to assume that the reduced catch in Area 1A can be made up from Area 3. They explain that vessel size and weather make it difficult for their vessels to work offshore and make up for reduced landings from Area 1A.

Response: The analysis of the economic impacts of the proposed TACs takes into account the same points made by the commenter. The specific per-vessel revenue impacts cited by the commenter are part of the analysis of revenue impacts on vessels that have harvested herring from Area 1A in the past, and are likely to qualify for the limited access permit established by Amendment 1. The analysis presumes that these vessels will continue to harvest the same proportion of the Area 1A TAC as in the past. The analysis notes that there are several things that could affect this assumption, notably that the reduced TAC may create an incentive for vessel owners to compete more aggressively for the reduced Area 1A TAC, thus altering the proportion of fish available to past participants. The analysis also notes that, while there are opportunities to harvest fish from other management areas to compensate for the reduction in Area 1A, this may not be possible for all vessels. It notes that there are a number of reasons it may not be possible for all vessels to fish in other areas, particularly offshore Areas 2 and 3, because the size of some vessels creates safety concerns, and because there are higher operating costs associated with longer trips, notably the costs associated with additional steaming time and associated fuel costs.

Comment 12: One organization argued that, because of the mixing between offshore and inshore components during the spring, only the fall surveys should be considered as an indicator of the status of the inshore stock component. It also argued that a number of the survey results, as well as observed encounter rates, indicate that the health of the stock is not in decline.

Response: Overall, the herring stock is in good shape, but for reasons outlined in the response to Comment 2 there are concerns about the inshore stock component that resulted in the reduction of the Area 1A TAC.

Classification

This action is authorized by 50 CFR part 648 and has been determined to be not significant for purposes of Executive Order 12866.

A FRFA was prepared. The FRFA incorporates the IRFA, a summary of the signficant issues raised by the public comments in response to the IRFA, NMFS responses to those comments, and a summary of the analyses completed to support the action. A copy of the analyses is available from NMFS (see **ADDRESSES**).

A description of the reasons for this action, the objectives of this action, and the legal basis for this final rule is found

in the preambles to the proposed rule and this final rule and is not repeated here.

Statement of Need for this Action

The purpose of this action is to establish specifications to conserve and manage the herring resource for the period 2007–2009, as required by the FMP.

A Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA, a Summary of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Proposed Rule as a Result of Such Comments

NMFS received 460 comments on the proposed specifications. Only one comment was specific to the IRFA. Comment 12 outlines concerns expressed by five vessel owners that the analysis of the Area 1A TACs underestimated the economic impacts they would experience due to the reductions in the allocation for the area. NMFS' assessment of the issues raised by this comment is contained in the preamble and not repeated here. The comment did not result in any changes to the Area 1A TAC, which was reduced for biological reasons.

Description and Estimate of Number of Small Entities to Which the Rule Will Apply

During the 2005 fishing year, 143 vessels landed herring, 33 of which averaged more than 2,000 lb (907 kg) of herring per trip. The Small Business Administration's size standard for small commercial fishing entities is $4 million in gross sales. Thus, all the entities participating in this fishery are considered small entities, as defined in section 601 of the RFA. Therefore, there are no disproportionate economic impacts between large and small entities.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

This action does not contain any new collection-of-information, reporting, recordkeeping, or other compliance requirements.

Description of the Steps the Agency Has Taken to Minimize the Significant Economic Impact on Small Entities Consistent with the Stated Objective of Applicable Statutes, including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each of the Other Significant Alternatives to the Rule Considered by the Agency which Affect the Impact on Small Entities was Rejected

The economic impacts of this action were assessed by the Council and NMFS in an analysis that compares the alternatives considered to the herring landings made in 2005, the most recent year for which complete data are available. From a fishery-wide perspective, these specifications are not expected to produce a negative economic impact to vessels prosecuting the fishery because it allows for landings levels that are significantly higher than the landings in recent years. The 2007–2009 specifications should allow for incremental growth in the industry, while appropriately addressing biological concerns. However, because of the allocation of the management area TACs, and the reduction in the Area 1A TAC in particular, these specifications could have a negative impact on various industry participants, despite the fact that overall landings levels could be higher than in recent years.

The specification of OY and DAH is 145,000 mt for 2007–2009. While higher levels of OY were considered (150,000 mt and 170,000 mt) the OY of 145,000 mt will allow an annual increase of up to 51,610 mt in herring landings compared to the 93,390 mt landed in 2005. This will generate $10.4 million in revenues, based on an average price (in 2005) of $202/mt. Therefore, there are no negative economic impacts associated with the specification of OY in this action. Individual vessels could increase their revenues under the proposed 2007–2009 specifications, depending on the number of vessels participating in the fishery, which will become a limited access fishery with the implementation of Amendment 1 to the FMP on June 1, 2007.

Several other specifications established by this action would also allow an increase in revenue to industry participants when compared to the 2005 landings. These include DAH and DAP, which are specified at 145,000 mt and 141,000 mt, respectively; USAP, which is specified at 20,000 mt; the Area 1B TAC, which is specified at 10,000 mt; the Area 2 TAC, which is specified at 30,000 mt; and the Area 3 TAC, which is specified at 55,000 mt in 2007 and 60,000 mt in 2008–2009. In each instance, there are no negative economic impacts associated with these specifications because they would allow industry participants to harvest and/or process more herring than in 2005. There are no potential economic impacts associated with the allocation for JVPt of zero, because it is unchanged from 2005.

The only specification that could constrain the industry when compared to landings and revenue in 2005 is reduction of the Area 1A TAC to 50,000 mt in 2007, and 45,000 mt in 2008 and 2009. The impacts of these reductions were analyzed for the purse seine fleet, the single midwater trawl fleet, and the paired midwater trawl fleet.

In 2005, the currently active purse seine fleet caught 27 percent of the Area 1A TAC. With a 10,000–15,000–mt reduction in the Area 1A TAC, if the proportion of the herring catch by the purse seine fleet remains the same and the decrease in the Area 1A TAC cannot be made up from fishing in other areas, there would be a 2,700–mt loss in catch under this action in 2007, and a 4,050–mt loss in catch in 2008 and 2009. Using the 2005 average price of herring of $202 per metric ton, this loss in catch would be worth $545,400 and $818,000, respectively, across the sector (there are four vessels in the currently active purse seine fleet). To make up for such a loss, these vessels would have to either increase their proportion of the herring catch in Area 1A relative to midwater trawlers, or move to other areas. There were no landings from Area 3 by these purse seine vessels in 2005, likely reflecting the fact that the vessels are too small to fish in these offshore areas. Moving offshore would also entail additional operating costs because the trips would be longer.

The impact of the 10,000–15,000–mt decrease in the Area 1A TAC on the single midwater trawl fleet is difficult to predict, because the Purse Seine/Fixed Gear (PS/FG) only area established by Amendment 1 will eliminate single midwater trawl vessels from Area 1A during the most productive part of the Area 1A fishery (June through September). The establishment of a PS/FG only area might intensify the race to fish in Area 1A, as midwater trawl vessels (single and paired) may try to catch more fish from the area prior to the closure to trawling on June 1.

If herring are plentiful in Area 1A during the spring (Area 1A catches increase in May, historically), the single midwater trawlers may be able to maintain their historical proportion of the Area 1A TAC. However, it is likely

that purse seine vessels and midwater pair trawl vessels would also participate in the pre-June race in order to keep their landings on par with previous years. In addition, single midwater trawl vessels might convert to purse seine gear in order to fish in Area 1A in the summer.

In 2005, the currently active single midwater trawl fleet caught 18 percent of the Area 1A TAC. If the proportion of the herring catch by the single midwater trawl fleet remains the same, and the decrease in the Area 1A TAC cannot be made up from fishing in other areas, there would be a 1,800–mt loss in catch under this action during 2007, and a 2,700–mt loss in catch in 2008 and 2009. Using the 2005 average price of herring of $202 per metric ton, this loss in catch would be worth $363,600 and $545,400, respectively, across the sector (there are four vessels that were active in Area 1A from 2003–2005 in the single midwater trawl fleet). To make up for such a loss, the single midwater trawl vessels would have to either increase their proportion of the herring catch in Area 1A relative to purse seine vessels, or move to other areas. Moving to offshore areas may be problematic for two of the four single midwater trawl vessels, since these two are relatively smaller vessels and landed herring only from Area 1A during 2003 through 2005. The other two vessels are somewhat larger and have Area 3 catch history, so their loss of Area 1A catch may be mitigated by their ability to fish in Area 3. If the single midwater trawl vessels make up their catch in Areas 2 and 3, the vessel operating cost will increase because the trips will be longer.

With decreases in the Area 1A TAC of 10,000 mt to 15,000 mt under this action, the impact on the midwater pair trawl fleet could also be large. It is difficult to predict what the impact will be on the midwater pair trawl fleet, because these vessels will also be excluded from Area 1A for the period June-September due to the PS/FG only measure. In 2005, the currently active pair trawl fleet caught 55 percent of the Area 1A TAC. If the proportion of the herring catch by the pair trawl fleet remains the same and the decrease in the Area 1A TAC cannot be made up from fishing in other areas, there would be a 5,500–mt loss in catch under this action in 2007, and a 8,250–mt loss in 2008 and 2009. Using the 2005 average price of herring of $202 per metric ton, this catch is worth $1,111,000 and $1,666,500 respectively, across the sector (there are 12 vessels in the pair trawl fleet that were active from 2003–2005). To make up for such a loss, pair trawl vessels would have to either increase their proportion of the herring catch in Area 1A or move to other areas. All pair trawl vessels have Area 3 catch history, so their loss of Area 1A catch may be mitigated by their ability to fish in Area 3. If the pair trawl vessels make up their catch in Areas 2 and 3, the vessel operating cost will increase because the trips would be longer.

The 10,000–mt to 15,000–mt reduction in TAC in Area 1A may cause participants using all 3 gear types to increase their fishing activity in Area 1B. The Area 1B TAC has not been reached every year, and only 60 percent was harvested in 2005. Since Area 1B is farther from shore than Area 1A, vessel operating costs would increase because trips would be longer. Harvesting in Area 1B will only provide limited relief for vessels impacted by the reduction in the Area 1A TAC since the TAC is limited to 10,000 mt.

There were seven alternatives considered. Three of the alternatives would have set the Area 1A TAC at 60,000 mt. They were rejected because the biological concerns about the inshore herring stock component require a significant reduction in harvest within Area 1A. More specifically, NMFS concluded that the SSC's advice, the retrospective pattern in the stock assessment, and the conclusions of the PDT's risk assessment combine to make a sound case for being precautionary about protecting the inshore component and for specifying the Area 1A TAC at 45,000 mt.

One alternative would have set the Area 1A TAC at 50,000 mt for all three years. This was rejected for the reasons cited above; namely, that the SSC's advice, the retrospective pattern in the stock assessment, and the conclusions of the PDT's risk assessment combine to make a sound case for being precautionary about protecting the inshore component and for specifying the Area 1A TAC at 45,000 mt.

Two of the alternatives would have reduced the Area 1A TAC to 45,000 mt for all three years. These were rejected because NMFS believed that it is sufficient to achieve biological objectives to implement the 45,000 mt TAC for 2008–2009, and establish the 2007 TAC at 50,000 mt, consistent with action taken by the states under the Atlantic States Marine Fisheries Commission's Interstate Fisheries Management Plan for Atlantic Sea Herring. The preferred alternative was selected because the SSC's advice, the retrospective pattern in the stock assessment, and the conclusions of the PDT's risk assessment combine to make a sound case for specifying the Area 1A TAC at 45,000 mt in fishing years 2008 and 2009.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule, or group of related rules, for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a small entity compliance guide will be sent to all holders of permits issued for the herring fishery. In addition, copies of this final rule and guide (i.e., permit holder letter) are available from the Regional Administrator (see **ADDRESSES**) and may be found at the following web site: *http://www.nero.noaa.gov*.

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

Dated: April 2, 2007.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. E7–6648 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 72, No. 68
Tuesday, April 10, 2007

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 1

[Docket No. APHIS–2006–0158]

Animal Welfare; Petition for Rulemaking

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition and request for comments.

SUMMARY: We are notifying the public of our receipt of a petition for rulemaking, and we are soliciting public comment on that petition. The petition, sponsored by The Hunte Corporation, requests that we replace the definition of Class ''B'' licensee in the Animal Welfare Act regulations with four new categories of licensees: Pet distributor, exhibitor animal distributor, laboratory animal distributor, and other distributor.

DATES: We will consider all comments that we receive on or before June 11, 2007.

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

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*, select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2006–0158 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.

• *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0158, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0158.

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

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

FOR FURTHER INFORMATION CONTACT: Dr. Jerry DePoyster, Senior Veterinary Medical Officer, Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 734–7586.

SUPPLEMENTARY INFORMATION:

Background

The Animal Welfare Act (the Act, 7 U.S.C. 2131 *et seq.*) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The Secretary of Agriculture has delegated the responsibility of administering the Act to the Administrator of the Animal and Plant Health Inspection Service (APHIS). The regulations established under the Act are contained in title 9 of the Code of Federal Regulations (9 CFR), chapter I, subchapter A, parts 1, 2, and 3. Part 1 defines various terms used in parts 2 and 3.

In part 1, § 1.1 sets forth definitions for three classes of licensees: Class ''A,'' Class ''B,'' and Class ''C.'' Class ''A'' licensees are dealers whose business consists only of animals that are bred and raised on the premises and acquired for the sole purpose of maintaining or enhancing the breeding colony. Class ''B'' licensees are dealers whose business includes the purchase or resale of any animal. Class ''B'' licensees do not usually take actual physical possession or control of the animals or hold them in any facilities. Class ''C'' licensees are exhibitors whose business involves the showing or displaying of animals to the public. Class ''C'' licensees may buy and sell animals as a minor part of their business to maintain or add to their animal collection.

APHIS has received a petition for rulemaking sponsored by The Hunte Corporation, a Class ''B'' licensee, requesting changes to the definition of Class ''B'' licensee contained in § 1.1 of the regulations. Specifically, the petition requests that we replace the definition of Class ''B'' licensee with four new categories of dealers: Pet distributor, exhibitor animal distributor, laboratory animal distributor, and other distributor.

The petition is available for review on the Regulations.gov Web page and in our reading room (see **ADDRESSES** above for instructions for accessing Regulations.gov and for information on the location and hours of the reading room). Copies may also be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**. We invite comments on the changes discussed in the petition.

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 4th day of April 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–6701 Filed 4–9–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–156420–06]

RIN 1545–BG25

Anti-Avoidance and Anti-Loss Reimportation Rules Applicable Following a Loss on Disposition of Stock of Consolidated Subsidiaries

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal**

Register, the IRS is issuing temporary regulations under section 1502 of the Internal Revenue Code (Code). The temporary regulations provide guidance to corporations filing consolidated returns. The temporary regulations apply an anti-avoidance rule and revise an anti-loss reimportation rule that applies after a disposition of stock of a subsidiary at a loss. The text of those regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments or a request for a public hearing must be received by July 9, 2007.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–156420–06), 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–156420–06), 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–156420–06).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Theresa Abell (202) 622–7700 or Phoebe Bennett (202) 622–7770; concerning submission of comments and request for public hearing, Richard Hurst at *Richard.A.Hurst@irscounsel.treas.gov* or (202) 622–7180 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to section 1502. The temporary regulations provide guidance to corporations filing consolidated returns. The temporary regulations apply an anti-avoidance rule and revise an anti-loss reimportation rule that applies following a disposition of stock of a subsidiary at a loss. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12666. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations primarily will affect affiliated groups of corporations that have elected to file consolidated returns, which tend to be larger entities. Therefore, a Regulatory Flexibility Analysis under Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for 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 Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Phoebe Bennett, Office of the Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, 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 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.1502–32 is amended by revising paragraph (b)(3)(iii)(D) and adding paragraph (k) to read as follows:

§ 1.1502–32 Investment adjustments.

* * * * *

(b) * * *

(3) * * *

(iii)* * *

(D) [The text of the proposed amendment to § 1.1502–32(b)(3)(iii)(D) is the same as the text of § 1.1502–32T(b)(3)(iii)(D) published elsewhere in this issue of the **Federal Register**].

* * * * *

(k) [The text of the proposed amendment to § 1.1502–32(k) is the same as the text of § 1.1502–32T(k) published elsewhere in this issue of the **Federal Register**].

Par. 3. Section 1.1502–35 is amended by:

1. Revising paragraphs (g)(3) and (h).

2. Adding new paragraph (g)(6).

3. Revising paragraph (j).

The revisions and additions read as follows:

§ 1.1502–35 Transfers of subsidiary stock and deconsolidations of subsidiaries.

* * * * *

(g) * * *

(3) [The text of the proposed amendment to § 1.1502–35(g)(3) is the same as the text of § 1.1502–35T(g)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(6) [The text of the proposed amendment to § 1.1502–35(g)(6) is the same as the text of § 1.1502–35T(g)(6) published elsewhere in this issue of the **Federal Register**].

(h) [The text of the proposed amendment to § 1.1502–35(h) is the same as the text of § 1.1502–35T(h) published elsewhere in this issue of the **Federal Register**].

* * * * *

(j) [The text of the proposed amendment to § 1.1502–35(j) is the same as the text of § 1.1502–35T(j) published elsewhere in this issue of the **Federal Register**].

* * * * *

Linda M. Kroening,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. E7–6534 Filed 4–9–07; 8:45 am]

BILLING CODE 4830–01–P

Notices

Federal Register
Vol. 72, No. 68
Tuesday, April 10, 2007

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

Roadless Area Conservation; National Forest System Lands in Idaho

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service, U.S. Department of Agriculture, is initiating a public rulemaking process to address the management of roadless areas on National Forest System (NFS) lands within the State of Idaho. This rulemaking is the result of a petition submitted by Governor James Risch on behalf of the State of Idaho pursuant to 7 CFR § 1.28, reviewed and recommended by the Department's Roadless Area Conservation National Advisory Committee, and accepted by the Secretary. The State requests specific regulatory protections with certain management flexibility for the 9.3 million acres of affected NFS lands. The Forest Service will prepare an environmental impact statement to analyze and disclose potential environmental consequences associated with this rulemaking.

DATES: Comments concerning the scope of the analysis must be received by May 10, 2007.

ADDRESSES: Comments may be sent via e-mail to *IDcomments@fsroadless.org.* Written comments concerning this notice should be addressed to Roadless Area Conservation-Idaho, P.O. Box 162909, Sacramento, CA 95816–2909, or via facsimile to 916–456–6724.

All comments, including names and addresses, when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at *http://roadless.fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Brad Gilbert, Idaho Roadless Interdisciplinary Team Leader, 208–765–7438, *bjgilbert@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

As a leader in natural resource conservation, the Forest Service provides direction for the management and use of the Nation's forests, rangeland, and aquatic ecosystems. The Forest Service is charged to collaborate cooperatively with states and other interested parties regarding the use and management of the National Forest System (NFS).

The 2001 Roadless Area Conservation Rule (Roadless Rule)

On January 12, 2001, the Department promulgated the Roadless Rule at 36 CFR 294 (66 FR 3244), which fundamentally changed the Forest Service's longstanding approach to management of inventoried roadless areas by establishing nationwide prohibitions that, with some exceptions, generally limited timber harvest, road construction, and road reconstruction within inventoried roadless areas on NFS lands. Prior to 2001, inventories of roadless areas were used primarily as tools for evaluating wilderness potential. Unless otherwise provided for by law, during forest planning the Forest Service generally evaluated each area's wilderness potential, made preliminary legislative recommendations, and assigned appropriate management area direction in land management plans. Land management plans were developed for each unit of the NFS through a public notice and comment process, building on years of scientific findings, analyses, and extensive public involvement.

Following promulgation of the Roadless Rule, concerns were immediately expressed by states, Tribes and local communities. These concerns included the sufficiency and the accuracy of the information available for public review during the rulemaking process; the inclusion of an estimated 2.8 million acres of roaded lands in the inventoried roadless area land base; the denial of requests to lengthen the public review period; the denial of cooperating agency status requested by several Western States; the sufficiency of the range of alternatives considered in the rulemaking process; the need for flexibility and exceptions to allow for needed resource management activities; and the changes made in the final rule after the closure of the public comment period. Concerns were also expressed about applying one set of standards uniformly to every inventoried roadless area.

The Roadless Rule became the subject of 10 lawsuits in Federal District Courts in Idaho, Utah, North Dakota, Wyoming, Alaska, and the District of Columbia. In one of these lawsuits, the U.S. District Court for the District of Idaho issued a preliminary injunction prohibiting implementation of the Roadless Rule on May 10, 2001. The preliminary injunction was reversed by the U.S. Court of Appeals for the Ninth Circuit on December 12, 2002.

Secretary Veneman expressed the Department's commitment to conserving inventoried roadless area values in the NFS while acknowledging concerns raised by local communities, Tribes, and states regarding the Roadless Rule. In May 2001, the Secretary indicated that the Department would move forward with a responsible and balanced approach to re-examining the Roadless Rule. The Department was able to reach a settlement agreement with the State of Alaska leading to the adoption of a final rule on December 30, 2003, that withdrew the Tongass National Forest from the prohibitions of the Roadless Rule.

However, on July 14, 2003, the U.S. District Court for the District of Wyoming set aside the Roadless Rule and issued a nationwide, permanent injunction against its implementation. The ruling was appealed.

The State Petitions Rule

On May 13, 2005, the Department adopted a new rule (70 FR 25654), the State Petitions Rule, that established a process allowing Governors an opportunity to seek establishment of or adjustment to management requirements for NFS inventoried roadless areas within their states. The opportunity for submitting state petitions was available for 18 months. Under the State Petitions Rule, submission of a petition was strictly voluntary, and management of

inventoried roadless areas was to be guided by individual land management plans until and unless these management requirements were changed through a state-specific rulemaking. At the same time, the Department established the Roadless Area Conservation National Advisory Committee in accordance with the Federal Advisory Committee Act (5 U.S.C. App. II) to assist the Secretary with the implementation of this rule.

On July 12, 2005, the Tenth Circuit Court of Appeals held that the appeal was moot after promulgation of the State Petitions Rule (see below). The Tenth Circuit dismissed the appeal and vacated the district court decision in May 2005, the States of California, New Mexico, Washington, and Oregon, as well as a coalition of environmental groups, challenged the State Petitions Rule in the Northern District of California. On September 20, 2006, the District Court set aside the State Petitions Rule and reinstated the Roadless Rule. The California court's order triggered the State of Wyoming to seek reinstatement by the Wyoming District Court of the vacated 2003 injunction against the original Roadless Rule. The State of Wyoming also filed a new complaint, again challenging the Roadless Rule.

State of Idaho Petition

On June 23, 2005, the State of Idaho announced it would submit a petition pursuant to the State Petitions Rule, requesting specific regulatory protections and certain management flexibility for the 9.3 million acres of NFS inventoried roadless areas in Idaho. As part of that announcement, the State invited affected county commissioners to develop specific recommendations for the NFS inventoried roadless areas in their respective counties. Additionally, over 50 public meetings were held and the general public was encouraged to send individual comments directly to the Governor's office for consideration.

Idaho's petition was submitted to the Secretary of Agriculture for consideration on September 20, 2006. When the State Petitions Rule was injoined, Idaho submitted a petition on October 5, 2006, under section 553(e) of the Administrative Procedure Act and Department regulations at 7 CFR 1.28 which allow an interested person the opportunity to petition for the issuance, amendment, or repeal of a rule.

The Roadless Area Conservation National Advisory Committee reviewed the Idaho petition on November 29 and 30, 2006, in Washington, DC. Governor James Risch, on behalf of the State of Idaho discussed his views on the scope and intent of the petition during the first day of the meeting. The Committee also heard comments from other State and Forest Service officials, and members of the public. On December 19, 2006, the Committee issued a unanimous consensus-based recommendation that the Secretary direct the Forest Service, with the State of Idaho as a cooperating agency, to proceed with rulemaking.

On December 22, 2006, the Secretary accepted the petition based on the Advisory Committee's review and report and directed the Forest Service to initiate rulemaking.

Estimated Dates

The Draft environmental impact statement is expected September, 2007 and the final environmental impact statement is expected August, 2008.

Purpose and Need for Action

Following promulgation of the Roadless Rule, the State of Idaho was one of several states to express concerns about applying one set of standards regulating road construction, reconstruction, and timber harvest uniformly to every inventoried roadless area. The State undertook an extensive public comment process to assess the desired management objectives for each individual inventoried roadless area. This information was then used to construct the petition, including where and under what circumstances road construction and timber harvest should be prohibited in inventoried roadless areas. The State examined a management continuum that includes at one end, a restrictive approach emphasizing passive management and natural restoration approaches, and on the other end, a fairly unrestrictive approach emphasizing flexibility and active management. The petition, as presented by Governor Risch, requests that road construction and timber harvest be administered in accordance with five management themes applied to NFS inventoried roadless areas within the State of Idaho. While developing the petition, the State developed a set of guiding principles to evaluate the strength of submitted comments including: Current land management plan prescriptions, County/Tribal/Public comments, the wildland urban interface and forest health, consistency between National Forests within the State, and consistency between interstate National Forests.

Although the State is seeking a rule with accompanying management themes that only directly administers timber harvest and road construction and/or reconstruction within NFS lands in Idaho, the State indicates that each theme would be an important consideration for the Forest Service's future management of inventoried roadless areas for activities and uses outside of the proposed regulations. The State has identified that the description of the themes is not intended to mandate or direct the Forest Service to propose or implement a proposed action; rather, the description of each theme is envisioned to function as a backdrop for future discussions between the Forest Service and the Governor's Roadless Rule Implementation Commission that was established by Idaho Executive Order 2006–43. The State also anticipates that the rulemaking will direct the Forest Service to develop a Memorandum of Understanding with the Implementation Commission outlining their relationship and responsibilities.

Petitioned Action

The Forest Service, in cooperation with the State of Idaho is initiating a public rulemaking process to address the management of roadless areas on National Forest System (NFS) lands within the State of Idaho. The regulation sought would administer road construction and timber harvest in inventoried roadless areas in accordance with five management themes and allow most appropriate uses in inventoried roadless areas to be decided through the forest planning process in accordance with the National Forest Management Act. The management themes are Wild Land Recreation (1.3 million acres), Primitive Areas (1.7 million acres), Backcountry/Restoration (5.5 million acres) General Forest Areas (0.5 million acres) and Areas of Cultural, Historical, and Tribal Significance (0.25 million acres).

In Wild Land Recreation Areas, road construction and reconstruction would be prohibited. Timber harvest would be permitted in these areas only if the responsible official determines it is for personal or administrative use as defined at 36 CFR § 223; the areas show little evidence of historical or human use; natural processes are predominant; and people visiting these areas can find outstanding opportunities for recreation, including exploration, solitude, risk, and challenge.

In Primitive Areas, road construction and reconstruction would be prohibited. Timber harvest would be permitted only if existing roads or aerial systems are used and the responsible official determines the harvest falls within exceptions consistent with those outlined in the Roadless Rule. These

areas generally reflect the primitive character of the Wild Land Recreation theme, however, they fall short of the Forest Service's recommended wilderness suitability criteria. They are naturally appearing and are relatively undisturbed by human management activities.

In Backcountry/Restoration Areas, roads may be constructed or reconstructed only if the responsible official determines the roads fall within exceptions consistent with those outlined in the Roadless Rule. Timber harvest will be permitted if the responsible official determines that it meets exceptions consistent with those outlined in the Roadless Rule. These areas may display increased evidence of management activities, however, they would generally retain their roadless character. Areas are to provide a variety of recreation opportunites, while also ensuring adequate flexibility to maintain forest health.

In General Forest, Grassland and Rangeland Areas, road construction and timber harvest would be permitted after necessary environmental analysis is completed. Areas may display high levels of human use including roads, facilities, evidence of vegetative manipulation, and mineral exploration/extraction.

Three areas of cultural, historic, and tribal significance (Pilot Knob, Mallard-Larkins Pioneer Area, and Lewis and Clark Trail) will be defined and managed similarly to areas designated under the Primative theme.

The petition does not seek to address leasable and locatable minerals. The public sale of salable minerals would be prohibited in areas designated as Wild Land Recreation or Primitive.

The petition does not seek to address recreation, grazing, or other multiple uses not expressly prohibited in Idaho inventoried roadless areas. Those management activities will be governed by existing land management planning, travel planning, and grazing allotment analysis processes. The petition does not affect current or future management status of existing roads or trails in Idaho inventoried roadless areas or the status of existing grazing allotments.

The petition does not address whether or how the Roadless Rule or State Petitions Rule apply to the inventoried roadless acres in national forests and grasslands outside of Idaho.

Possible Alternatives

The NEPA implementing regulations require that an Environmental Impact Statement evaluate alternatives. Possible alternatives to be considered in the Draft Environmental Impact Statement include:

- Promulgation of a rule pursuant to the Idaho petition.
- Roadless management direction as set forth in the Roadless Rule.
- Roadless management direction as set forth in current Land and Resource Management Plans.

Additional alternatives may arise from public comments or new information.

Lead and Cooperating Agencies

State governments are important partners in management of the Nation's land and natural resources. States, particularly in the West, own and manage large tracts of land with tremendous social and biological value. State governments have frequently pioneered innovative land management programs and policies. State governments exert considerable influence over statewide economic development and private land use, both of which significantly affect natural resource management. In addition, state conservation agencies' relationships with others, including the general public offer additional opportunities for collaborative decisionmaking. Strong state and Federal cooperation regarding land management can facilitate long-term, community-oriented solutions.

As part of its petition, the State of Idaho committed to participation as a cooperating agency in the preparation of any environmental analysis for this rulemaking.

Responsible Official

The Responsible Official is the Secretary, USDA or his designee.

Nature of Decision To Be Made

The Forest Service is initiating a public rulemaking process to address the management of roadless areas on National Forest System lands within the State of Idaho. This rulemaking is the result of a petition submitted by the State of Idaho pursuant to 7 CFR 1.28 and presented by Governor Risch on November 29, 2006. The State requests specific regulatory protections with certain management flexibility for the 9.3 million acres of affected land.

Scoping Process

This Notice of Intent initiates the scoping process in compliance with the National Environmental Policy Act and its implementing regulations (40 CFR part 1500). As part of the scoping period, the Forest Service solicits public comment on the nature and scope of the environmental, social, and economic issues related to the rulemaking that should be analyzed in depth in the Draft Environmental Impact Statement. Comments collected during promulgation of the Roadless Rule and the extensive public involvement process used by the State to craft their petition will be heavily relied upon. The nature and scope of the analysis for the Draft Environmental Impact Statement will focus on the land management direction sought in the petition, and the alternative to it. Because of the extensive amount of public comment that has already been received on the issue of protecting roadless areas in Idaho (see background above) no public meetings are planned for this scoping effort. However, public meetings will be held after the Draft Environmental Impact Statement and proposed rule have been issued, and the public has had a chance to take a careful look at the site-specific proposed rule, alternatives, and effects.

Supplemental Addresses

Additional information on how the State of Idaho petition was developed can be found in the State's petition at *http://gov.idaho.gov/roadless_petition.html.*

Detailed maps of the management themes, Idaho's petition, a summary of the November 29 and 30, 2006 Advisory Committee meeting, the recommendation made by the Roadless Area Conservation National Advisory Committee to the Secretary, and the Secretary's letter to the Governor can be found at the Forest Service Roadless Area Conservation Web site: *http://roadless.fs.fed.us.*

Comment Requested

Reviewers should provide their comments during the comment period. Timely comments will enable the agency to analyze and respond to them at one time and to use them in the preparation of the Environmental Impact Statement, thus avoiding undue delay in the decisionmaking process. Furthermore, the more specific and substantive the comments, the better for reviewers and the agency alike. Reviewers have an obligation to ''structure their participation in the National Environmental Policy Act process so that it is meaningful and alerts the agency to the reviewer's position and contentions.'' *Vermont Yankee Nuclear Power Corp.* v. *NRDC, 435 U.S. 519, 552 (1978). Dept. of Transportation* v. *Public Citizen, 541 U.S. 752, 764 (2004).* Environmental concerns that could have been raised at the draft stage may therefore be forfeited if not raised until after completion of the Final Environmental Impact

Statement. Comments on the draft should be specific and should address the adequacy of the draft and the merits of the alternatives discussed (40 CFR 1503.3).

Dated: March 30, 2007.

Frederick Norbury,

Associate Deputy Chief, National Forest System.

[FR Doc. E7–6756 Filed 4–9–07; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

National Tree-marking Paint Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The National Tree-marking Paint Committee will meet in Portland, Oregon on May 15–17, 2007. The purpose of the meeting is to discuss activities related to improvements in, concerns about, and the handling and use of tree-marking paint by personnel of the Forest Service and the Department of the Interior's Bureau of Land Management.

DATES: The meeting will be May 15–17, 2007, from 9 a.m. to 5 p.m. each day.

ADDRESSES: The meeting will be at the Portland Marriott Downtown Waterfront, 1401 SW Naito Parkway, Portland, OR 97201. Persons who wish to file written comments before or after the meeting must send written comments to Dave Haston, Chairperson, National Tree-marking Paint Committee, Forest Service, USDA, San Dimas Technology and Development Center, 444 East Bonita Avenue, San Dimas, California 91773, or electronically to *dhaston@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Dave Haston, Sr. Project Leader, San Dimas Technology and Development Center, Forest Service, USDA, 909–599–1267, extension 294 or *dhaston@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The National Tree-marking Paint Committee is comprised of representatives from the Forest Service national headquarters, each of the nine Forest Service Regions, the Forest Products Laboratory, the Forest Service San Dimas Technology and Development Center, and the Bureau of Land Management. The General Services Administration and the National Institute for Occupational Safety and Health are ad hoc members and provide technical advice to the committee.

A field trip on May 15 is designed to supplement information related to tree-marking paint. This trip is open to any member of the public participating in the meeting on May 16–17. However, transportation is provided only for committee members.

The main session of the meeting, May 16–17, is open to public attendance.

Closed Sessions

While certain segments of this meeting are open to the public, there will be two closed sessions during the meeting. The first closed session is on May 16 from approximately 10 a.m. to 12 p.m. This session is reserved for individual paint manufacturers to present products and information about tree-marking paint for consideration in future testing and use by the agency. Paint manufacturers also may provide comments on tree-marking paint specifications or other requirements. This portion of the meeting is open only to paint manufacturers, the Committee, and committee staff to ensure that trade secrets will not be disclosed to other paint manufacturers or to the public. Paint manufacturers wishing to make presentations to the Tree-marking Paint Committee during the closed session should contact the committee chairperson at the telephone number listed at **FOR FURTHER INFORMATION CONTACT** in this notice. The second closed session is on May 17 from approximately 9 a.m. to 11 a.m. This session is for Steering Committee members only.

Any person with special access needs should contact the Chairperson to arrange for accommodations. Space for individuals who are not members of the National Tree-marking Paint Committee is limited and will be available to the public on a first-come, first-served basis.

Dated: April 3, 2007.

Frederick Norbury,

Associate Deputy Chief—NFS.

[FR Doc. E7–6666 Filed 4–9–07; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Marysville Irrigation Company Gravity Pressurized Irrigation Delivery System; Fremont County, ID

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a Finding of No Significant Impact.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Natural Resources Conservation Service Guidelines (7 CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Marysville Irrigation Company, Gravity Pressurized, Irrigation Delivery System, Fremont County, Idaho.

FOR FURTHER INFORMATION CONTACT: Richard Sims, State Conservationist, Natural Resources Conservation Service, 9173 W. Barnes Dr., Suite C, Boise, Idaho 83709–1574, telephone (208) 378–5700.

SUPPLEMENTARY INFORMATION: The Plan/Environmental Assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national adverse impacts affecting the quality of the human environment. As a result of these findings, Richard Sims, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The Proposed Action consists of replacing an open ditch irrigation delivery system with buried plastic pipelines to distribute gravity pressurized irrigation water. The Proposed Action includes the construction and operation and maintenance of three plastic pipelines that provide for the delivery of gravity pressurized irrigation water to approximately 6,130 acres surrounding Marysville, Idaho, eliminating most of the need for pumping by electric motors. Approximately 1,000 acres would require booster pumps. Water would only be drawn from the pipe when irrigation is required, eliminating overflow to the Henry's Fork River. The Proposed Action would eliminate about 90% of the water seepage loss from the canals and the need for approximately 1,600 horsepower from electric pump motors while not adversely affecting the environment.

The Notice of Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency. The basic data developed during the plan/environmental assessment is on file and may be reviewed by contacting Mr. Richard Sims. The FONSI has been sent to various Federal, State, and local agencies, and interested parties. A limited number of copies of the FONSI

are available to fill single copy requests at the address stated above.

No administrative action on the proposal will be initiated until 30 days after the date of this publication in the **Federal Register**.

Dated: April 3, 2007.

Richard Sims,

State Conservationist.

[FR Doc. E7–6740 Filed 4–9–07; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Meeting of the Agricultural Air Quality Task Force

AGENCY: Natural Resources Conservation Service (NRCS), USDA.

ACTION: Notice of meeting.

SUMMARY: The Agricultural Air Quality Task Force (AAQTF) will meet to continue discussions on air quality issues relating to agriculture.

DATES: The meeting will convene at 8 a.m. on Tuesday, May 8, 2007, through 12 p.m. on Thursday, May 10, 2007. A public comment period will be held on May 9, 2007. Individuals making oral presentations should register in person at the meeting site and must bring with them 50 copies of any materials they would like distributed. Written materials for AAQTF's consideration prior to the meeting, must be received by Ms. Michele Laur (address given below) no later than Monday, April 16, 2007.

ADDRESSES: The meeting will be held at the Hyatt Regency Islandia/Hyatt Mission Bay, 1441 Quivira Road, San Diego, California, 92109; telephone: (619) 224–1234.

FOR FURTHER INFORMATION: Questions and comments should be directed to Michele Laur, Designated Federal Officer. Ms. Laur may be contacted at USDA Natural Resources Conservation Service, Post Office Box 2890, Room 6165-South, Washington, DC 20013; telephone: (202) 720–1858: e-mail: *Michele.Laur@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. Additional information concerning AAQTF may be found on the Internet at *http://www.airquality.nrcs.usda.gov/AAQTF/.*

Draft Agenda of the May 8–10, 2007, Meeting of AAQTF

Tuesday, May 8, Beginning at 8 a.m.

A. *Welcome to San Diego, California*

B. *Discussion of Subcommittee Action Plans and Activities*

C. *Discussion of Biofuels and Other Environmental Issues*

Wednesday, May 9 and Thursday, May 10

D. *Discussion of Subcommittee Action Plans and Activities*

E. *Discussion of California Air Quality Issues*

F. *Discussion of Ozone*

G. *Discussion of Climate Change*

H. *Next Meeting, Time and Place*

I. *Public Comments*

(Time will be reserved on May 9, 2007, in the afternoon to receive public comment. Individual presentations will be limited to 5 minutes).

Procedural

This meeting is open to the public. At the discretion of the Chair, members of the public may give oral presentations during the meeting. Those persons wishing to make oral presentations should register in person at the meeting site. Those wishing to distribute written materials at the meeting itself, in conjunction with spoken comments, must bring 50 copies of the materials with them. Written materials for distribution to AAQTF members prior to the meeting must be received by Ms. Michelle Laur no later than Monday, April 16, 2007.

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, please contact Ms. Laur. USDA prohibits discrimination in its programs and activities on the basis of race, color, national origin, gender, religion, age, sexual orientation, or disability. Additionally, discrimination on the basis of political beliefs and marital or family status is also prohibited by statutes enforced by USDA (not all prohibited bases apply to all programs). Persons with disabilities who require alternate means for communication of program information (Braille, large print, audio tape, etc.) should contact the USDA's Target Center at (202) 720–2000 (voice and TDD). USDA is an equal opportunity provider and employer.

Signed in Washington, DC on March 30, 2007.

Arlen L. Lancaster,

Chief.

[FR Doc. E7–6737 Filed 4–9–07; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Announcement of Funding Availability and Solicitation of Applications

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Funding Availability and Solicitation of Applications.

SUMMARY: The United States Department of Agriculture (USDA) Rural Development administers rural utilities programs through the Rural Utilities Service. USDA Rural Development announces its Distance Learning and Telemedicine (DLT) grant, combination loan-grant and loan program application windows for Fiscal Year (FY) 2007, and a new initiative within the combination loan-grant program for the conversion of medical recordkeeping systems to emerging electronic formats.

In addition to announcing the application windows, the Agency announces the available funding, and the minimum and maximum amounts for DLT grants, combination loan-grants and loans applicable for the fiscal year.

DATES: You may submit completed applications for grants on paper or electronically according to the following deadlines:

- Paper copies must be postmarked and mailed, shipped, or sent overnight *no later* than June 11, 2007 to be eligible for FY 2007 grant funding. Late or incomplete applications will not be eligible for FY 2007 grant funding.
- Electronic copies must be received by June 11, 2007 to be eligible for FY 2007 grant funding. Late or incomplete applications will not be eligible for FY 2007 grant funding.

ADDRESSES: You may obtain copies of the FY 2007 application guides and materials for the DLT grant program at the DLT Web site: *http://www.usda.gov/rus/telecom/dlt/dlt.htm.* For your reference, you may also request last year's FY 2006 application guide and materials by contacting the DLT Program at (202) 720–0413.

Submit completed paper applications for grants to the United States Department of Agriculture, Rural Development, Telecommunications Program, 1400 Independence Ave., SW., Room 2845, STOP 1550, Washington, DC 20250–1550. Applications should be

marked ''*Attention:* Director, Advanced Services Division.''

Submit electronic grant applications at *http://www.grants.gov* (Grants.gov), following the instructions you find on that Web site.

FOR FURTHER INFORMATION CONTACT: Director, Advanced Services Division, Telecommunications Program, USDA Rural Development, United States Department of Agriculture, *telephone:* (202) 720–0413, *fax:* (202) 720–1051.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service (RUS).

Funding Opportunity Title: Distance Learning and Telemedicine Grants, Combination Loan-grants, and Loans.

Announcement Type: Initial announcement.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.855.

Dates: You may submit completed applications for grants on paper or electronically according to the following deadlines:

- Paper copies must be postmarked and mailed, shipped, or sent overnight no later than June 11, 2007 to be eligible for FY 2007 grant funding. Late or incomplete applications are not eligible for FY 2007 grant funding.
- Electronic copies must be received by June 11, 2007 to be eligible for FY 2007 grant funding. Late or incomplete applications are not eligible for FY 2007 grant funding.

Items in Supplementary Information

I. Funding Opportunity: Brief introduction to the DLT program.

II. Minimum and Maximum Application Amounts: Projected Available Funding.

III. Eligibility Information: Who is eligible, what kinds of projects are eligible, what criteria determine basic eligibility.

IV. Application and Submission Information: Where to get application materials, what constitutes a completed application, how and where to submit applications, deadlines, items that are eligible.

V. Application Review Information: Considerations and preferences, scoring criteria, review standards, selection information.

VI. Award Administration Information: Award notice information, award recipient reporting requirements.

VII. Agency Contacts: Web, phone, fax, e-mail, contact name.

I. Funding Opportunity

Distance learning and telemedicine loans and grants are specifically designed to provide access to education, training and health care resources for people in rural America. The Distance Learning and Telemedicine (DLT) Program provides financial assistance to encourage and improve telemedicine services and distance learning services in rural areas through the use of telecommunications, computer networks, and related advanced technologies by students, teachers, medical professionals, and rural residents.

Grants, which are awarded through a competitive process, may be used to fund telecommunications-enabled information, audio and video equipment and related advanced technologies which extend educational and medical applications into rural locations. Grants are made for projects where the benefit is primarily delivered to end users that are not at the same location as the source of the education or health care service.

As in years past, the FY 2007 grant application guide has been changed to reflect recent changes in technology and application trends. Details of changes from the FY 2006 application guide are highlighted throughout this Notice and described in full in the FY 2007 application guide. All applicants must carefully review and *exactly* follow the FY 2007 application guide and sample materials when compiling a DLT grant application.

Applications for loans and combination loan-grants are not competitively scored. In addition to the items listed for grants, loans and combination loan-grants may be used to fund projects where the benefit is primarily at the same location as the source of the service. Loans and combination loan-grants may also fund construction of necessary transmission facilities on a technology-neutral basis. Examples of such facilities include satellite uplinks, microwave towers and associated structures, T–1 lines, DS–3 lines, and other similar facilities. Loan funds may also be used to obtain mobile units and for some building construction. Please see 7 CFR part 1703, subparts D, E, F and G for specifics.

II. Maximum and Minimum Amount of Applications; Projected Available Funding

Under 7 CFR 1703.124, the Administrator has determined the maximum amount of an application for a grant in FY 2007 is $500,000 and the minimum amount of a grant is $50,000. The anticipated amount available to fund grant awards in FY 2007 is $15 million.

The USDA Rural Development will make awards and execute documents appropriate to the project prior to any advance of funds to successful applicants.

Combination loan-grants will be offered at a loan-to-grant ratio of 9:1, *i.e.* $9 in loan to $1 in grant. Under 7 CFR 1703.133, the maximum amount of an application for a combination loan-grant in FY 2007 is $20 million and the minimum amount of a combination loan-grant is $50,000. For this program, the Administrator has determined that $45,000,000 in loans, paired with $5,000,000 in grants, for a total of $50,000,000, will be available.

For projects that are for electronic medical records systems, combination loan-grants will be offered at a special rate. The loan-to-grant ratio for the special ratio combination loan-grant program will be 4:1, *i.e.* $4 in loan to $1 in grant. Under 7 CFR 1703.133, the Administrator has determined that maximum amount of a special ratio combination loan-grant application is $1 million, and the minimum amount is $50,000. For this special ratio program, $20,000,000 in loans will be paired with $5,000,000 in grants, for a total available of $25,000,000.

The Administrator has determined that $62,900,000 will be available for DLT loans. Under 7 CFR 1703.143, the maximum amount of an application for a loan in FY 2007 is $20 million and the minimum amount of a loan is $50,000.

DLT grants, combination loan-grants and loans cannot be renewed. Award documents specify the term of each award. Applications to extend existing projects are welcomed (grant applications must be submitted during the application window) and will be evaluated as new applications.

III. Eligibility Information

A. Who is eligible for grants, combination loan-grants, and loans? (See 7 CFR 1703.103.)

1. *Only entities legally organized as one of the following are eligible for DLT financial assistance:*

a. An incorporated organization or partnership,

b. An Indian tribe or tribal organization, as defined in 25 U.S.C. 450b (b) and (c),

c. A state or local unit of government,

d. A consortium, as defined in 7 CFR 1703.102, or

e. Other legal entity, including a private corporation organized on a for-profit or not-for-profit basis.

2. Individuals are not eligible for DLT program financial assistance directly.

3. Electric and telecommunications borrowers under the Rural Electrification Act of 1936 (7 U.S.C. 950aaa *et seq.*) are not eligible for grants

or combination loan-grants, but are eligible for loans.

B. What are the basic eligibility requirements for a project?

1. *Required matching contributions for grants:* See 7 CFR 1703.125(g) and the FY 2007 application guide for information on required matching contributions.

a. Grant applicants must demonstrate matching contributions, in cash or in kind (new, non-depreciated items), of at least fifteen (15) percent of the total amount of financial assistance requested. Matching contributions *must* be used for eligible purposes of DLT grant assistance (see 7 CFR 1703.121, paragraphs IV.G.1.b of this Notice and the FY 2007 application guide).

b. Greater amounts of eligible matching contributions may increase an applicant's score (see 7 CFR 1703.126(b)(4), paragraph V.B.2.d of this notice, and the FY 2007 application guide).

c. Applications that do not provide evidence of the required fifteen percent match which helps determine eligibility will be declared ineligible and returned. See paragraphs IV.G.1.c and V.B.2.d of this Notice, and the FY 2007 application guide for specific information on documentation of matching contributions.

d. Applications that do not document all matching contributions are subject to budgetary adjustment by USDA Rural Development, which may culminate in rejection of an application as ineligible due to insufficient match.

3. The DLT loan, combination loan-grant and grant programs are designed to flow the benefits of distance learning and telemedicine to residents of rural America (see 7 CFR 1703.103(a)(2)). Therefore, in order to be eligible, applicants must:

a. Operate a rural community facility; or

b. Deliver distance learning or telemedicine services to entities that operate a rural community facility or to residents of rural areas, at rates calculated to ensure that the benefit of the financial assistance is passed through to such entities or to residents of rural areas.

4. Rurality.

a. All projects proposed for DLT grant assistance must meet a minimum rurality threshold, to ensure that benefits from the projects flow to rural residents. The minimum eligibility score is 20 points. Please see Section IV of this notice, 7 CFR 1703.126(a)(2), and the FY 2007 application guide for an explanation of the rurality scoring and eligibility criterion.

b. Each application must apply the following criteria to each of its end-user sites, and hubs that are also proposed as end-user sites, in order to determine a rurality score. The rurality score is the average of all end-user sites' rurality scores.

Criterion	Character	Population	DLT points
Exceptionally Rural Area	Area not within an Urbanized Area or Urban Cluster.	≤ 5000	45
Rural Area	Area in an Urban Cluster	> 5000 and ≤ 10,000	30
Mid-Rural Area	Area in an Urban Cluster	>10,000 and ≤ 20,000	15
Urban Area	Area in an Urbanized Area or Urban Cluster.	> 20,000	0

c. The rurality score is one of the competitive scoring criteria applied to grant applications.

4. Projects located in areas covered by the Coastal Barrier Resources Act (16 U.S.C. 3501 *et seq.*) are not eligible for financial assistance from the DLT Program. Please see 7 CFR 1703.123(a)(11), 7 CFR 1703.132(a)(5), and 7 CFR 1703.142(b)(3).

C. See Section IV of this Notice and the FY 2007 application guide for a discussion of the items that make up a complete application. For requirements of completed applications you may also refer to 7 CFR 1703.125 for grant applications, 7 CFR 1703.134 for combination loan-grant applications, and 7 CFR 1703.144 for loan applications. The FY 2007 application guide provides specific, detailed instructions for each item that constitutes a complete application. The Agency strongly emphasizes the importance of *including every required item* (as explained in the FY 2007 application guide) and strongly encourages applicants to follow the instructions *exactly,* using the examples and illustrations in the FY 2007 application guide. Applications which do not include all items that determine project eligibility and applicant eligibility by the application deadline will be returned as ineligible. Applications that do not include all items necessary for scoring will be scored as is. Please see the FY 2007 application guide for a full discussion of each required item and for samples and illustrations.

IV. Application and Submission Information

A. Where To Get Application Information

FY 2007 application guides, copies of necessary forms and samples, and the DLT Program regulation are available from these sources:

1. The Internet: *http://www.usda.gov/rus/telecom/dlt/dlt.htm.*

2. The DLT Program for paper copies of these materials: (202) 720–0413.

B. What's new for FY 2007?

1. For DLT Grants, USDA Rural Development clarifies end-user identification for portable and residential end-user projects such as ambulance and home health care applications. A simplified method of calculating rurality and National School Lunch Program (NSLP) scores for these applications will eliminate the need for identification and scoring of every community an applicant serves. Past applications from these applicants have contained hundreds of pages of community identification and scoring supporting documents. This was burdensome for applicants and increased the possibility of end-user site inconsistency, a cause of ineligibility for some in the FY 2006 DLT grant program.

2. For DLT Combination loan grants, USDA Rural Development adds a special ratio combination loan-to-grant funding program to address the growing lag in implementation of electronic medical records systems in rural hospitals and healthcare networks. The new ratio is available only to projects whose entire cost is directly attributable to the conversion to or extension of an electronic medical records system.

3. The standard rate DLT Combination loan-grant program adopts a new funding ratio of $9 loan for each $1 grant, to simplify post-grant administration.

4. For DLT rurality scoring, a new measurement tool is used to improve accuracy and consistency of scoring. Rurality scoring is now referenced to the U.S. Census current Urbanized Area and Urban Cluster designations. This will prevent scoring anomalies caused by jurisdictional peculiarities of different states.

C. What constitutes a completed application?

1. For DLT Grants:

a. Detailed information on each item in the table in paragraph IV.C.1.f. of this Notice can be found in the sections of the DLT Program regulation listed in the table, and the DLT grant application guide. Applicants are strongly encouraged to read and apply both the regulation and the application guide.

(1) When the table refers to a narrative, it means a written statement, description or other written material prepared by the applicant, for which no form exists. USDA Rural Development recognizes that each project is unique and requests narratives to allow applicants to explain their request for financial assistance.

(2) When documentation is requested, it means letters, certifications, legal documents or other third-party documentation that provide evidence that the applicant meets the listed requirement. For example, to confirm Enterprise Zone (EZ) designations, applicants use various types of documents, such as letters from appropriate government bodies and copies of appropriate USDA Web pages. Leveraging documentation sometimes includes letters of commitment from other funding sources. In-kind matches must be items essential to the project and documentation from the donor must demonstrate the relationship of each item to the project's function. Evidence of legal existence is sometimes proven by submitting articles of incorporation. None of the foregoing examples is intended to limit the types of documentation that may be submitted to fulfill a requirement. DLT Program regulations and the application guide provide specific guidance on each of the items in the table.

b. The DLT application guide and ancillary materials provide all necessary forms and sample worksheets.

c. While the table in paragraph IV.C.1.f of this Notice includes all items of a completed application, USDA Rural Development may ask for additional or clarifying information for applications which, as submitted by the deadline, appear to clearly demonstrate that they meet eligibility requirements.

d. Submit the required application items in the order provided in the FY 2007 application guide. The FY 2007 application guide specifies the format and order of all required items. Applications that are not assembled and tabbed in the order specified prevent timely determination of eligibility. Given the high volume of program interest, incorrectly assembled applications will be returned as ineligible.

e. *DUNS Number.* As required by the OMB, all applicants for grants must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying. The Standard Form 424 (SF–424) contains a field for you to use when supplying your DUNS number. Obtaining a DUNS number costs nothing and requires a short telephone call to Dun and Bradstreet. Please see *http://www.grants.gov/RequestaDUNS* for more information on how to obtain a DUNS number or how to verify your organization's number.

f. Compliance with other Federal statutes. The applicant must provide evidence of compliance with other federal statutes and regulations, including, but not limited to the following:

(i) 7 CFR part 15, subpart A—Nondiscrimination in Federally Assisted Programs of the Department of Agriculture—Effectuation of Title VI of the Civil Rights Act of 1964.

(ii) 7 CFR part 3015—Uniform Federal Assistance Regulations.

(iii) 7 CFR part 3017—Governmentwide Debarment and Suspension (Non-procurement).

(iv) 7 CFR part 3018—New Restrictions on Lobbying.

(v) 7 CFR part 3021—Governmentwide Requirements for Drug-Free Workplace

g. Table of Required Elements of a Completed Grant Application.

Application item	REQUIRED items	
	Grants (7 CFR 1703.125 and CFR 1703.126)	Comment
SF–424 (Application for Federal Assistance form)	Yes	*Completely* filled out.
Executive Summary	Yes	Narrative.
Objective Scoring Worksheet	Yes	RUS worksheet.
Rural Calculation Table	Yes	RUS worksheet.
National School Lunch Program Determination	Yes	RUS worksheet; must include source documentation.
EZ/EC or Champion Communities designation	Yes	Documentation.
Documented Need for Services/Benefits Derived from Services	Yes	Narrative & documentation, if necessary.
Innovativeness of the Project	Yes	Narrative & documentation.
Budget	Yes	Table or spreadsheet; Recommend using the RUS format.
Leveraging Evidence and Funding Commitments from All Sources	Yes	RUS worksheet and source documentation.
Financial Information/Sustainability	Yes	Narrative.
System/Project Cost Effectiveness	Yes	Narrative & documentation.
Telecommunications System Plan	Yes	Narrative & documentation; maps or diagrams, if appropriate.
Proposed Scope of Work	Yes	Narrative or other appropriate format.
Statement of Experience	Yes	Narrative 3-page, single-spaced limit.
Consultation with the USDA State Director, Rural Development	Yes	Documentation.
Application conforms with State Strategic Plan per USDA State Director, Rural Development, (if plan exists).	Yes	Documentation.
Certifications		
Equal Opportunity and Nondiscrimination	Yes	Recommend using the RUS sample form.

Application item	REQUIRED items	
	Grants (7 CFR 1703.125 and CFR 1703.126)	Comment
Architectural Barriers	Yes	Recommend using the RUS sample form.
Flood Hazard Area Precautions	Yes	Recommend using the RUS sample form.
Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970	Yes	Recommend using the RUS sample form.
Drug-Free Workplace	Yes	Recommend using the RUS sample form.
Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions.	Yes	Recommend using the RUS sample form.
Lobbying for Contracts, Grants, Loans, and Cooperative Agreements	Yes	Recommend using the RUS sample form.
Non Duplication of Services	Yes	Recommend using the RUS sample form.
Environmental Impact/Historic Preservation Certification	Yes	Recommend using the RUS sample form.
Federal Obligations on Delinquent Debt	Yes	Recommend using the RUS sample form.
Evidence of Legal Authority to Contract with the Government (documentation)	Yes	Recommend using the RUS sample form.
Evidence of Legal Existence (documentation)	Yes	Recommend using the RUS sample form.
Supplemental Information (if any)	Optional	Narrative, documentation or other appropriate format.

2. For combination loan-grant and loan applications:

a. Detailed information on each item in the table in paragraph IV.C.2.f. of this Notice can be found in the sections of the DLT Program regulation listed in the table, and the DLT application guide. Applicants are strongly encouraged to read and apply both the regulation and the application guide.

(1) When the table refers to a narrative, it means a written statement, description or other written material prepared by the applicant, for which no form exists. USDA Rural Development recognizes that each project is unique and requests narratives to allow applicants to explain their request for financial assistance.

(2) When documentation is requested, it means letters, certifications, legal documents or other third party documentation that provide evidence that the applicant meets the listed requirement. For example, evidence of legal existence is sometimes proven by applicants who submit articles of incorporation. This example is not intended to limit the types of documentation that may be submitted to fulfill a requirement. DLT program regulations and the application guide provide specific guidance on each of the items in the table.

b. The DLT application guide and ancillary materials provide all necessary forms and sample worksheets.

c. While the table in paragraph IV.C.2.f. of this Notice includes all items of a completed application for each program, USDA Rural Development may ask for additional or clarifying information.

d. Submit the required application items in the listed order.

e. DUNS Number. As required by the OMB, all applicants for combination loan-grants must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying. The Standard Form 424 (SF–424) contains a field for you to use when supplying your DUNS number. Obtaining a DUNS number costs nothing and requires a short telephone call to Dun and Bradstreet. Please see the DLT Web site or Grants.gov for more information on how to obtain a DUNS number or how to verify your organization's number.

f. Table of required items in a combination loan-grant or loan application:

Application item	REQUIRED items	
	Combination loan/grants (7 CFR 1703.134)	Loans
Completed SF–424 (Application for Federal Assistance form)	Yes	Yes.
Executive Summary (narrative)	Yes	Yes.
Rural Calculation Table	Yes	Yes.
Budget (table or other appropriate format)	Yes	Yes.
Financial Information/Sustainability (narrative)	Yes	Yes.
Pro Forma Financial Data (documentation)	Yes	Yes.
Ability to execute a note with maturity greater than 1 year (documentation)	Yes	Yes.
Budget	Yes	Yes.
Revenue/expense reports and balance sheet (documentation: table or other appropriate format	Yes \1\	Yes \1\.
Balance sheet (table or other appropriate format) for a partnership, corporation, company, other entity; or consortia of such entities (documentation)..	Yes\2\	Yes \2\.
Property list (collateral/adequate security (documentation))	Yes	Yes.

Application item	REQUIRED items	
	Combination loan/grants (7 CFR 1703.134)	Loans
Depreciation Schedule	Yes	Yes.
Revenue source(s) for each hub and end-user site (documentation).	Yes	Yes.
Economic analysis of rates—if applicant proposes to provide services for another entity	Yes	Yes.
Telecommunications System Plan (narrative & documentation; maps or diagrams, if appropriate	Yes	Yes.
Scope of Work (narrative or other appropriate format)	Yes	Yes.
Statement of Experience (narrative 3-page, single-spaced limit.	Yes	Yes.
Certifications:		
*Equal Opportunity and Nondiscrimination	All Yes	All Yes.
*Architectural Barriers		
*Flood Hazard Area Precautions		
*Uniform Relocation Assistance and Real Property Acquisitions Policies Act of 1970		
*Drug Free Workplace		
*Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions		
*Lobbying for Contracts, Grants, Loans, and Cooperative Agreements		
*Non-Duplication of Services		
*Environmental Impact/Historic Preservation Certification		
*Environmental Impact/Historic Preservation Questionnaire		
*Federal Obligations on Delinquent Debt		
Evidence of Legal Authority to Contract with the Government (documentation)	Yes	Yes.
Evidence of Legal Existance (documentation).	Yes	Yes.
Supplemental Information (if any) (narrative, documentation or other appropriate format.)	Optional	Optional.

D. How many copies of an application are required?

1. Applications submitted on paper.

a. Submit the original application and two (2) copies to USDA Rural Development.

b. Submit one (1) additional copy to the state government single point of contact (SPOC) (if one has been designated) at the same time as you submit the application to the Agency. See *http://www.whitehouse.gov/omb/grants/spoc.html* for an updated listing of State government single points of contact.

2. Electronically submitted applications. USDA Rural Development cannot accept loan applications electronically at this time. Only grants and combination loan-grants may be requested electronically.

a. The additional paper copies are not necessary if you submit the application electronically through Grants.gov.

b. Submit one (1) copy to the state government single point of contact (if one has been designated) at the same time as you submit the application to the Agency. See *http://www.whitehouse.gov/omb/grants/spoc.html* for an updated listing of State government single points of contact.

E. How and Where To Submit an Application

Grant and combination loan-grant applications may be submitted on paper or electronically.

1. Submitting applications on paper.

a. Address paper applications to the Telecommunications Program, USDA Rural Development, United States Department of Agriculture, 1400 Independence Ave., SW., Room 2845, STOP 1550, Washington, DC 20250–1550. Applications should be marked ''*Attention:* Director, Advanced Services Division.''

b. Paper grant applications must show proof of mailing or shipping by the deadline consisting of one of the following:

(i) A legibly dated U.S. Postal Service (USPS) postmark;

(ii) A legible mail receipt with the date of mailing stamped by the USPS; or

(iii) A dated shipping label, invoice, or receipt from a commercial carrier.

c. Due to screening procedures at the Department of Agriculture, packages arriving via regular mail through the USPS are irradiated, which can damage the contents and delay delivery to the DLT Program. USDA Rural Development encourages applicants to consider the impact of this procedure in selecting their application delivery method.

2. Electronically submitted applications.

a. Applications will not be accepted via fax or electronic mail.

b. Electronic applications for grants and combination loan-grants will be accepted if submitted through the Federal government's Grants.gov initiative at *http://www.grants.gov.*

c. How to use Grants.gov.

(i) Grants.gov contains full instructions on all required passwords, credentialing and software.

(ii) Central Contractor Registry. Submitting an application through Grants.gov requires that you list your organization in the Central Contractor Registry (CCR). Setting up a CCR listing takes up to five business days, so the Agency strongly recommends that you obtain your organization's DUNS number and CCR listing well in advance of the deadline specified in this notice.

(iii) Credentialing and authorization of applicants. Grants.gov will also require some credentialing and online authentication procedures. These procedures may take several business days to complete, further emphasizing the need for early action by applicants to complete the sign-up, credentialing and authorization procedures at Grants.gov before you submit an application at that Web site.

(iv) Some or all of the CCR and Grants.gov registration, credentialing and authorizations require updates. If you have previously registered at Grants.gov to submit applications electronically, please ensure that your registration, credentialing and authorizations are up to date well in advance of the grant application deadline.

d. USDA Rural Development encourages applicants who wish to apply through Grants.gov to submit their applications in advance of the deadlines.

e. If a system problem occurs or you have technical difficulties with an electronic application, please use the customer support resources available at the Grants.gov Web site.

F. Deadlines

1. Paper grant applications must be postmarked and mailed, shipped, or sent overnight no later than June 11, 2007 to be eligible for FY 2007 grant funding. Late applications, applications which do not include proof of mailing or shipping as described in paragraph IV.E.b., and incomplete applications are not eligible for FY 2007 grant funding.

2. Electronic grant applications must be received by June 11, 2007 to be eligible for FY 2007 funding. Late or incomplete applications will not be eligible for FY 2007 grant funding.

G. *Intergovernmental Review*. The DLT grant program is subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' As stated in paragraph IV.D.1. of this Notice, a copy of a DLT grant application must be submitted to the state single point of contact if one has been designated. Please see *http://www.whitehouse.gov/omb/grants/spoc.html* to determine whether your state has a single point of contact.

H. Funding Restrictions

1. Eligible purposes.

a. For grants, end-user sites may receive financial assistance; hub sites (rural or non-rural) may also receive financial assistance if they are necessary to provide DLT services to end-user sites. Please see 7 CFR 1703.101(h).

b. To fulfill the policy goals laid out for the DLT Program in 7 CFR 1703.101, the following table lists purposes for financial assistance and whether each purpose is generally considered to be eligible for the form of financial assistance. Please consult the FY 2007 application guide and the regulations (7 CFR 1703.102 for definitions, in combination with the portions of the regulation cited in the table) for detailed requirements for the items in the table. USDA Rural Development *strongly* recommends that applicants exclude ineligible items from the grant and match portions of grant application budgets. However, some items ineligible for funding or matching contributions may be vital to the project. USDA Rural Development encourages applicants to document those costs in the application's budget. Please see the FY 2007 application guide for a recommended budget format, and detailed budget compilation instructions.

	Grants	Combination loan-grants	Loans
Lease or purchase of eligible DLT equipment and facilities.	Yes, equip. only	Yes.	
Acquire instructional programming	Yes	Yes.	
Technical assistance, develop instructional programming, engineering or environmental studies.	Yes, up to 10% of the grant.	Yes, up to 10% of the financial assistance.	
Medical or education equipment or facilities necessary to the project.	Yes.		
Vehicles using distance learning or telemedicine technology to deliver services.	No	Yes.	
Teacher-student links located at the same facility	No	Yes, if part of a broader DLT network that meets other eligible program purposes.	
Links between medical professionals located at the same facility.	No	Yes, if part of a broader DLT network that meets other eligible program purposes.	
Site development or building alteration	No	Yes, if the activity meets other program purposes.	
Land of building purchase	No	Yes, if the activity meets other program purposes.	
Building Construction	No	Yes, if the activity meets other program purposes.	
Acquiring telecommunications transmission facilities	No	Yes, if other telecommunications carriers will not install in a reasonable time period and at an economically viable cost to the project.	
Salaries, wages, benefits for medical or educational personnel.	No.		
Salaries or administrative expenses of applicant or project.	No.		
Recurring project costs or operating expenses	No (equipment & facility leases are not recurring project costs)		Yes, for the first two years after approval (equipment & facility leases are not recurring project costs).
Equipment to be owned by the LEC or other telecommunications service provider, if the provider is the applicant.	No	Yes.	
Duplicative distance learning or telemedicine services	No.		
Any project that for its success, depends on additional DLT financial assistance or other financial assistance that is not assured.	No.		
Application Preparation Costs	No.		
Other project costs not in regulation	No		Yes, for the first two years of operation.

	Grants	Combination loan-grants	Loans
Cost of facilities providing distance learning broadcasting (amount).	No		Yes, financial assistance directly proportional to the distance learning portion of use.
Reimburse applicants of others for costs incurred prior to USDA RURAL DEVELOPMENT receipt of completed application.	No.		

c. *Discounts.* The DLT Program regulation has long stated that manufacturers' and service providers' discounts are not eligible matches. The Agency will not consider as eligible any proposed match from a vendor, manufacturer, or service provider whose products or services will be used in the DLT project as described in the application. In recent years, the Agency has noted a trend of vendors, manufacturers and other service providers offering their own products and services as in-kind matches for a project when their products or services will also be purchased with either grant or cash match funds for that project. Such activity is a discount and is therefore not an eligible match. Similarly, if a vendor, manufacturer or other service provider proposes a cash match (or any in-kind match) when their products or services will be purchased with grant or match funds, such activity is a discount and is not an eligible match. The Agency actively discourages such matching proposals and will adjust budgets as necessary to remove any such matches, which may reduce an application's score or result in the application's ineligibility due to insufficient match.

d. For special ratio combination loan-grant applications, the only eligible purpose is for the conversion to electronic medical records systems, or for the extension of an existing electronic medical records system to a new rural location.

2. *Eligible Equipment & Facilities.* Please see 7 CFR 1703.102 for definitions of eligible equipment, eligible facilities and telecommunications transmission facilities as used in the table above. In addition, the FY 2007 application guide supplies a wealth of information and examples of eligible and ineligible items.

3. *Apportioning budget items.* Many DLT applications propose to use items for a blend of specific DLT project purposes and other purposes. USDA Rural Development will now fund such items, if the applicants attribute the proportion (by percentage of use) of the costs of each item to the project's DLT purpose or to other purposes to enable consideration for a grant of the portion of the item that is for DLT usage. See the FY 2007 application guide for detailed information on how to apportion use and apportioning illustrations.

V. Application Review Information

A. Special Considerations or Preferences

1. American Samoa, Guam, Virgin Islands, and Northern Mariana Islands applications are exempt from the matching requirement up to a match amount of $200,000 (see 48 U.S.C. 1469a; 91 Stat. 1164).

2. 7 CFR 1703.112 directs that USDA Rural Development Telecommunications Borrowers receive expedited consideration of a loan application or advance under the Rural Electrification Act of 1936 (7 U.S.C. 901–950aa, *et seq.*) if the loan funds in question are to be used in conjunction with a DLT grant, loan, or combination loan-grant (See 7 CFR 1737 for loans and 7 CFR 1744 for advances).

B. Criteria

1. Grant application scoring criteria (total possible points: 235). See 7 CFR 1703.125 for the items that will be reviewed during scoring, and 7 CFR 1703.126 for scoring criteria.

2. Grant applications are scored competitively subject to the criteria listed below.

a. Need for services proposed in the application, and the benefits that will be derived if the application receives a grant (up to 55 points).

(i) Up to 45 of the 55 possible points under this criterion are available to all applicants. Points are awarded based on the required narrative crafted by the applicant. USDA Rural Development encourages applicants to carefully read the cited portions of the Program regulation and the FY 2007 application guide for full discussions of this criterion.

(ii) Up to 10 of the possible 55 possible points are to recognize economic need not reflected in the project's National School Lunch Program (NSLP) score, and can be earned only by applications whose overall NSLP eligibility is less than 50%. To be eligible to receive points under this, the application must include an affirmative request for consideration of the possible 10 points, and compelling documentation of reasons why the NSLP eligibility percentage does not represent the economic need of the proposed project beneficiaries.

b. Rurality of the proposed service area (up to 45 points).

c. Percentage of students eligible for the NSLP in the proposed service area (objectively demonstrates economic need of the area) (up to 35 points).

d. Leveraging resources above the required matching level (up to 35 points). Please see paragraph III.B of this Notice for a brief explanation of matching contributions.

e. Level of innovation demonstrated by the project (up to 15 points).

f. System cost-effectiveness (up to 35 points).

g. Project overlap with Empowerment Zone, Enterprise Communities or Champion Communities designations (up to 15 points).

C. Grant Review Standards

1. In addition to the scoring criteria that rank applications against each other, USDA Rural Development evaluates grant applications for possible awards on the following items, according to 7 CFR 1703.127:

a. Financial feasibility.

b. Technical considerations. If the application contains flaws that would prevent the successful implementation, operation or sustainability of a project, USDA Rural Development will not award a grant.

c. Other aspects of proposals that contain inadequacies that would undermine the ability of the project to comply with the policies of the DLT Program.

2. Applications which do not include all items that determine project eligibility and applicant eligibility by the application deadline will be returned as ineligible. Applications that do not include all items necessary for scoring will be scored as is. Please see the FY 2007 application guide for a full

discussion of each required item and for samples and illustrations. The USDA Rural Development will not request missing items that affect the application's score.

3. The FY 2007 grant application guide specifies the format and order of all required items. Applications that are not assembled and tabbed in the order specified. Incorrectly assembled applications will be returned as ineligible.

4. Most DLT grant projects contain numerous project sites. USDA Rural Development requires that site information be consistent throughout an application. Sites must be referred to by the same designation throughout all parts of an application. USDA Rural Development has provided a site worksheet that requests the necessary information, and can be used as a guide by applicants. USDA Rural Development strongly recommends that applicants complete the site worksheet, listing all requested information for each site. Applications without consistent site information will be returned as ineligible.

5. DLT grant applications which have non-fixed end-user sites, such as ambulance and home health care services, are now scored using a simplified scoring method that finds the relative rurality of the applicant's service area. See the FY 2007 application guide for specific guidance on this method of scoring. When an application contains non-fixed sites, it must be scored using the non-fixed site scoring method.

D. Selection Process

1. Grants. Applications are ranked by final score, and by application purpose (education or medical). USDA Rural Development selects applications based on those rankings, subject to the availability of funds. USDA Rural Development may allocate grant awards between medical and educational purposes, but is not required to do so. In addition, USDA Rural Development has the authority to limit the number of applications selected in any one state, or for one project, during a fiscal year. See 7 CFR 1703.127.

2. Combination loan-grants and loans.

a. Combination loan-grant applications and loan applications are evaluated on the basis of technical, financial, economic and other criteria.

b. USDA Rural Development evaluates applications' financial feasibility using the following information. Please see paragraph IV.C.2. of this Notice for the items that constitute a completed combination loan-grant or loan application. Also, see 7 CFR part 1703 subpart F for combination loan-grants and 7 CFR part 1703 subpart G for loans:

(1) Applicant's financial ability to complete the project;

(2) Project feasibility;

(3) Applicant's financial information;

(4) Project sustainability;

(5) Ability to repay the loan portion of a combination loan-grant, including revenue sources;

(6) Collateral for which the applicant has perfected a security interest; and

(7) Adequate security for a loan or the loan portion of a combination loan-grant.

(c) USDA Rural Development also evaluates the following project and application characteristics:

(1) Services to be provided by the project.

(2) Project cost.

(3) Project design.

(4) Rurality of the proposed service area. Please see paragraph III.B.4. of this Notice for information on determining rurality.

(5) Other characteristics.

d. Selection process. Based on the review standards listed above and in the DLT Program regulation, USDA Rural Development will process successful combination loan-grant and loan applications on a first-in, first-out basis, dependent upon the availability of funds. Please see 7 CFR 1703.135 for combination loan-grant application processing and selection; and 7 CFR 1703.145 for loan application processing and selection.

VI. Award Administration Information

A. Award Notices

USDA Rural Development generally notifies applicants whose projects are selected for awards by faxing an award letter. USDA Rural Development follows the award letter with an agreement that contains all the terms and conditions for the grant, combination loan-grant or loan. USDA Rural Development recognizes that each funded project is unique, and therefore may attach conditions to different projects' award documents. An applicant must execute and return the agreement, accompanied by any additional items required by the agreement, within the number of days shown in the selection notice letter.

B. Administrative and National Policy Requirements

The items listed in Section IV of this notice, and the DLT Program regulation, FY 2007 application guide and accompanying materials implement the appropriate administrative and national policy requirements.

C. Reporting

1. *Performance reporting.* All recipients of DLT financial assistance must provide annual performance activity reports to USDA Rural Development until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project in meeting DLT Program objectives. See 7 CFR 1703.107.

2. *Financial reporting.* All recipients of DLT financial assistance must provide an annual audit, beginning with the first year a portion of the financial assistance is expended. Audits are governed by United States Department of Agriculture audit regulations. Please see 7 CFR 1703.108.

3. *Record Keeping and Accounting* The loan, or grant contract will contain provisions relating to record keeping and accounting requirements.

VII. Agency Contacts

A. *Web site: http://www.usda.gov/rus/telecom/dlt/dlt.htm.* The DLT Web site maintains up-to-date resources and contact information for DLT programs.

B. *Phone:* 202–720–0413.

C. *Fax:* 202–720–1051.

D. *E-mail: dltinfo@usda.gov.*

E. *Main point of contact:* Orren E. Cameron III, Director, Advanced Services Division, Telecommunications Program, Rural Development, United States Department of Agriculture.

Dated: March 13, 2007.

James M. Andrew,

Administrator, Rural Utilities Service.

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BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Announcement of Grant Application Deadlines and Funding Levels

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of funds availability.

SUMMARY: The United States Department of Agriculture (USDA) Rural Development administers loan and grant programs through the Rural Utilities Service. USDA Rural Development announces the Public Television Digital Transition Grant Program funding level and application window for fiscal year (FY) 2007.

DATES: You may submit completed applications for grants on paper or electronically according to the following deadlines:

• Paper copies must carry proof of shipping *no later* June 11, 2007 to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

• Electronic copies must be received by June 11, 2007 to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007[MPD1][MPD2] grant funding.

ADDRESSES: You may obtain the application guide and materials for the Public Television Station Digital Transition Grant Program via the Internet at the following Web site: *http://www.usda.gov/rus/telecom/*. You may also request the application guide and materials from USDA Rural Development by contacting the appropriate individual listed in Section VII of the **SUPPLEMENTARY INFORMATION** section of this notice.

• Submit completed paper applications for grants to the Telecommunications Program, United States Department of Agriculture Rural Development, 1400 Independence Ave., SW., Room 2844, STOP 1550, Washington, DC 20250–1550. Applications should be marked ''Attention: Director, Advanced Services Division.''

• Submit electronic grant applications to Grants.gov at the following web address: *http://www.grants.gov/* (Grants.gov), and follow the instructions you find on that Web site.

FOR FURTHER INFORMATION CONTACT: Orren E. Cameron III, Director, Advanced Services Division, Telecommunications Program, United States Department of Agriculture Rural Development, telephone: (202) 690–4493, fax: (202) 720–1051.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service (RUS).

Funding Opportunity Title: Public Television Station Digital Transition Grant Program.

Announcement Type: Initial announcement.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.861.

Dates: You may submit completed applications for grants on paper or electronically according to the following deadlines:

• Paper copies must carry proof of shipping no later than June 11, 2007, to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

• Electronic copies must be received by June 11, 2007, to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

Items in Supplementary Information

I. Funding Opportunity: Brief introduction to the Public Television Station Digital Transition Grant Program.

II. Award Information: Available funds and maximum amounts.

III. Eligibility Information: Who is eligible, what kinds of projects are eligible, what criteria determine basic eligibility.

IV. Application and Submission Information: Where to get application materials, what constitutes a completed application, how and where to submit applications, deadlines, items that are eligible.

V. Application Review Information: Considerations and preferences, scoring criteria, review standards, selection information.

VI. Award Administration Information: Award notice information, award recipient reporting requirements.

VII. Agency Contacts: Web, phone, fax, e-mail, contact name.

I. Funding Opportunity

As part of the nation's transition to digital television, the Federal Communications Commission (FCC) requires all television broadcasters to begin broadcasting using digital signals, and to cease analog broadcasting, by February 17, 2009. This exciting step forward in broadcast television will bring more lifelike picture and sound, and more viewing choice, into urban and suburban homes across America. For rural households, however, the digital transition could bring the end of over-the-air public television service. These rural households are the focus of the USDA Rural Development Public Television Station Digital Transition Grant Program.

As the nation's 355 public television stations have moved into this transition, the first priority has been to initiate digital broadcasting from their main transmitters. This was necessary in part to protect the broadcasters' FCC licenses, but it also has delivered the benefits of digital television to those within the new digital coverage areas. Some public television stations, especially those where funding of the transition has been limited, installed low-power transmitters which could not reach as far as the stations' analog broadcast coverage areas. The FCC allowed this in recognition of funding challenges, but it has had an unintended result. The apparent achievement of nearly industry-wide digital transmitter capability overstates public televisions' transition progress—and almost exclusively in terms of actual coverage of rural America. When those rural public television stations turn off their analog transmitters, their most distant rural viewers will not be able to receive the surviving digital transmitters' low-power signals.

A similar situation exists for rural areas served by translators. Translators predominately serve rural areas and communities that are isolated from a station's main transmitter by great distance or barriers such as mountains that block terrestrial broadcast signals. Transition strategies for translators have not been as aggressive as those for main transmitters.

Most applications to the Public Television Station Digital Transition Grant Program have sought assistance towards the goal of replicating analog coverage areas through transmitter and translator transitions, and in FY 2006 applications for power upgrades increased in number. The Public Television Station Digital Transition Grant Program can fund program management and creation equipment, but for reasons involving funding, many rural public television stations have not turned their attention to these needs. Some stations may not achieve full analog parity in program management and creation until after the February 2009 deadline. Continuation of reliable public television service to all current patrons understandably is still the focus for many broadcasters.

It is important for public television stations to be able to tailor their programs and services (e.g., education services, public health, homeland security, and local culture) to the needs of their rural constituents. If public television programming is lost, many school systems may be left without educational programming they count on for curriculum compliance.

This notice has been formatted to conform to a policy directive issued by the Office of Federal Financial Management (OFFM) of the Office of Management and Budget (OMB), published in the **Federal Register** on June 23, 2003, (68 FR 37370). This Notice does not change the Public Television Station Digital Transition Grant Program regulation (7 CFR part 1740).

II. Award Information

A. Available Funds

1. *General.* The Administrator has determined that the following amounts are available for grants in FY 2007 under 7 CFR 1740.1.

2. *Grants.*

a. $4,950,000 is available for grants from FY 2007. Under 7 CFR 1740.2, the

maximum amount for grants under this program is $1 million per applicant.

b. Assistance instrument: Grant documents appropriate to the project will be executed with successful applicants prior to any advance of funds.

B. Public Television Station Digital Transition grants cannot be renewed

Award documents specify the term of each award, and due to uncertainties in regulatory approvals of digital television broadcast facilities, the Agency will extend the period during which grant funding is available upon request.

III. Eligibility Information

A. Who is eligible for grants? (See 7 CFR 1740.3.)

1. Public television stations which serve rural areas are eligible for Public Television Station Digital Transition Grants. A public television station is a noncommercial educational television broadcast station that is qualified for Community Service Grants by the Corporation for Public Broadcasting under section 396(k) of the Communications Act of 1934.

2. Individuals are not eligible for Public Television Station Digital Transition Grant Program financial assistance directly.

B. What are the basic eligibility requirements for a project?

1. Grants shall be made to perform digital transitions of television broadcasting serving rural areas. Grant funds may be used to acquire, lease, and/or install facilities and software necessary to the digital transition. Specific purposes include:

a. Digital transmitters, translators, and repeaters, including all facilities required to initiate DTV broadcasting. All broadcast facilities acquired with grant funds shall be capable of delivering DTV programming and HDTV programming, at both the interim and final channel and power authorizations. There is no limit to the number of transmitters or translators that may be included in an application;

b. Power upgrades of existing DTV transmitter equipment, including replacement of existing low-power digital transmitters with digital transmitters capable of delivering the final authorized power level;

c. Studio-to-transmitter links;

d. Equipment to allow local control over digital content and programming, including master control equipment;

e. Digital program production equipment, including cameras, editing, mixing and storage equipment;

f. Multicasting and datacasting equipment;

g. Cost of the lease of facilities, if any, for up to three years; and,

h. Associated engineering and environmental studies necessary to implementation.

2. Matching contributions: There is no requirement for matching funds in this program (see 7 CFR 1740.5).

3. To be eligible for a grant, the Project must not (see 7 CFR 1740.7):

a. Include funding for ongoing operations or for facilities that will not be owned by the applicant, except for leased facilities as provided above;

b. Include costs of salaries, wages, and employee benefits of public television station personnel unless they are for construction or installation of eligible facilities;

c. Have been funded by any other source;

d. Include items bought or built prior to the application deadline specified in this Notice of Funds Availability.

C. See paragraph IV.B of this Notice for a discussion of the items that make up a completed application. You may also refer to 7 CFR 1740.9 for completed grant application items.

IV. Application and Submission Information

A. Where to get application information. The application guide, copies of necessary forms and samples, and the Public Television Station Digital Transition Grant Program regulation are available from these sources:

1. The Internet: *http://www.usda.gov/rus/telecom/*, or *http://www.grants.gov.*

2. The USDA Rural Development Advanced Services Division, for paper copies of these materials:

(202) 690–4493.

B. What constitutes a completed application?

1. Detailed information on each item required can be found in the Public Television Station Digital Transition Grant Program regulation and application guide. Applicants must read and apply both the regulation and the application guide. This Notice does not change the requirements for a completed application specified in the program regulation. The program regulation and application guide provide specific guidance on each of the items listed and the application guide provides all necessary forms and sample worksheets.

2. A completed application must include the following documentation, studies, reports and information in form satisfactory to USDA Rural Development. Applications should be prepared in conformance with the provisions in 7 CFR part 1740, subpart A, and applicable USDA regulations including 7 CFR parts 3015, 3016, and 3019. Applicants must use the application guide for this program containing instructions and all necessary forms, as well as other important information, in preparing their application. Completed applications must include the following:

a. An application for federal assistance, Standard Form 424.

b. An executive summary, not to exceed two pages, describing the public television station, its service area and offerings, its current digital transition status, and the proposed project.

c. Evidence of the applicant's eligibility to apply under this Notice, proving that the applicant is a Public Television Station as defined in this Notice, and that it is required by the FCC to perform the digital transition.

d. A spreadsheet showing the total project cost, with a breakdown of items sufficient to enable USDA Rural Development to determine individual item eligibility.

e. A coverage contour map showing the digital television coverage area of the application project. This map must show the counties (or county) comprising the Core Coverage Area, as defined in 7 CFR 1740.2, by shading and by name. Partial counties included in the applicant's Core Coverage Area must be identified as partial and must contain an attachment with the applicant's estimate of the percentage that its coverage contour comprises of the total area of the county (total area is available from American Factfinder, referenced above). If the application is for a translator, the coverage area may be estimated by the applicant through computer modeling or some other reasonable method, and this estimate is subject to acceptance by USDA Rural Development.

f. The applicant's own calculation of its Rurality score, as calculated pursuant to 7 CFR 1740.8(c), supported by a worksheet showing the population of its Core Coverage Area, and the urban and rural populations within the Core Coverage Area. The data source for the urban and rural components of that population must be identified. If the application includes computations made by a consultant or other organization outside the public television station, the application shall state the details of that collaboration.

g. The applicant's own calculation of its Economic Need score, as calculated pursuant to 7 CFR 1740.8(d), supported by a worksheet showing the National School Lunch Program eligibility levels

for all school districts within the Core Coverage Area and averaging these eligibility percentages. The application must include a statement from the state or local organization that administers the NSLP program certifying the school district scores used in the computations.

h. If applicable, a presentation not to exceed five pages demonstrating the Critical Need for the project, as outlined in 7 CFR 1740.8(e).

i. Evidence that the FCC has authorized the initiation of digital broadcasting at the project sites. In the event that an FCC construction permit has not been issued for one or more sites, USDA Rural Development may include those sites in the grant, and make advance of funds for that site conditional upon the submission of a construction permit.

j. Compliance with other Federal statutes. The applicant must provide evidence or certification that it is in compliance with all applicable Federal statutes and regulations, including, but not limited to the following:

(1) Executive Order (E.O.) 11246, Equal Employment Opportunity, as amended by E.O. 11375 and as supplemented by regulations contained in 41 CFR part 60;

(2) Architectural barriers;

(3) Flood hazard area precautions;

(4) 7 CFR part 3015—Uniform Federal Assistance Regulations.

(5) Assistance and Real Property Acquisition Policies Act of 1970;

(6) Drug-Free Workplace Act of 1998 (41 U.S.C. 701);

(7) E.O.s 12549 and 12689, Debarment and Suspension; and

(8) Byrd Anti-Lobbying Amendment (31 U.S.C. 1352).

k. Environmental impact and historic preservation. The applicant must provide details of the digital transition's impact on the environment and historic preservation, and comply with 7 CFR part 1794, which contains the Agency's policies and procedures for implementing a variety of federal statutes, regulations, and executive orders generally pertaining to the protection of the quality of the human environment. This must be contained in a separate section entitled ''Environmental Impact of the Digital Transition,'' and must include the Environmental Questionnaire/ Certification, available from USDA Rural Development, describing the impact of its digital transition. Submission of the Environmental Questionnaire/Certification alone does not constitute compliance with 7 CFR part 1794.

3. DUNS Number. As required by the OMB, all applicants for grants must now supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying. The Standard Form 424 (SF–424) contains a field for you to use when supplying your DUNS number. Obtaining a DUNS number costs nothing and requires a short telephone call to Dun and Bradstreet. Please see the Public Television Station Digital Transmitter Grant Program Web site or Grants.gov for more information on how to obtain a DUNS number or how to verify your organization's number.

C. How many copies of an application are required?

1. Applications submitted on paper: Submit the original application and two (2) copies to USDA Rural Development.

2. Electronically submitted applications: The additional paper copies for USDA Rural Development are not necessary if you submit the application electronically through Grants.gov.

D. How and where to submit an application. Grant applications may be submitted on paper or electronically.

1. Submitting applications on paper.

a. Address paper applications for grants to the Telecommunications Program, USDA Rural Development, 1400 Independence Ave., SW., Room 2844, STOP 1550, Washington, DC 20250–1550. Applications should be marked ''Attention: Director, Advanced Services Division.''

b. Paper applications must show proof of mailing or shipping consisting of one of the following:

(i) A legibly dated postmark applied by the U. S. Postal Service;

(ii) A legible mail receipt with the date of mailing stamped by the USPS; or

(iii) A dated shipping label, invoice, or receipt from a commercial carrier.

c. Non-USPS-applied postage dating, *i.e.* dated postage meter stamps, do not constitute proof of the date of mailing.

d. Due to screening procedures at the Department of Agriculture, packages arriving via the USPS are irradiated, which can damage the contents. USDA Rural Development encourages applicants to consider the impact of this procedure in selecting their application delivery method.

2. Electronically submitted applications.

a. Applications will not be accepted via facsimile machine transmission or electronic mail.

b. Electronic applications for grants will be accepted if submitted through the Federal government's Grants.gov initiative at *http://www.grants.gov*.

c. How to use Grants.gov:

(i) Navigate your Web browser to *http://www.grants.gov*.

(ii) Follow the instructions on that Web site to find grant information.

(iii) Download a copy of the application package.

(iv) Complete the package off-line.

(v) Upload and submit the application via the Grants.gov Web site.

d. Grants.gov contains full instructions on all required passwords, credentialing and software.

e. USDA Rural Development encourages applicants who wish to apply through Grants.gov to submit their applications in advance of the deadline. Difficulties encountered by applicants filing through Grants.gov will not justify filing deadline extensions.

f. If a system problem occurs or you have technical difficulties with an electronic application, please use the customer support resources available at the Grants.gov Web site.

E. Deadlines.

1. Paper applications must be postmarked and mailed, shipped, or sent overnight no later than June 11, 2007 to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

2. Electronic grant applications must be received by June 11, 2007 to be eligible for FY 2007 funding. Late applications are not eligible for FY 2007 grant funding.

V. Application Review Information

A. Criteria

1. Grant applications are scored competitively and subject to the criteria listed below.

2. Grant application scoring criteria are detailed in 7 CFR 1740.8. There are 100 points available, broken down as follows:

a. The Rurality of the Project (up to 50 points);

b. The Economic Need of the Project's Service Area (up to 25 points); and

c. The Critical Need for the project, and of the applicant, including the benefits derived from the proposed service (up to 25 points).

B. Review Standards

1. All applications for grants must be delivered to USDA Rural Development at the address and by the date specified in this notice to be eligible for funding. USDA Rural Development will review each application for conformance with the provisions of this part. USDA Rural Development may contact the applicant for additional information or clarification.

2. Incomplete applications as of the deadline for submission will not be considered. If an application is

determined to be incomplete, the applicant will be notified in writing and the application will be returned with no further action.

3. Applications conforming with this part will be evaluated competitively by a panel of USDA Rural Development employees selected by the Administrator of RUS, and will be awarded points as described in the scoring criteria in 7 CFR 1740.8. Applications will be ranked and grants awarded in rank order until all grant funds are expended.

4. Regardless of the score an application receives, if USDA Rural Development determines that the Project is technically or financially infeasible, USDA Rural Development will notify the applicant, in writing, and the application will be returned with no further action.

C. Scoring Guidelines

1. The applicant's self scores in Rurality and Economic Need will be checked and, if necessary, corrected by USDA Rural Development.

2. The Critical Need score will be determined by USDA Rural Development based on information presented in the application. This score is intended to capture from the rural public's standpoint the necessity and usefulness of the proposed project. This scoring category will also recognize that some transition purchases are more essential than others, so that applications for first digital transmitter capability, and translators[ec3] and transmitter power upgrades that extend coverage into rural-only areas, will receive scoring advantages. Master control facilities which tailor programming to local needs will also be recognized in this category.

VI. Award Administration Information

A. Award Notices

USDA Rural Development recognizes that each funded project is unique, and therefore may attach conditions to different projects' award documents. The Agency generally notifies applicants whose projects are selected for awards by faxing an award letter. USDA Rural Development follows the award letter with a grant agreement that contains all the terms and conditions for the grant. An applicant must execute and return the grant agreement, accompanied by any additional items required by the grant agreement.

B. *Administrative and National Policy Requirements.*

The items listed in the program regulation at 7 CFR 1740.9(j) implement the appropriate administrative and national policy requirements.

C. Performance Reporting

All recipients of Public Television Station Digital Transition Grant Program financial assistance must provide annual performance activity reports to USDA Rural Development until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project.

VII. Agency Contacts

A. Web site: *http://www.usda.gov/rus/.* The Web site maintains up-to-date resources and contact information for the Public Television Station Digital Transition Grant Program.

B. Phone: 202–690–4493.

C. Fax: 202–720–1051.

D. Main point of contact: Orren E. Cameron III, Director, Advanced Services Division, Telecommunications Program, USDA Rural Development.

Dated: March 19, 2007.

Curtis M. Anderson,

Acting Administrator, Rural Utilities Service.

[FR Doc. E7–6702 Filed 4–9–07; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Fisheries Certificates of Origin.

Form Number(s): NOAA 370.

OMB Approval Number: 0648–0335.

Type of Request: Regular submission.

Burden Hours: 3,667.

Number of Respondents: 350.

Average Hours Per Response: 20 minutes.

Needs and Uses: Due to the information required by the International Dolphin Conservation Program Act, amendment to the Marine Mammal Protection Act, is needed: To document the dolphin-safe status of tuna import shipments; to verify that import shipments of fish were not harvested by large scale, high seas driftnets; and to verify that imported tuna was not harvested by an embargoed nation or one that is otherwise prohibited from exporting tuna to the United States. Forms are submitted by importers and processors.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

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 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 David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: April 4, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–6663 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Commercial Operator's Annual Report (COAR).

Form Number(s): None.

OMB Approval Number: 0648–0428.

Type of Request: Regular submission.

Burden Hours: 792.

Number of Respondents: 99.

Average Hours Per Response: Interim reports, 9 hours and 45 minutes; and final reports, 11 hours and 45 minutes.

Needs and Uses: The Commercial Operator's Annual Report (COAR) provides information on ex-vessel value (the total dollar value for fish in any product form of groundfish pounds before any deductions are made for goods and services, e.g., bait, ice, fuel, repairs, machinery replacement, etc., provided to groundfish harvesters. Includes price adjustments made in the current year to groundfish harvesters for landings made during the fishing year); and first wholesale value for statewide Alaska fish and shellfish products.

This information is used to analyze and measure the impact of proposed or

enacted management measures. The National Marine Fisheries Service requires owners of catcher/processors and motherships operating in the Exclusive Economic Zone off Alaska to complete the State of Alaska, Department of Fish and Game COAR.

Affected Public: Business or other for-profit organizations.

Frequency: Annually.

Respondent's Obligation: Mandatory.

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 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 David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: April 4, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–6664 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the emergency provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security (BIS).

Title: Voluntary Self-Disclosure of Antiboycott Violations.

Form Number(s): None.

OMB Approval Number: None.

Type of Request: Emergency submission.

Burden Hours: 1,280.

Number of Respondents: 10.

Average Hours Per Response: Regular companies, 10 hours; and very large companies, 600 hours.

Needs and Uses: To strengthen antiboycott enforcement efforts, BIS is proposing the addition of a new section, ''Voluntary Self-Disclosure of Antiboycott Violations,'' to the Export Administration Regulations (EAR). The information collection requirements are modeled after those in the existing self-disclosure collection, (1) General; (2) Initial Notification; (3) Narrative Account; (4) Supporting Documentation; (5) Certification; (6) Oral Presentations and (7) Where To Make Voluntary Self-Disclosure. The voluntary self-disclosures allow BIS to conduct investigations of the disclosed incidents faster than would be the case if BIS had to detect the violations without such disclosure.

Affected Public: Business or other for-profit organizations.

Frequency: Annually.

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 the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent by May 4, 2007 to David Rostker, OMB Desk Officer, FAX number (202) 395–7258 or via the Internet at *David_Rostker@omb.eop.gov*.

Dated: April 4, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–6665 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Report of Requests for Restrictive Trade Practice or Boycott—Single or Multiple Transactions

ACTION: Proposed Information Collection: Comment Request.

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: Written comments must be submitted on or before June 11, 2007.

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 Larry Hall, BIS ICB Liaison, Department of Commerce, Room 6622, 14th & Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

I. Abstract

The information obtained from this collection authorization is used to carefully and accurately monitor requests for participation in foreign boycotts against countries friendly to the U.S. which are received by U.S. persons. The information is also used to identify trends in such boycott activity and to assist in carrying out U.S. policy of opposition to such boycotts.

II. Method of Collection

Submitted on forms.

III. Data

OMB Number: 0694–0012.

Form Number: BIS 621–P; BXA 621–P; BIS 6051–P; BXA 6051–P; BIS–6051 P-a; and BXA–6051 P-a.

Type of Review: Regular submission.

Affected Public: Individuals or households; business or other for-profit organizations; and not-for-profit institutions.

Estimated Number of Respondents: 1,243.

Estimated Time Per Response: 61 to 91 minutes.

Estimated Total Annual Burden Hours: 1,371.

Estimated Total Annual Cost: $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. In addition, the public is encouraged to provide suggestions on how to reduce and/or consolidate the current frequency of reporting.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: April 4, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–6661 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Procedure for Voluntary Self-Disclosure of Violations of the Export Administration Regulations

ACTION: Proposed Information Collection; Comment Request.

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: Written comments must be submitted on or before June 11, 2007.

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 Larry Hall, BIS ICB Liaison, Department of Commerce, Room 6622, 14th & Constitution Avenue, NW., Washington, DC, 20230.

SUPPLEMENTARY INFORMATION:

I. Abstract

The information is needed to detect violations of the Export Administration Act and Regulations to determine if an investigation or prosecution is necessary and to reach settlement with violators. The respondents are likely to be export-related businesses.

II. Method of Collection

Submitted in written form.

III. Data

OMB Number: 0694–0058.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Individuals or households, business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 67.

Estimated Time Per Response: 10 hours.

Estimated Total Annual Burden Hours: 670.

Estimated Total Annual Cost: $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. In addition, the public is encouraged to provide suggestions on how to reduce and/or consolidate the current frequency of reporting.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: April 3, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–6662 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–401–806]

Stainless Steel Wire Rod from Sweden: Final Results of Antidumping Duty Administrative Review

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

SUMMARY: On October 6, 2006, the Department of Commerce published the preliminary results of the 2004–2005 administrative review of the antidumping duty order on stainless steel wire rod from Sweden. The review covers one manufacturer/exporter, Fagersta Stainless AB (''FSAB''). The period of review (''POR'') is September 1, 2004, through August 31, 2005.

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

EFFECTIVE DATE: April 10, 2007.

FOR FURTHER INFORMATION CONTACT: Brian C. Smith, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1766.

SUPPLEMENTARY INFORMATION:

Background

The review covers one manufacturer/exporter: Fagersta Stainless AB (''FSAB''). The period of review is September 1, 2004, through August 31, 2005.

On October 6, 2006, the Department of Commerce (''the Department'') published the preliminary results of this administrative review of the antidumping duty order on stainless steel wire rod from Sweden. *See Stainless Steel Wire Rod from Sweden: Preliminary Results of Antidumping Duty Administrative Review*, 71 FR 59082 (October 6, 2006) (''*Preliminary Results*''). We invited interested parties to comment on the preliminary results of review.[1]

FSAB filed its case brief on November 27, 2006, and the petitioners[2] filed their rebuttal brief on December 4, 2006. Per FSAB's November 3, 2006, request, we held a hearing on December 6, 2006.

On January 11, 2007, we extended the time limit for the final results in this review until April 4, 2007. *See Notice of Extension of Time Limit for Final Results of Antidumping Duty Administrative Review: Stainless Steel*

[1] In the Preliminary Results, we determined it appropriate to treat FSAB and its affiliates, AB Sandvik Materials Technology (''SMT'') and Kanthal AB (''Kanthal''), as one entity for margin calculation purposes because they met the regulatory criteria for collapsing affiliated producers. See April 13, 2006, Memorandum from the Team to The File, entitled ''Stainless Steel Wire Rod from Sweden: Whether to Collapse FSAB, SMT, and Kanthal.'' No party objected to this preliminary determination. Therefore, we have continued to treat these affiliated companies as one entity in the final results.

[2] The petitioners include the following companies: Carpenter Technology Corporation; Crucible Specialty Metals Division, Crucible Materials Corporation; and Electroalloy Corporation, a Division of G.O. Carlson, Inc.

Wire Rod from Sweden, 72 FR 2261 (January 18, 2007).

We have conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (''the Act'').

Scope of the Order

For purposes of this order, SSWR comprises products that are hot–rolled or hot–rolled annealed and/or pickled and/or descaled rounds, squares, octagons, hexagons or other shapes, in coils, that may also be coated with a lubricant containing copper, lime or oxalate. SSWR is made of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. These products are manufactured only by hot–rolling or hot–rolling annealing, and/or pickling and/or descaling, are normally sold in coiled form, and are of solid cross-section. The majority of SSWR sold in the United States is round in cross-sectional shape, annealed and pickled, and later cold–finished into stainless steel wire or small–diameter bar. The most common size for such products is 5.5 millimeters or 0.217 inches in diameter, which represents the smallest size that normally is produced on a rolling mill and is the size that most wire–drawing machines are set up to draw. The range of SSWR sizes normally sold in the United States is between 0.20 inches and 1.312 inches in diameter.

Certain stainless steel grades are excluded from the scope of the order. SF20T and K–M35FL are excluded. The following proprietary grades of Kanthal AB are also excluded: Kanthal A–1, Kanthal AF, Kanthal A, Kanthal D, Kanthal DT, Alkrothal 14, Alkrothal 720, and Nikrothal 40. The chemical makeup for the excluded grades is as follows:

SF20T

Carbon	0.05 max	Chromium	19.00/21.00
Manganese	2.00 max	Molybdenum	1.50/2.50
Phosphorous	0.05 max	Lead	added (0.10/0.30)
Sulfur	0.15 max	Tellurium	added (0.03 min)
Silicon	1.00 max		

K–M35FL

Carbon	0.015 max	Nickel	0.30 max
Silicon	0.70/1.00	Chromium	12.50/14.00
Manganese	0.40 max	Lead	0.10/0.30
Phosphorous	0.04 max	Aluminum	0.20/0.35
Sulfur	0.03 max		

KANTHAL A–1

Carbon	0.08 max	Aluminum	5.30 min, 6.30 max
Silicon	0.70 max	Iron	balance
Manganese	0.40 max	Chromium	20.50 min, 23.50 max

KANTHAL AF

Carbon	0.08 max	Aluminum	4.80 min, 5.80 max
Silicon	0.70 max	Iron	balance
Manganese	0.40 max		
Chromium	20.50 min, 23.50 max		

KANTHAL A

Carbon	0.08 max	Aluminum	4.80 min, 5.80 max
Silicon	0.70 max	Iron	balance
Manganese	0.50 max		
Chromium	20.50 min, 23.50 max		

KANTHAL D

Carbon	0.08 max	Aluminum	4.30 min, 5.30 max
Silicon	0.70 max	Iron	balance
Manganese	0.50 max		
Chromium	20.50 min, 23.50 max		

KANTHAL DT

Carbon	0.08 max	Aluminum	4.60 min, 5.60 max
Silicon	0.70 max	Iron	balance
Manganese	0.50 max		

KANTHAL DT—Continued

Chromium	20.50 min, 23.50 max		

ALKROTHAL 14

Carbon	0.08 max	Aluminum	3.80 min, 4.80 max
Silicon	0.70 max	Iron	balance
Manganese	0.50 max		
Chromium	14.00 min, 16.00 max		

ALKROTHAL 720

Carbon	0.08 max	Aluminum	3.50 min, 4.50 max
Silicon	0.70 max	Iron	balance
Manganese	0.70 max		
Chromium	12.00 min, 14.00 max		

NIKROTHAL 40

Carbon	0.10 max	Nickel	34.00 min, 37.00 max
Silicon	1.60 min, 2.50 max	Iron	balance
Manganese	1.00 max		
Chromium	18.00 min, 21.00 max		

The subject merchandise is currently classifiable under subheadings 7221.00.0005, 7221.00.0015, 7221.00.0030, 7221.00.0045, and 7221.00.0075 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by the parties to this antidumping duty administrative review are addressed in the ''Issues and Decision Memorandum'' (*Decision Memo*) from Stephen J. Claeys, Deputy Assistant Secretary for Import Administration, to David M. Spooner, Assistant Secretary for Import Administration, dated April 4, 2006, which is hereby adopted by this notice. A list of the issues that parties have raised and to which we have responded, all of which are in the *Decision Memo*, is attached to this notice as an appendix. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, room B–099 of the main Department building. In addition, a complete version of the *Decision Memo* can be accessed directly on the Web at http://ia.ita.doc.gov/frn. The paper copy and electronic version of the *Decision Memo* are identical in content.

Changes from the Preliminary Results

Based on the information submitted and our analysis of the comments received, we have made certain changes to the margin calculations for FSAB as follows.

(1) We matched products of identical grade first before matching products of the next most similar grade and, where appropriate, attempted to match products beyond the top three most similar grades before resorting to constructed value (''CV''), consistent with our intent in the preliminary results and in accordance with the Department's practice. *See* Comment 2 for further discussion.

(2) We included in our final margin analysis a U.S. sales transaction made by FSAB's U.S. affiliate, Fagersta Stainless Inc. (''FSI''), for which the entry date was within the POR but the sale date preceded the POR, in accordance with the Department's normal practice to review sales associated with entries made during the review period. See Comment 3 for further discussion.

(3) We corrected a clerical error by applying the general and administrative (''G&A'') expenses and further manufacturing costs, which were recalculated in the Preliminary Results, to only the U.S. sales of FSAB's other U.S. affiliate, Sandvik Metallurgical Technology U.S. (''SMT U.S.''), for which SMT U.S. reported an amount for further manufacturing. *See* Comment 4 for further discussion.

(4) For SMT U.S.' sales of merchandise that was further manufactured but for which SMT U.S. did not report a further manufacturing cost, we applied as facts available under section 776(a)(1) of the Act, a weighted average of the costs reported by SMT U.S. for its other U.S. sales of further–manufactured merchandise, as recalculated for purposes of the *Preliminary Results*, and deducted this amount from the prices of the U.S. sales at issue. *See* Comment 4 for further discussion.

(5) We used SMACC's[3] cost of producing billets reported in the August 18, 2006, Section D supplemental questionnaire response to compare to the market price of billets and to the transfer price FSAB paid to SMACC for billets used to make the merchandise under consideration. We also excluded an additional G&A expense relevant to Outokumpu Oyj[4] which had been

[3] SMACC or Outokumpu Stainless Ltd. Sheffield is affiliated with FSAB.

[4] Outokumpu Oyj is the consolidated parent of SMACC.

incorrectly added to SMACC's cost of production for purposes of the *Preliminary Results*. In addition, we included the total net foreign exchange gain or loss in the calculation of Outokumpu Oyj's consolidated financial expense rate that was applied to SMACC's cost of producing the billets, in accordance with Department practice. *See* Comment 5 for further discussion.

(6) We corrected a clerical error by subtracting the adjustment to SMT's[5] transfer price from FSAB's cost of billets prior to calculating FSAB's total cost of manufacturing.

(7) We corrected a clerical error by converting FSAB's U.S. affiliate's reported U.S. inventory carrying costs from SEK/kg. to USD/lb. in the margin calculations.

See April 4, 2007, Memorandum from Case Analyst to The File, entitled ''Calculation Memorandum for the Final Results for Fagersta Stainless AB≥; and April 4, 2007, Memorandum to Neal M. Halper from Michael P. Harrison, entitled ''Cost of Production, Constructed Value and Further Manufacturing Calculation Adjustments for the Final Results - Fagersta Stainless AB,'' for further details.

Final Results of Review

We determine that the following weighted–average margin percentage exists:

Manufacturer/exporter	Margin (percent)
Fagersta Stainless AB/ AB Sandvik Materials Technology/Kanthal AB	20.42

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212(b). The Department will issue appropriate appraisement instructions for the company subject to this review directly to CBP 15 days after publication of these final results of review. In accordance with 19 CFR 351.106(c), we will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer–specific assessment rate calculated in the final results of this review is above *de minimis (i.e.*, is not less than 0.50 percent *ad valorem*). For entries made by FSAB on behalf of its U.S. affiliate, FSI, we calculated the importer–specific *ad valorem* duty assessment rate based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of those sales. However, for shipments of subject merchandise produced by FSAB and imported by its U.S. affiliate, SMT U.S., where the respondent was unable to provide the entered value, we calculated the importer–specific per–unit duty assessment rate by aggregating the total amount of antidumping duties calculated for the examined sales and divided this amount by the total quantity of those sales. To determine whether the per–unit duty assessment rate is *de minimis*, in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated an importer–specific *ad valorem* ratio based on the estimated entered value.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by the company included in these final results of review for which the reviewed company did not know that the merchandise it sold to the intermediary (*e.g.*, reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the ''All Others'' rate if there is no rate for the intermediary involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) the cash deposit rate for FSAB/SMT/Kanthal will be the rate indicated above; (2) for previously investigated companies not listed above, the cash deposit rate will continue to be the company–specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less–than-fair–value (''LTFV'') investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 5.71 percent. This rate is the ''All Others'' rate from the LTFV investigation. These deposit requirements shall remain in effect until further notice.

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 antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221.

Dated: April 4, 2007,

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

Appendix List of Issues

Comment 1: Whether to Include Electroslag Refining As a Model–Matching Criterion

Comment 2: Grade–Matching Methodology

Comment 3: Treatment of One U.S. Sale Entered During the POR But Sold Prior to the POR

Comment 4: Application of Further Manufacturing G&A Expenses to Sales of Non–Further Manufactured Merchandise

Comment 5: Calculation of Affiliated Supplier's Billet Cost

[FR Doc. E7–6749 Filed 4–9–07; 8:45 am]

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[5] AB Sandvik Materials Technology or SMT is affiliated with FSAB and is also the parent company of SMT U.S.

DEPARTMENT OF COMMERCE

International Trade Administration

(C–533–825)

Polyethylene Terephthalate Film, Sheet, and Strip from India: Notice of Partial Rescission of Administrative Review of the Countervailing Duty Order

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

EFFECTIVE DATE: April 10, 2007

FOR FURTHER INFORMATION CONTACT: Elfi Blum, Nicholas Czajkowski, or Toni Page, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0197, (202) 482–1395, or (202) 482–1398, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 3, 2006, the Department of Commerce (the Department) published a notice of opportunity to request an administrative review of the countervailing duty order on Polyethylene Terephthalate (PET) Film, Sheet, and Strip from India. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 71 FR 37890 (July 3, 2006). On July 26, 2006, MTZ Polyfilms, Ltd. (MTZ) timely requested that the Department conduct an administrative review of merchandise it produced and exported. On July 31, 2006, Polyplex Corporation, Ltd. (Polyplex), Jindal Poly Films Limited of India (Jindal), and Garware Polyester, Ltd. (Garware) also timely requested that the Department conduct an administrative review of merchandise they produced and exported.

Polyplex withdrew its request for an administrative review on August 22, 2006, before the initiation of this review. Shortly thereafter, the Department published a notice of the initiation of the countervailing duty administrative review of PET Film from India for MTZ, Garware, and Jindal for the period January 1, 2005 through December 31, 2005. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 71 FR 51573 (August 30, 2006). On November 28, 2006, Jindal withdrew its request for an administrative review.

Partial Rescission of Review

The Department's regulations at section 351.213(d)(1) provide that the Department will rescind an administrative review if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review, or withdraws its request at a later date if the Department determines that it is reasonable to extend the time limit for withdrawing the request. Jindal submitted its request within the 90 day limit set by the regulations. Since no other parties requested a review of Jindal, the Department is rescinding, in part, the administrative review of the countervailing duty order on PET film from India for the period January 1, 2005 through December 31, 2005, for Jindal. Both Garware and MTZ remain subject to this administrative review. The preliminary results for this administrative review for these companies are currently due July 31, 2007.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. Jindal shall be assessed countervailing duty rates equal to the cash deposit of the estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of this notice.

Cash Deposit Rates

Jindal's cash deposit rate will be the rate in effect on the date of entry. This cash deposit requirement shall remain in effect until publication of the final results of this administrative review.

Notification Regarding APOs

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 that is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: April 4, 2007.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E7–6748 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

The President's Export Council: Meeting of the President's Export Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an Open Meeting via Teleconference.

SUMMARY: The President's Export Council will hold a meeting via teleconference to deliberate a draft recommendation to the President regarding Trade Promotion Authority.

Date: April 24, 2007.

Time: 12 p.m. (EDST).

For the Conference Call-In Number and Further Information, Contact: The President's Export Council Executive Secretariat, Room 4043, Washington, DC 20230 (Phone: 202–482–1124), or visit the PEC Web site, *http://www.ita.doc.gov/td/pec.*

Dated: April 5, 2007.

J. Marc Chittum,

Staff Director and Executive Secretary, President's Export Council.

[FR Doc. 07–1800 Filed 4–6–07; 1:39 pm]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 070320063–7064–01]

Advanced Technology Program Notice of Availability of Funds and Announcement of Public Meetings (Proposers' Conferences)

AGENCY: National Institute of Standards and Technology (NIST), Department of Commerce.

ACTION: Notice.

SUMMARY: NIST's Advanced Technology Program (ATP) announces that it will hold a single fiscal year 2007 ATP competition and is soliciting proposals for financial assistance. ATP also

announces that it will hold public meetings (Proposers' Conferences) for all interested parties. ATP is soliciting proposals in all technology areas (Competition Number 2007–A) as well as the following four broad Crosscutting Areas of National Interest: (1) Technologies for Advanced and Complex Systems (Competition Number 2007–B), (2) Challenges in Advanced Materials and Devices (Competition Number 2007–C), (3) 21st Century Manufacturing (Competition Number 2007–D), and (4) Nanotechnology (Competition Number 2007–E). Details regarding these four broad Crosscutting Areas of National Interest are included in the Federal Funding Opportunity announcement available at *http://www.grants.gov.* ATP provides cost-shared multi-year funding to single companies and to industry-led joint ventures to accelerate the development and dissemination of challenging, high risk technologies with the potential for significant commercial payoffs and widespread benefits for the nation. This unique government-industry partnership aids companies in accelerating the development of emerging or enabling technologies that lead to revolutionary new products and industrial processes and services that can compete in rapidly changing world markets. ATP challenges the research and development (R&D) community to take on higher technical risk with commensurately higher potential payoffs for the nation than they would otherwise pursue.

DATES: The due date for submission of all proposals is 3 p.m. Eastern Time, Monday, May 21, 2007. This deadline applies to any mode of proposal submission, including hand-delivery, courier, express mailing, and electronic. Do not wait until the last minute to submit a proposal. ATP will not make any allowances for late submissions, including incomplete Grants.gov registration.

ADDRESSES: Proposals must be submitted to ATP as follows:

Paper submission: Send to National Institute of Standards and Technology, Advanced Technology Program, 100 Bureau Drive, Stop 4701, Gaithersburg, MD 20899–4701.

Electronic submission: http://www.grants.gov.

FOR FURTHER INFORMATION CONTACT: Barbara Lambis at 301–975–4447 or by e-mail at *barbara.lambis@nist.gov.*

SUPPLEMENTARY INFORMATION:

Additional Information: The full Federal Funding Opportunity (FFO) announcement for this request for proposals is available at *http://www.grants.gov.* The full FFO announcement text can also be accessed on the ATP Web site at *http://www.atp.nist.gov/atp/helpful.htm.* To request a copy of the April 2007 ATP Proposal Preparation Kit submit an electronic request at *http://www.atp.nist.gov/atp/atpform.htm* or call ATP at 1–800–ATP–FUND (1–800–287–3863). The Kit is also available at *http://www.atp.nist.gov/atp/helpful.htm.* Note that ATP is mailing the Kit to all individuals whose names are currently on the ATP mailing list. Those individuals need not contact ATP to request a copy.

Meetings: ATP is holding several public meetings (Proposers' Conferences) at several locations around the country. These public meetings provide general information regarding the program, tips on preparing proposals, and the opportunity for questions and answers. Proprietary technical or business discussions about specific project ideas with NIST staff are not permitted at these conferences or at any time before submitting the proposal to ATP. Therefore, you should not expect to have proprietary issues addressed at proposers' conferences. NIST/ATP staff will not critique proprietary project ideas while they are being developed by a proposer. However, NIST/ATP staff will, at any time, answer questions that you may have about our project selection criteria, selection process, eligibility requirements, cost-sharing requirements, and the general characteristics of a competitive ATP proposal.

ATP Proposers' Conferences are being held from 9 a.m.–12:30 p.m. local time on the following dates and locations:

April 13, 2007: NIST Red Auditorium, 100 Bureau Drive, Gaithersburg, MD (301–975–2776)

April 16, 2007: Hyatt Regency Dearborn Fairlane Town Center, Dearborn, Detroit, MI (313–593–1234)

April 18, 2007: Hyatt Harborside at Boston's Logan International Airport, 101 Harborside Drive, Boston, MA (617–568–1234)

April 18, 2007: Los Angeles Airport Marriott, 5855 West Century Blvd., Los Angeles, CA (310–641–5700)

April 20, 2007: Hilton Austin Airport, 9515 Hotel Drive, Austin, TX (512–385–6767)

No registration fee will be charged. Presentation materials from proposers' conferences will be made available on the ATP Web site.

Pre-Registration Required By April 9, 2007 for All Proposers' Conferences as Follows

NIST Gaithersburg Conference: Due to increased security at NIST, NO on-site registrations will be accepted and all attendees MUST be pre-registered. Photo identification must be presented at the NIST main gate to be admitted to the April 13, 2007 conference. Attendees must wear their conference badge at all times while on the NIST campus. Same day registration will be allowed at the other locations.

Electronic Registration: At *https://rproxy.nist.gov/CRS/.* Please select the ATP Proposers' Conference and appropriate data to register for the meeting of your choice.

Telephone Registration: Call 301–975–2776.

Fax Registration: Provide the following and fax to 301–948–2067: last name, first name; title; organization; room or mail code, city, state, zip code, country; telephone; facsimile; e-mail; any special needs; and the meeting date and location.

Funding Availability: Fiscal year 2007 appropriations include funds in the amount of approximately $60 million for new ATP awards. Approximately 60 awards are anticipated.

Statutory Authority: 15 U.S.C. 278n.

CFDA: 11.612, Advanced Technology Program (ATP).

Eligibility: U.S.-owned, single, for-profit companies and industry-led joint ventures may apply for ATP funding. In addition, companies incorporated in the United States that have parent companies incorporated in another country may apply. The term company means a for-profit organization, including sole proprietorships, partnerships, limited-liability companies (LLCs), and corporations (15 CFR 295.2).

Cost Sharing Requirements: Small (as defined at 15 CFR 295.2) and medium sized companies applying as single-company proposers are not required to provide cost sharing of direct costs; however, they may propose to pay a portion of the direct costs in addition to all indirect costs throughout the project. Large companies applying as single-company proposers must cost share at least 60 percent of the yearly total project costs (direct plus all of the indirect costs). A large company is defined as any business, including any parent company plus related subsidiaries, having annual revenues in excess of $3.960 billion. (Note that this number will likely be updated annually and will be noted in future annual announcements of availability of funds

and revised editions of the ATP Proposal Preparation Kit.) Joint ventures must cost share more than 50 percent of the yearly total project costs (direct plus indirect costs).

Selection Procedures: All proposals are selected based on a multi-stage peer-review process, as described in 15 CFR 295.4. All proposals are carefully reviewed by technical and business experts against the established ATP evaluation/selection criteria. A Source Evaluation Board (SEB) (a committee made up of nine Federal employees) reviews proposals and makes recommendations for funding to a Selecting Official based on the technical and business evaluations and the selection criteria. The SEB ratings shall provide a rank order to the Selecting Official for final recommendation to the NIST Grants Officer. NIST/ATP reserves the right to negotiate the cost and scope of the proposed work with the proposers who have been selected to receive awards. For example, NIST/ATP may require that the proposer delete from the scope of work a particular task that is deemed by NIST/ATP to be product development or otherwise inappropriate for ATP support. All funding decisions are final and cannot be appealed.

Evaluation Criteria: The evaluation criteria used to select a proposal for funding and their respective weights are found in 15 CFR 295.6.

Selection Factors: The Selecting Official shall recommend for award in rank order unless a proposal is justified to be selected out of rank order based upon the availability of funds, the adherence to ATP selection criteria, or the appropriate distribution of funds among technologies and their applications. NIST reserves the right to deny awards in any case where NIST determines that a reasonable doubt exists regarding a proposer's ability to comply with ATP requirements or to handle Federal funds responsibly.

Ineligible Projects

a. Straightforward improvements of existing products or product development.

b. Projects that are basic research.

c. Projects that are Phase II, III, or IV clinical trials. ATP rarely funds Phase I clinical trials and reserves the right not to fund a Phase I clinical trial. The portion of a Phase I trial that may be funded must be critical to meeting the scientific and technological merit selection criterion and the trial must be essential for completion of the study. The definitions of all phases of clinical trials are provided in the ATP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects located at *http://www.atp.nist.gov/atp/helpful.htm.*

d. Pre-commercial-scale demonstration projects where the emphasis is on demonstrating that some technology works on a large scale or is economically sound rather than on R&D that advances the state of the art.

e. Projects that ATP believes would likely be completed without ATP funds in the same time frame or nearly the same time frame, or with the same scale or scope.

f. Predominantly straightforward, routine data gathering (e.g., creation of voluntary consensus standards, data gathering/handbook preparation, testing of materials, or unbounded research aimed at basic discovery science) or application of standard engineering practices.

g. Projects that are simply a follow-on or a continuation of tasks previously funded in ATP projects from essentially the same proposing team.

h. Projects in which the only risk is market oriented—that is, the risk that the end product may not be embraced by the marketplace.

i. Projects with software work, that are predominantly about final product details and product development, and that have significant testing that involve users outside the research team to determine if the software meets the original research objectives, are likely to be either uncompetitive or possibly ineligible for funding. However, R&D projects with limited software testing, involving users outside of the research team, may be considered eligible costs within an ATP award when the testing is critical to meeting the scientific and technological merit selection criterion and the testing is essential for completion of the proposed research. These types of projects may also be considered to involve human subjects in research.

Unallowable/Ineligible Costs. The following items, regardless of whether they are allowable under the federal cost principles, are unallowable under ATP:

a. Bid and proposal costs unless they are incorporated into a federally approved indirect cost rate.

b. Construction costs for new buildings or extensive renovations of existing laboratory buildings. However, costs for the construction of experimental research and development facilities to be located within a new or existing building are allowable provided that the equipment or facilities are essential for carrying out the proposed scientific and technical project and are approved by the NIST Grants Officer.

c. For research involving human and/or animal subjects, any costs used to secure Institutional Review Board or Institutional Animal Care and Use Committee approvals before the award or during the award.

d. General purpose office equipment and supplies that are not used exclusively for the research, e.g., office computers, printers, copiers, paper, pens, and toner cartridges.

e. Indirect costs for single-company recipients, which must be absorbed by the company. (Note that with large businesses submitting proposals as single-company proposers, indirect costs absorbed by the large business may be used to meet the cost-sharing requirement.)

f. Marketing, sales, or commercialization costs, including marketing surveys, commercialization studies, and general business planning, unless they are included in a federally approved indirect cost rate.

g. Office furniture costs, unless they are included in a federally approved indirect cost rate.

h. Patent costs and legal fees, unless they are included in a federally approved indirect cost rate.

i. Preaward costs.

j. Profit, management fees, interest on borrowed funds, or facilities capital cost of money.

k. Relocation costs, unless they are included in a federally approved indirect cost rate.

l. Subcontractor expenses such as those for office supplies and conferences/workshops.

m. Subcontracts to another part of the same company or to another company with identical or nearly identical ownership. Work proposed by another part of the same company or by another company with identical or nearly identical ownership should be shown as funded through interorganizational transfers that do not contain profit. Interorganizational transfers should be broken down in the appropriate budget categories.

n. Tuition costs. However, a university participating in an ATP project as a subcontractor or as a joint venture partner may charge ATP for tuition remission or other forms of compensation in lieu of wages paid to university students working on ATP projects but only as provided in OMB Circular A–21, Section J.41. In such cases, tuition remission would be considered a cash contribution rather than an in-kind contribution.

Intellectual Property Requirements: Title to any inventions arising from an ATP-funded project must be held by a for-profit company, or companies,

incorporated or organized in the United States. A university, government laboratory, independent research organization, or other nonprofit organization cannot retain title to patents, although such organizations can receive mutually agreeable payments (either one-time or continuing) from the company or companies holding title to the patent. However, a for-profit corporation organized by a university can be considered a for-profit company for the purpose of retaining title to patents arising from an ATP award. In such a case, documentation of the for-profit status must be provided in the proposal. If your organization is not a for-profit company but plans to be involved in an ATP project, you will not be able to retain title to any patentable inventions arising from the ATP project. Please make sure your legal department is aware that ATP cannot waive this mandated provision (15 U.S.C. 278n(d)(11)(A) and 15 CFR 295.2 and 295.8). Title to any such invention shall not be transferred or passed, except to a for-profit company organized in the United States, until the expiration of the first patent obtained in connection with such invention.

The United States reserves a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any patentable invention arising from an ATP award. The federal government shall not, however, in the exercise of such license, publicly disclose proprietary information related to the license. The federal government also has march-in rights in accordance with 15 CFR 295.8. Since its inception in 1990, ATP has not exercised its march-in rights nor has it used its nontransferable, irrevocable, paid-up license.

Projects Involving Human Subjects: Research involving human subjects must be in compliance with applicable Federal regulations and NIST policies for the protection of human subjects. Human subjects research involves interactions with live human subjects or the use of data, images, tissue, and/or cells/cell lines (including those used for control purposes) from human subjects. Research involving human subjects may include activities such as the use of image and/or audio recording of people, taking surveys or using survey data, using databases containing personal information, testing software with volunteers, and many tasks beyond those within traditional biomedical research. A Human Subjects Determination Checklist is included in the April 2007 ATP Proposal Preparation Kit as Exhibit 2 (*http://www.atp.nist.gov/atp/helpful.htm*) to assist you in determining whether your proposal has human subjects involvement, which would require additional documents with your proposal. Detailed information regarding the use of human subjects in research projects and required documentation is available in the ATP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects located at *http://www.atp.nist.gov/atp/helpful.htm* or by calling 1–800–287–3863.

Projects Involving Animal Subjects: Research involving animal subjects must be in compliance with applicable federal regulations and NIST policies for the protection of animal subjects. Vertebrate animal research involves live animals that are being cared for, euthanized, or used by the project participants to accomplish research goals or for teaching or testing. The regulations do not apply to animal tissues purchased from commercial processors or tissue banks or to uses of preexisting images of animals (e.g., a wildlife documentary or pictures of animals in newscasts). The regulations do apply to any animals that are housed and cared for by a project participant and used for custom collection of biological samples or observation data of health and behavior. Detailed information regarding the use of animal subjects in research projects and required documentation is available in the ATP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects located at *http://www.atp.nist.gov/atp/helpful.htm* or by calling 1–800–287–3863.

Administrative and National Policy Requirements: The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements: The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of December 30, 2004 (69 FR 78389) is applicable to this announcement. On the form SF–424 (R&R), the applicant's 9-digit Dun and Bradstreet Data Universal Numbering System (DUNS) number must be entered in the Organizational DUNS line.

Paperwork Reduction Act: This notice contains collection of information requirements subject to the Paperwork Reduction Act (PRA). The use of Forms NIST–1262 and NIST–1263, SF–424 (R&R), Research and Related Other Project Information, SF–424B, SF–LLL, CD–346, and Budget Narrative form has been approved by OMB under the respective control numbers 0693–0009, 4040–0001, 4040–0001, 4040–0007, 0348–0046, 0605–0001, and 0693–0009. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

Executive Order 12866: This notice has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 12372 (Intergovernmental Review of Federal Programs): ATP does not involve the mandatory payment of any matching funds from state or local government and does not affect directly any state or local government. Accordingly, the Department of Commerce has determined that Executive Order 12372 is not applicable to this program.

Executive Order 13132 (Federalism): It has been determined that this notice does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

Administrative Procedure Act/ Regulatory Flexibility Act: Notice and comment are not required under the Administrative Procedure Act (5 U.S.C. 553) or any other law, for notices relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553(a)). Because notice and comment are not required under the Administrative Procedure Act, a Regulatory Flexibility Analysis is not required and has not been prepared for this notice, 5 U.S.C. 601 *et seq.*

Dated: April 3, 2007.

William Jeffrey,

Director, NIST.

[FR Doc. E7–6650 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advisory Committee on Earthquake Hazards Reduction Meeting

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Earthquake Hazards Reduction Program (NEHRP) Advisory Committee on Earthquake Hazards Reduction (ACEHR), will meet at the National Institute of Standards and Technology (NIST) on Thursday, May 10, 2007 from 9:30 a.m. to 5:45

p.m. and Friday, May 11, 2007, from 8:30 a.m. to 12 p.m. The primary purpose of this meeting is to discuss NEHRP program activities. The NEHRP Advisory Committee will also discuss its annual report to the NIST Director. The agenda may change to accommodate Committee business. The final agenda will be posted on the NEHRP Web site at *http://nehrp.gov/*.

DATES: The meeting will convene on May 10, 2007, at 9:30 a.m. and will adjourn at 5:45 p.m. on May 10, 2007. The meeting will resume on May 11, 2007 at 8:30 a.m. and end at 12 p.m. The meeting will be open to the public.

ADDRESSES: The meeting will be held in the Employee Lounge, in the Administration Building at NIST, Gaithersburg, Maryland. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Dr. Jack Hayes, National Earthquake Hazards Reduction Program Director, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8600, Gaithersburg, Maryland 20899–8600. Dr. Hayes' e-mail address is *jack.hayes@nist.gov* and his phone number is (301) 975–5640.

SUPPLEMENTARY INFORMATION: The Committee was established in accordance with the requirements of Section 103 of the NEHRP Reauthorization Act of 2004 (Pub. L. 108–360). The Committee is composed of 15 members appointed by the Director of NIST who were selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues affecting the National Earthquake Hazards Reduction Program. In addition, the Chairperson of the United States Geological Survey (USGS) Scientific Earthquake Studies Advisory Committee (SESAC) will serve in an ex officio capacity on the Committee. *The Committee will assess:*

- Trends and developments in the science and engineering of earthquake hazards reduction;
- The effectiveness of NEHRP in performing its statutory activities (improved design and construction methods and practices; land use controls and redevelopment; prediction techniques and early-warning systems; coordinated emergency preparedness plans; and public education and involvement programs);
- Any need to revise NEHRP; and
- The management, coordination, implementation, and activities of NEHRP.

Background information on NEHRP and the Advisory Committee is available at *http://nehrp.gov/*.

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that the National Earthquake Hazards Reduction Program (NEHRP) Advisory Committee on Earthquake Hazards Reduction (ACEHR), will meet Thursday, May 10, 2007, at 9:30 a.m. and will adjourn at 5:45 p.m. on May 10, 2007. The meeting will resume on Friday, May 11, 2007 at 8:30 a.m. and end at 12 p.m. The meeting will be held at NIST headquarters in Gaithersburg, Maryland.

The primary purpose of this meeting is to discuss NEHRP program activities. The NEHRP Advisory Committee will also discuss its annual report to the NIST Director. The meeting will be open to the public. The final agenda will be posted on the NIST Web site at *http://nehrp.gov/*.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda. On May 10, 2007, approximately one-half hour will be reserved for public comments, and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the NEHRP Advisory Committee, National Institute of Standards and Technology, 100 Bureau Drive, MS 8610, Gaithersburg, Maryland 20899–8610, via fax at (301) 975–4032, or electronically by e-mail to *info@nehrp.gov*.

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting must register by close of business Thursday, May 3, 2007, in order to attend. Please submit your name, time of arrival, e-mail address and phone number to Amber Stillrich and she will provide you with instructions for admittance. Non-U.S. citizens must also submit their country of citizenship, title, employer/sponsor, and address. Ms. Stillrich's e-mail address is *amber.stillrich@nist.gov* and her phone number is (301) 975–3777.

Dated: April 4, 2007.

William Jeffrey,

Director.

[FR Doc. E7–6746 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 030907B]

Taking of Marine Mammals Incidental to Specified Activities; An On-ice Marine Geophysical Research and Development Program in the Beaufort Sea

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

ACTION: Notice of issuance of an incidental harassment authorization.

SUMMARY: In accordance with provisions of the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to conducting an on-ice marine geophysical research and development (R&D) program in the U.S. Beaufort Sea, has been issued to Shell Offshore, Inc. (SOI) for a period between March and May 2007.

DATES: This authorization is effective from March 30 until May 31, 2007.

ADDRESSES: A copy of the application, IHA, an Environmental Assessment (EA) on the *Proposed OCS Lease Sale 202 Beaufort Sea Planning Area* by the Mineral Management Service (MMS), and/or a list of references used in this document may be obtained by writing to P. Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning one of the contacts listed here (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 713–2289, ext 137 or Brad Smith, Alaska Region, NMFS, (907) 271–5006.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals

by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Permission shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses, and that the permissible methods of taking and requirements pertaining to the mitigation, monitoring, and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except for certain categories of activities not pertinent here, the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On January 17, 2007, NMFS received an application from SOI for the taking, by harassment, of three species of marine mammals incidental to conducting an on-ice marine geophysical R&D program.

The proposed R&D program would occur on the U.S. Minerals Management Service (MMS) Outer Continental Shelf (OCS) lease blocks located offshore from Oliktok Point, Milne Point, West Dock, or Endeavor Islands, in the Alaskan Beaufort Sea. This on-ice R&D will consist of 35 linear miles (56 km) of surveying with in a 16 km^2 (6.2 mi^2) area. The prospective locations have been selected on the basis of suitability for the scientific testing and proximity to facilities to help minimize impact on the region. The water depth at each location is less than 20 m (66 ft); deep enough that the ice is not grounded. Ice conditions within the proposed survey area will determine the area selected, and SOI will consult with MMS and NMFS before the selection is made. The proposed program is expected to begin in March and last until May, 2007.

Sources and receivers would be placed above and below the ice in attempts to find pairings that provide the best mitigation of seismic noise in a shallow marine environment where conventional seismic vessels cannot operate. A variety of instruments will be used to create a complete catalogue of data for development of noise mitigation techniques. Sources include standard and lightweight vibrators, accelerated weight drop (impact) sources on the ice, and small volume airgun arrays deployed through holes augered in the ice. Receivers will be deployed both on the ice surface, as well as below the ice suspended in the water column and on the ocean floor. The program will also require a temporary camp facility geared to accommodate up to 100 people. A detailed description of these activities was published in the **Federal Register** on February 6, 2007 (72 FR 5421). No changes have been made to these proposed R&D activities.

Comments and Responses

A notice of receipt and request for public comment on the application and proposed authorization was published on February 6, 2007 (72 FR 5421). During the 30–day public comment period, NMFS received the following comments from one private citizen, the North Slope Borough (NSB), the Inupiat Community of the Arctic Slope (ICAS), and the Marine Mammal Commission (Commission). Overall, the NSB supports the efforts to collect geological data from the ice instead of during the open water period when bowhead whales (*Balaena mysticetus*) and other marine mammals might be present and significant subsistence activity takes place. The Commission recommends that NMFS issue the IHA provided that the proposed monitoring and mitigation measures are carried out as described in the application and the previous **Federal Register** notice (72 FR 5421, February 6, 2007), with the exception of the proposed adjustment of the initial exclusion zone around active seal structures (see Commission comments below).

Comment 1: One private citizen opposes the project out of concern that marine mammals would be killed by the proposed project in Beaufort Sea.

NMFS Response: As described in detail in the **Federal Register** notice of receipt of the application (72 FR 5421, February 6, 2007), no marine mammals will be killed or injured as a result of the proposed on-ice seismic R&D program by SOI. The project would only result in Level B behavioral harassment of a small number of ringed seals and bearded and spotted seals. No take by Level A harassment (injury) or death is anticipated or authorized from this project.

Comment 2: The NSB questions the statement SOI stated in its application that it wants to ''... create a complete catalogue of data for development of noise mitigation techniques.'' NSB mentions that it is not clear what this statement means given that SOI would be using an airgun and vibrators, which would create noise, not mitigate it.

SOI Response: The proposed on-ice work is being conducted in an effort to develop mitigative alternatives to open water seismic acquisition. Several technologies are being evaluated both for their efficacy for acquiring subsurface data and for reducing environmental impacts of seismic operations. By evaluating multiple technologies during an on-ice experiment, it is hoped that a mitigative alternative to open water seismic surveys can be identified or developed.

Comment 3: The NSB points out that in the SOI's application, it stated that the geophysical program would occur in a 16 km^2 (6.2 mi^2) area. However, the accompanying map shows a much larger area of approximately 15 by 60 miles (24 x 97 km) in size. The NSB questions in which portion of this larger area the proposed on-ice R&D program would be conducted.

SOI Response: The included map depicts general regions being considered for project placement. Final location will depend on a combination of suitable ice conditions, operational efficiency, and locations away from permit restrictions (e.g., seal lairs, etc.). SOI will consult with NMFS and MMS regarding the selection of the final location. Nonetheless, the project footprint is 16 km^2 (6.2 mi^2).

Comment 4: The NSB states that in discussion with SOI, it appears that the company has already conducted considerable work for the establishment of a camp on the ice and perhaps has even already set up the camp or begun geophysical work. This is peculiar given

that an IHA has not yet been issued and that comments are due on the application on March 8, 2007. If SOI is already conducting operations, especially seismic, it is likely they are already taking ringed seals. The NSB suggests that NMFS investigate SOI's operations for the taking of marine mammals if those operations have already begun.

SOI Response: SOI's contractor, Veritas DGC has been performing ice profiling reconnaissance visits to measure ice thickness. These visits were necessary to assess at which location ice is thick enough to safely execute the project. Veritas DGC conducted these flights under the coverage of a USFWS Letter of Authorization for the incidental take of polar bears. Arnold Brower, Sr. accompanied Veritas DGC on these flights to provide wildlife observations and traditional knowledge on ice thicknesses based on his observations of surface ice conditions. No marine mammals were observed during these ice thickness assessments during which ice was bored and thicknesses measured. No marine mammals were taken.

NMFS Response: NMFS Office of Protected Resources has contacted the Office for Law Enforcement (OLE) in the Alaska Division regarding NSB's comment. The OLE has initiated an investigation on this issue.

Comment 5: The NSB states that it agrees with NMFS and SOI's assessment on the potential take of ringed, bearded, and spotted seas, and further states that it's extremely unlikely that any spotted seal will be in the project vicinity. However, the NSB is concerned that bowhead whales and belugas (*Delphinapterus leucas*) could be potentially taken as a result of the proposed action. NSB states that bowheads and belugas typically begin passing by Barrow in mid-April, and that in a typical year, bowheads and belugas could be off the project area by mid-April within several days of passing Barrow. The NSB further states that in 2007, ice is very light and there are considerable areas of open water between Barrow and the Beaufort Sea.

NMFS *Response:* The nature of the proposed on-ice seismic R&D program would require ice thickness of at least 50 in (1.3 m) to support the heavy equipment and personnel, and the nearest lead would be at least 10 mi (16 km) away. This is not typical habitat for cetacean species, including bowhead and beluga whales, thus, no cetacean species is likely to be found in the vicinity of the project area. Therefore, NMFS does not believe the proposed project would affect bowhead or beluga whales. Due to safety concerns, SOI will not operate in an area where the ice condition is thin enough to allow an open lead to develop. As stated in the previous **Federal Register** notice (72 FR 5421, February 6, 2007), SOI will consult with NMFS and MMS before camp mobilization within the project area based on ice conditions and safety of access to ice.

Comment 6: The NSB states that the propagation data from the open water period is not sufficient for establishing safety or disturbance zones. The NSB states that while the sea ice is likely to dampen some frequencies of sound, there is also the likelihood that the ice may channel sounds, especially just below the ice.

NMFS Response: It is well supported by scientific research that a major source of low-frequency loss in the Arctic is conversion of acoustic waves into flexural waves of the ice sheet, thus attenuating acoustic propagation under ice (Richardson **3**, 1995). Thus, NMFS does not believe there are sound channeling effects caused by ice in the proposed project area. In particular, the NSB did not provide any scientific support for its comment regarding ''ice channeling sounds.''

In the Arctic region, the axis of the deep sound channel may exist at or near the surface, which is due to cold temperature at the surface that causes the sound ray to refract upward, but it is not induced by ice-cover and it only occurs in area where the ocean is sufficiently deep (Urick, 1983). The proposed project area is only 20 m (66 ft), therefore, it is highly unlikely an arctic surface channel will form in the proposed project area.

Although Richardson *et al.* (1995) noted that smooth annual ice may enhance propagation of high-frequency sounds under-ice at compared with open water conditions, those sounds are not a major component from the proposed seismic program. In addition, the safety zone for seismic surveys by airgun will be empirically verified to match the 190 dB *re:* 1 microPa rms for pinnipeds to prevent any impacts on marine mammals from sound pressure levels higher than that.

Comment 7: The NSB states that ambient sounds are often lower during periods of ice cover compared to the open water period. Thus, the NSB is concerned that if channeling occurs and ambient levels under ice are lower than open water, marine mammals may be subjected to louder SPLs at farther distances than suggested by data collected during the open water period.

NMFS Response: Contrary to what the NSB claims in the comment, sea ice noise contributes a large part of the ambient sound level at high latitudes. Sea ice noise often results from (1) thermal stress, in which temperature changes induce cracking; and (2) mechanical stress, in which ice deformation under pressure from wind and currents; and causes significant noise at low frequencies (Richardson et al., 1995). It was noted that a pressure ridge active over a 3–day period produced tones at frequencies of 4 - 200 Hz. Although ambient noise levels have been found lower under certain types of stable sea ice, it is actually a result from the dampening effects by ice, where there is 100 percent ice cover and no waves or surf are present (Richardson *et al.*, 1995). As mentioned in *Response* to *Comment 6*, this dampening effect would reduce noise levels from the proposed project as well.

Regarding the ''ice channeling effects,'' please refer to NMFS *Response* to *Comment 6*.

Comment 8: The NSB is further concerned that if channeling occurs and leads in the Beaufort Sea are relatively near shore, bowheads and belugas could also be taken.

NMFS Response: Regarding the ''ice channeling affects,'' please refer to NMFS *Response* to *Comment 6*.

Also, as mentioned in Response to Comment 6 that although smooth annual ice may enhance propagation of high-frequency sounds under-ice at compared with open water conditions, with increased cracking, ridging, and other forms of roughness, transmission losses generally become higher than when the water is open (Richardson *et al.*, 1995). In addition, as mentioned in *Response* to *Comment 5*, no seismic program will be conducted within 10 mi (16 km) of open lead for safety concerns. As a result, NMFS believes that, because channeling in shallow waters of the nearshore Beaufort Sea is unlikely, no cetaceans are likely to be taken by this activity.

Comment 9: The NSB points out that the most recent information about spotted seal abundance in the Beaufort Sea was not included in the SOI's application and NMFS **Federal Register** notice (72 FR 5421, February 6, 2007). Citing R. Suydam's personal communication, the NSB states that there is a haul out area for spotted seals in Dease Inlet, in addition to the spotted seal haul out area in the Colville Delta discussed in the notice. The NSB suggests that NMFS consider this information about spotted seal numbers in the Beaufort Sea in future assessments of industrial impacts.

NMFS Response: NMFS has determined, and the NSB concurred (see

Comment 5), that few, if any, spotted seals would be taken by Level B behavioral harassment as a result of the SOI's on-ice geophysical R&D program.

Nonetheless, the information NMFS uses for making a determination whether the issuance of an IHA is consistent with the requirements of section 101(a)(5)(D) of the MMPA is based on the best scientific information available. This best scientific information is usually in the form of peer-reviewed material and scientific publications resulted from empirical research. Personal communications are sometimes considered when there is a lack of other information for making a determination. In such case, NMFS would contact the information source and assess whether the information acquired based on personal communications is scientifically supported before such information is used in decision making. NMFS encourages the NSB to provide information regarding spotted seal population abundance in the Dease Inlet region.

Comment 10: The NSB is concerned that not all the seal breathing holes or lairs will be located prior to SOI's on-ice program. The NSB points out that the description of how lairs and breathing holes will be located is not adequate to assess whether all lairs will be located. Citing a personal communication with Tom Smith, the NSB also points out that the contractor that SOI is planning to use to locate lairs would only locate 80 percent of the lairs unless repeated surveys are conducted.

NMFS Response: A detailed seal breathing holes and lairs survey protocol by 3 trained dogs by transects that are spaced 250 m (820 ft) apart was described in the **Federal Register** notice (72 FR 5421, February 6, 2007), and is not repeated here. A more detailed report using seal lair-detecting dogs by Smith (2006) is available upon request. This reported states that at distances of more than 0.25 miles (400 m, or 1,320 ft) the dogs can detect 80 percent or more of the seal structures in an area.Since the seal structure transects are more closely spaced for the SOI's on-ice program (250 m, or 820 ft), the detection rate will be over 90 percent (T. Smith. Eco Marine. Pers. Comm. March, 2007). In addition, this project will use 3 dogs, which would further increase the detection rate. It is also important to understand that even though 100 percent ringed seals would not be detected within the 16 km^2 (6.2 mi^2) R&D project area, the site where the equipment will be placed and the route where vehicles travel will be adequately surveyed and marked so that Level A harassment will be prevented.

Comment 11: The NSB states that ringed seals could also sustain hearing damage without understanding how sound may be channeled under the ice. NSB is concerned that female ringed seals will likely remain near their pups even with considerable amounts of human activities, therefore could be within the 190 dB zone of seismic activities if not all lairs are found or sound propagates farther than during the open water period.

NMFS *Response:* Please refer to NMFS *Response* to *Comment 6* regarding ''ice channeling effects.'' As stated in the **Federal Register** notice (72 FR 5421, February 6, 2007), during active seismic and impact source testing, an on-ice 500–m (1,640–ft) exclusion zone will be established. This 500–m (1,640–ft) exclusion zone is much large than the 180 dB re: 1 microPa isopleth (modeled at 330 m, or 1,083 ft). The modeled 190 dB re: 1 microPa coincides to a safety zone of 120 m (394 ft) in radius, which is easily surveyed for the presence of seals, and will be monitored throughout the seismic operations by qualified NMFS-approved marine mammal observers (MMOs). The presence of any marine mammals will be detected first by dog surveys, and then by continued monitoring during the operations. Therefore, NMFS does not believe any marine mammals will be exposed to SPLs higher than 190 dB *re:* 1 microPa.

Comment 12: The NSB points out that the data SOI used for ringed seal density estimates (Stirling *et al.*, 1982; Kingsley, 1986) are quite old. The NSB suggests that more recent data from BP's Northstar development island and from recent work conducted by either Tom Smith or Brendon Kelly be used (references not provided).

NMFS Response: In reviewing and making determination on the issuance of an IHA to SOI for its proposed on-ice R&D project, NMFS used the most recent available scientific data regarding ringed seal density in the proposed project area from works conducted by Kelly and Quakenbush (1990), Frost and Lowry (1999), and Moulton *et al.*, (2002), which was based from studies at the Northstar development. Earlier ringed seal density estimates reported by Stirling *et al.* (1982) and Kingsley (1986) were not included in NMFS' analysis. Please refer to **Federal Register** notice (72 FR 5421, February 6, 2007) for a detailed description.

Comment 13: The NSB points out that SOI's statement that ''[t]here has been no major displacement of seals away from on-ice seismic operations'' is a misinterpretation of Frost *et al.*'s (1988) paper. Citing personal communication with K. Frost, the NSB states that surveys for seals in the mid–1980s occurred too far after on-ice seismic had occurred to make any conclusions about impacts from on-ice seismic on ringed seal distribution. The NSB suggests that NMFS requires SOI to conduct adequate studies to further the knowledge of impacts of seismic activities on ringed seals.

NMFS Response: NMFS concurs with the NSB's comment that SOI's assessment regarding impacts of on-ice seismic operations on ringed seals based on research conducted in mid–1980s is inadequate. Nonetheless, the most recent studies by Moulton et al. (2005) and Williams *et al.* (2006) did show that effects of oil and gas development on local distribution of seals and seal lairs are no more than slight, and are small relative to the effects of natural environmental factors. A detailed description is provided in the February 6, 2007, **Federal Register** notice (72 FR 5421).

Although Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to institute requirements to grantees of incidental take authorizations pertaining to mitigation, monitoring, and reporting, NMFS has no clear legislative authority to require SOI to conduct studies to further the knowledge of impacts of seismic activities on ringed seals.

Comment 14: The NSB points out that SOI relied on outdated ringed seal density data for calculating the number of seals for harassment. The NSB states that site-specific data area needed on seal density, and that if data are not available for assessing and mitigating impacts to seals, then SOI should be required to collect data during this season so that a reasonable assessment of takes of ringed seals and other marine mammals is possible and adequate mitigation measures are available for reducing impacts in the future.

NMFS Response: NMFS concurs with the NSB that outdated ringed seal density data were used by SOI in calculating take estimates for the proposed on-ice R&D project. Nonetheless, these data were not used by NMFS in the analysis of the IHA issuance and the estimate of take numbers. NMFS used the most recent data regarding ringed seal abundance in the proposed project area from works conducted by Kelly and Quakenbush (1990), Frost and Lowry (1999), and Moulton *et al.*, (2002) to calculate the estimated take number. Please refer to **Federal Register** notice (72 FR 5421,

February 6, 2007) for detailed description and calculation of estimated take levels.

Comment 15: The Commission recommends that the safety zone for pinnipeds be enlarged to the 180 dB re: 1 microPa rms isopleth. The Commission believes that a more conservative approach should be taken and that less drastic changes to the exclusion zone should be contemplated. The Commission states that this is because the susceptibility of seals to sounds when in lairs may be higher and their options for avoiding sound sources more limited.

NMFS Response: The 190 dB *re:* 1 microPa rms is used in estimating the onset of temporary threshold shift (TTS) for pinniped hearing underwater when exposed to pulse sounds from airguns during seismic surveys. Based on the best available scientific information, this criteria is conservative in terms of preventing TTS occurrence in pinnipeds. Although it is tempting to set a larger safety zone to achieve a lower SPL for noise exposure, doing so often compromises the effectiveness of monitoring since a much larger area would have to be observed. Therefore, a larger safety zone based on 180 dB re: 1 microPa rms will not necessarily provide extra protection for seals.

Regarding the possibility of seals in the lairs being exposed to higher SPLs, NMFS does not believe that will occur under the proposed on-ice seismic R&D program. First, the work site will be surveyed by up to 3 trained dogs looking for seal structure prior to seismic operations. As a result, any work location will be at least 500 m (1,640 ft) away from the nearest seal structure, which corresponds to a zone with sound pressure levels below 180 dB re: 1 microPa on its outer boundary. Second, even if there were seals in lairs within the safety zone, most acoustic energies from the airgun are emitted under the water and may not even be audible by seals in lairs. Third, if audible and annoying, ringed seals have a number of lairs and breathing holes available in their area. As noted in previous **Federal Register** notices, ringed seals, and even new born pups, move frequently from lair to lair for various biological reasons. If sounds from an acoustic source are annoying to the ringed seal, with or without a pup, these animals can easily move to a new location, a Level B harassment. Therefore, NMFS does not believe it is beneficial to enlarge the safety zone to 180 dB re: 1 microPa rms isopleth.

Comment 16: The ICAS points out that the proposed project area is known to get a lot of ice pressure ridges and a few open leads during the project period, and that the ice may only be 3.5 ft (1 m) in thickness from the short time the ocean is frozen. The ICAS states that the early break-up of ice in recent years indicates that the proposed project may be jeopardized from unforeseen ice surges and movements. The ICAS is concerned that SOI may not be able to retrieve its heavy equipment if there is an early spring break-up, and that the sinking of any equipment into the ocean would affect bowhead migration later on.

NMFS Response: As discussed in *Response* to *Comment 5*, the proposed on-ice seismic R&D program would require ice thickness of at least 50 in (1.3 m) to support the heavy equipment and personnel, and the nearest lead would be at least 10 mi (16 km) away. Due to safety concerns, SOI will not operate in an area where ice is thin enough to allow an open lead. As stated in the previous **Federal Register** notice (72 FR 5421, February 6, 2007), SOI will consult with NMFS and MMS before camp mobilization within the project area based on ice conditions and safety of access to ice.

Comment 17: The ICAS recommends to SOI additional stipulations:

(1) that SOI employ 4 subsistence representatives for safety of the group from possible sudden ice surges and look out for opening of new lead to warm SOI personnel by contract or internal hire from SOI of this project;

(2) that the camp's solid waste be transported daily, to prevent the added attraction from polar bears and foxes;

(3) additional two night watchmen to look for open leads during down time of project;

(4) two snow machines for the open lead watchman for quick travel; and

(5) no fuel storage out on the ice road or ice pads.

NMFS Response: SOI has informed NMFS of the following:

(1) SOI, through its geophysical contractor, Veritas DGC, will employ 4 Inupiat subsistence representatives, 2 per 12–hour shift, to scout ice conditions and observe wildlife while the activities of the on-ice seismic project are conducted.

(2) All solid waste will be incinerated on site.

(3) Other than adverse weather days, there will be no down time on the project. Two Inupiat subsistence representatives will be on each shift scouting for open leads, in addition to observations of wildlife.

(4) Veritas DGC will transport subsistence advisors via a Tucker or Haaglund from the project camp site to and from the watchmen's on-ice shift duties.

(5) Veritas DGC has permitted for fuel storage facilities at camp, as per NSB Permit 07–176 and Alaska Department of Natural Resources, Division of Oil and Gas Permit MLUP/NS 06–14.

Description of Marine Mammals Affected by the Activity

Four marine mammal species are known to occur within the proposed survey area: ringed seal (*Phoca hispida*), bearded seal (*Erignathus barbatus*), spotted seal (*Phoca larghs*), and polar bear (*Ursus maritimus*). Although polar bears are now proposed to be listed as threatened, none of these species are listed under the Endangered Species Act (ESA) as endangered or threatened species. Other marina mammal species that seasonally inhabit the Beaufort Sea, but are not anticipated to occur in the project area during the proposed R&D program, include bowhead whales and beluga whales (*Delphinapterus leucas*). SOI will seek a take Authorization from the U.S. Fish and Wildlife Service (USFWS) for the incidental taking of polar bears because USFWS has management authority for this species. A detailed description of these species can be found in Angliss and Outlaw (2005), which is available at the following URL: *http://www.nmfs.noaa.gov/pr/pdfs/sars/ak2005.pdf*. A more detailed description of these species and stocks within the proposed action area provided in the February 6, 2007, **Federal Register** (72 FR 5421). Therefore, it is not repeated here.

Potential Effects on Marine Mammals and Their Habitat

Seismic surveys using acoustic energy, such as airguns and weigh drop impact sources, may have the potential to adversely impact marine mammals in the vicinity of the activities (Gordon *et al.*, 2004). The sound source level of the GL airgun to be used in the proposed project is 228 dB re: 1 microPa at 1 m, which is strong enough to cause hearing threshold shift (TS) in pinnipeds when exposed for an extended duration (Kastak et al., 1999).

However, it is extremely unlikely that any animals would be exposed to a sound pressure level (SPL) of this magnitude since acoustic energy is attenuated as it propagates through the water column. Preliminary results of the acoustic modeling, which did not take the ice effects into consideration, shows that the received sound pressure levels (SPLs) dropped down to 190, 180, and 160 dB re: 1 microPa root mean square (RMS) at distances of 120 m (394 ft), 330

m (1,083 ft), and 2.22 km (1.38 mi), respectively. However, with the sea ice dampening effects, actual received SPLs at these distances are expected to be lower (Richardson *et al.*, 1995). In addition, most acoustic energy from an airgun is directed downward, and the short duration of each pulse limits the total energy (Richardson et al., 1995).

Intense acoustic signals from seismic surveys are also known to cause behavioral alteration in marine mammals such as reduced vocalization rates (Goold, 1996), avoidance (Malme *et al.*, 1986, 1988; Richardson *et al.*, 1995; Harris *et al.*, 2001), and changes in blow rates (Richardson *et al.*, 1995) in several marine mammal species. One controlled exposure experiment using small airguns (source level: 215 224 dB re: 1 microPa peak-to-peak (p-p)) was conducted on harbor seals (*Phoca vitulina*) and gray seals (*Halichoerus grypus*) that had been fitted with telemetry devices showed fright responses in two harbor seals when playback started (Thompson *et al.*, 1998). Their heart rate dropped dramatically from 35 45 beats/min to 5 10 beats/min. However, these responses were short-lived and following a typical surfacing tachycardia; there were no further dramatic drops in heart rate. Harbor seals showed strong avoidance behavior, swimming rapidly away from the source. Stomach temperature tags revealed that they ceased feeding during this time. Only one seal showed no detectable response to the airguns and approached to within 300 m (984 ft) of the sound source. The behavior of harbor seals seemed to return to normal soon after the end of each trial. Similar avoidance responses were also documented in gray seals. By contrast, sighting rates of ringed seals from a seismic vessel in shallow Arctic waters showed no difference between periods with the full array, partial array, or no airguns firing (Harris *et al.*, 2001).

Incidental harassment to marine mammals could also result from physical activities associated with on-ice seismic operations, which have the potential to disturb and temporarily displace some seals. Pup mortality could occur if any of these animals were nursing and displacement were protracted. However, it is unlikely that a nursing female would abandon her pup given the normal levels of disturbance from the proposed activities, potential predators, and the typical movement patterns of ringed seal pups among different holes. Seals also use as many as four lairs spaced as far as 3,437 m (11,276 ft) apart. In addition, seals have multiple breathing holes. Pups may use more holes than adults, but the holes are generally closer together than those used by adults. This indicates that adult seals and pups can move away from seismic activities, particularly since the seismic equipment does not remain in any specific area for a prolonged time. Given those considerations, combined with the small proportion of the population potentially disturbed by the proposed activity, impacts are expected to be negligible for the ringed, bearded, and spotted seal populations.

The seismic surveys would only introduce acoustic energy into the water column and no objects would be released into the environment. In addition, the total footprint of the proposed seismic survey area covers approximately 16 km2 (6.2 mi2), which represents only a small fraction of the Beaufort Sea pinniped habitat. Sea-ice surface rehabilitation is often immediate, occurring during the first episode of snow and wind that follows passage of the equipment over the ice.

There is a relative lack of knowledge about the potential impacts of seismic energy on marine fish and invertebrates. Available data suggest that there may be physical impacts on eggs and on larval, juvenile, and adult stages of fish at very close range (within meters) to seismic energy source. Considering typical source levels associated with seismic arrays, close proximity to the source would result in exposure to very high energy levels. Where eggs and larval stages are not able to escape such exposures, juvenile and adult fish most likely would avoid them. In the cases of eggs and larvae, it is likely that the numbers adversely affected by such exposure would be very small in relation to natural mortality. Studies on fish confined in cages that were exposed under intense sound for extended period showed physical or physiological impacts (Scholik and Yan, 2001; 2002; McCauley *et al.*, 2003; Smith *et al.*, 2004). While limited data on seismic surveys regarding physiological effects on fish indicate that impacts are short-term and are most apparent after exposure at very close range (McCauley *et al.*, 2000a; 2000b; Dalen *et al.*, 1996), other studies have demonstrated that seismic guns had little effect on the day-to-day behavior of marine fish and invertebrates (Knudsen *et al.*, 1992; Wardle *et al.*, 2001). It is more likely that fish will swim away upon hearing the seismic impulses (Engas *et al.*, 1996).

Limited studies on physiological effects on marine invertebrates showed that no significant adverse effects from seismic energy were detected for Squid and cuttlefish (McCauley *et al.*, 2000) or in snow crabs (Christian *et al.*, 2003).

Based on the foregoing discussion, NMFS finds preliminarily that the proposed seismic surveys would not cause any permanent impact on the physical habitats and marine mammal prey species in the proposed project area.

Number of Marine Mammals Expected to Be Taken

NMFS estimates that up to 30 ringed seals and much fewer bearded and spotted seals could be taken by Level B harassment as a result of the proposed on-ice geophysical R&D program. The estimate take number is based on consideration of the number of ringed seals that might be disturbed within the 16 km^2 proposed project area plus up to 13 km (8 mi) travel route from camp site to work site (travel route is estimated to be 0.1 km wide), calculated from the adjusted ringed seal density of 1.73 seal per km^2 (Kelly and Quakenbush, 1990). This number represents approximately 0.17 percent of the total ringed seal population (estimated at 18,000) for the Beaufort Sea (Angliss and Outlaw, 2005).

Due to the unavailability of reliable bearded and spotted seals densities within the proposed project area, NMFS is unable to estimate take numbers for these two species. However, it is expected much fewer bearded and spotted seals would subject to takes by Level B harassment since their occurrence is much lower within the proposed project area, especially during spring (Moulton and Lawson, 2002; Treacy, 2002a; 2002b; Bengtson et al., 2005). Consequently, the levels of take of these 2 pinniped species by Level B harassment within the proposed project area would represent only small fractions of the total population sizes of these species in Beaufort Sea.

In addition, NMFS expected that the actual take of Level B harassment by the proposed geophysical program would be much lower with the implementation of the proposed mitigation and monitoring measures discussed below. Therefore, NMFS believes that any potential impacts to ringed, bearded, and spotted seals to the proposed on-ice geophysical seismic program would be insignificant, and would be limited to distant and transient exposure.

Potential Effects on Subsistence

Residents of the village of Nuiqsut are the primary subsistence users in the activity area. The subsistence harvest during winter and spring is primarily ringed seals, but during the open-water period both ringed and bearded seals are

taken. Nuiqsut hunters may hunt year round; however, most of the harvest has been in open water instead of the more difficult hunting of seals at holes and lairs (McLaren, 1958; Nelson, 1969). Subsistence patterns may be reflected through the harvest data collected in 1992, when Nuiqsut hunters harvested 22 of 24 ringed seals and all 16 bearded seals during the open water season from July to October (Fuller and George, 1997). Harvest data for 1994 and 1995 show 17 of 23 ringed seals were taken from June to August, while there was no record of bearded seals being harvested during these years (Brower and Opie, 1997). Only a small number of ringed seals was harvested during the winter to early spring period, which corresponds to the time of the proposed on-ice seismic operations.

Based on harvest patterns and other factors, on-ice seismic operations in the activity area are not expected to have an unmitigable adverse impact on subsistence uses of ringed and bearded seals because:

(1) Operations would end before the spring ice breakup, after which subsistence hunters harvest most of their seals.

(2) The area where seismic operations would be conducted is small compared to the large Beaufort Sea subsistence hunting area associated with the extremely wide distribution of ringed seals.

In order to ensure the least practicable adverse impact on the species and the subsistence use of ringed seals, SOI has notified and provided the affected subsistence community with a draft plan of cooperation. SOI held community meeting with the affected Beaufort Sea communities in mid-October 2006 and held meetings again in early 2007 to discuss proposed activities and to resolve potential conflicts regarding any aspects of either the operation or the plan of cooperation.

Mitigation and Monitoring

The following mitigation and monitoring measures are required for the subject on-ice seismic surveys. All activities shall be conducted as far as practicable from any observed ringed seal lair and no energy source will be placed over a seal lair.

To further reduce potential impact to pinniped habitat, no ice road will be built between the mobile camp and work site. Travel between mobile camp and work site will be done by vehicles driving through snow road, which is about 4 - 8 mi (6 - 13 km) depending on camp location.

SOI will employ trained seal lair sniffing dogs to locate seal structures under snow (subnivean) in the proposed work area and camp site before the seismic program begins. The recommended prospective area for the proposed project will be surveys for the subnivean seal structures using 3 trained dogs running together. Transects will be spaced 250 m (820 ft) apart and oriented 90o to the prevailing wind direction. The search tracks of the dogs will be recorded by GPS units on the dogs and the tracks will be downloaded daily. Subnivean structures located will be probed by steel rod to check if each is open (active), or frozen (abandoned). Structures will be categorized by size, structure and odor to ascertain whether the structure is a birth lair, resting lair, resting lair of rutting male seals, or a breathing hole. Locations of seal structures will be marked and monitored and adjustment to the seismic operation will be made to avoid the lairs.

SOI will also use trained dogs to survey the snow road and establish a route where no seal structure presents. The surveyed road will be entered into GPS and flagged for vehicles to follow.

Vehicles must avoid any pressure ridges, ice ridges, and ice deformation areas where seal structures are likely to be present.

Seismic sources for the program will be recorded into 5 sensor groups: analog surface receivers, digital surface receivers, hydrophones in the water column, and 3 different types of 4–component ocean bottom sensors on the seafloor. Each source will be recorded into the 5 receiver groups. Water column monitoring of SPLs will be most directly accomplished by monitoring SPLs from the hydrophones. Density of receivers is very high, with spacing of 5 m (16.4 ft), so a detailed characterization of the SPLs can be accomplished. A range of receiver offsets will be available up to the maximum program offset of 4,000 m (13,123 ft). Additionally, the surface and ocean bottom censors can be used as supplemental information in the determination of source levels and propagation distances for the experiment.

A 500–m (1,640–ft) exclusion zone will be established around all located active subnivean seal structures, within which no seismic or impact surveys will be conducted. During active seismic and impact source testing an on-ice 500–m (1,640–ft) safety zone will be established. The size of the safety zone shall then be adjusted to match the 190 dB *re:* 1 microPa rms isopleth based on seismic source monitoring. On ice monitoring must be conducted by a trained, NMFS-approved marine mammal observer (MMO) for entry by any marine mammal. No seismic or impact surveys will be conducted if a marine mammal is observed entering the monitored safety zone.

To further reduce the potential impacts to marine mammals, SOI must implement soft-start (ramp-up) procedure when starting operations of the airgun or impact sources. Airgun and impact sources will be initiated at 50 percent of its full level and slowly (not more than 6 dB per 5 minutes) increase their power to full capacity.

Reporting

A final report must be submitted to NMFS within 90 days of completing the project.The report must contain detailed description of any marine mammal, by species, number, age class, and sex if possible, that is sighted in the vicinity of the proposed project area; location and time of the animal sighted; whether the animal exhibits a behavioral reaction to any on-ice activities or is injured or killed; and the context of the behavior change.

Endangered Species Act (ESA)

NMFS has determined that no species listed as threatened or endangered under the ESA will be affected by issuing an incidental harassment authorization under section 101(a)(5)(D) of the MMPA to SOI for the proposed on-ice seismic survey.

National Environmental Policy Act (NEPA)

The information provided in the EA on the *Proposed OCS Lease Sale 202 Beaufort Sea Planning Area* by the MMS in August 2006 led NMFS to conclude that implementation of either the preferred alternative or other alternatives identified in the EA would not have a significant impact on the human environment. Therefore, an Environmental Impact Statement was not prepared. The proposed action discussed in this document is not substantially different from the 2006 actions, and a reference search has indicated that no significant new scientific information or analyses have been developed that would warrant new NEPA documentation. NMFS has prepared a Finding of No Significant Impact statement.

Determinations

For the reasons discussed in this document and in the identified supporting documents, NMFS has determined that the impact of the on-ice seismic R&D program would result, at worst, in the Level B harassment of small numbers of ringed seals, and that such taking will have no more than a

negligible impact on this species. In addition, NMFS has determined that bearded and spotted seals, if present within the vicinity of the project area could also be taken incidentally, by no more than Level B harassment and that such taking would have a negligible impact on such species or stocks. Although there is not a specfic number assessed for the taking of bearded and spotted seals due to their rare occurrence in the project area, NMFS believes that any take would be significantly lower than those of ringed seals. NMFS also finds that the action will not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence uses.

In addition, no take by Level A harassment (injury) or death is anticipated or authorized, and harassment takes should be at the lowest level practicable due to incorporation of the mitigation measures described in this document.

Authorization

NMFS has issued an IHA to SOI for the potential Level B harassment of small number of ringed seals, and potential Level B harassment of bearded and spotted seals incidental to conducting on-ice seismic R&D program in the U.S. Beaufort Sea, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: March 30, 2007.

Angela Somma,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040307B]

Small Takes of Marine Mammals Incidental to Specified Activities; Low-Energy Marine Seismic Survey in the Northeastern Indian Ocean, May-August 2007

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

ACTION: Notice; proposed incidental take authorization; request for comments.

SUMMARY: NMFS has received an application from Scripps Institute of Oceanography (SIO) for an Incidental Harassment Authorization (IHA) to take marine mammals incidental to conducting a low-energy marine seismic survey in the northeastern Indian Ocean during May-August 2007. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to SIO to incidentally take, by Level B harassment only, several species of marine mammals during the aforementioned activity.

DATES: Comments and information must be received no later than May 10, 2007.

ADDRESSES: Comments on the application should be addressed to Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing email comments is PR1.040307B@noaa.gov. NMFS is not responsible for e-mail comments sent to addresses other than the one provided here. Comments sent via e-mail, including all attachments, must not exceed a 10–megabyte file size.

A copy of the application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*.

Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Jolie Harrison, Office of Protected Resources, NMFS, (301) 713–2289, ext 166.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either approve or deny the authorization.

Summary of Request

On January 5, 2007, NMFS received an application from SIO for the taking, by Level B harassment only, of 32 species of marine mammals incidental to conducting, with research funding from the National Science Foundation (NSF), a low-energy marine seismic survey in the northeastern Indian Ocean from May-August 2007. The purpose of the research program is to conduct a scientific rock-dredging, magnetic, bathymetric, and seismic survey program at nine sites on the Ninety East Ridge in the northeastern Indian Ocean. The results will be used to (1) determine the morphology, structure, and tectonics of ridge volcanoes to see whether they reflect centralized (plume) or distributed (crack) eruptions; (2) infer the magmatic evolution of the ridge, whether it fits the plume hypothesis, and its connection to existing hotspots; (3) examine the duration of volcanism at the various sites and along the ridge to see whether the age progression fits the simple plume model; and (4) survey broad characteristics of subseafloor in

order to refine the planning of the IODP drilling proposal. Included in the research planned for 2007 are scientific rock dredging at all nine sites, high-resolution seismic methods to image the subsea floor at five of the sites, and the use of a magnetometer, gravimeter, multi-beam sonar, and sub-bottom profiler throughout the cruise.

Description of the Activity

The seismic surveys will involve one vessel, the *R/V Roger Revelle* (*Roger Revelle*), which is scheduled to depart from Fremantle, Australia, between May 22 and June 19, 2007. The *Roger Revelle* will conduct the cruise in the Indian Ocean and arrive at Colombo, Sri Lanka, between July 16 and August 13, 2007. The exact dates of the activities may vary by a few days because of weather conditions, repositioning, streamer operations and adjustments, airgun deployment, or the need to repeat some lines if data quality is substandard. Additional seismic operations may be occasionally needed to investigate significant new findings as revealed by the other survey systems. The overall area within which the seismic surveys will occur is located between approximately 5° N. and 25° S., along approximately 90o E. (Figure 1 in the application), in the Indian Ocean. The surveys will be conducted entirely in International Waters.

The *Roger Revelle* will deploy a pair of low-energy Generator-Injector (GI) airguns as an energy source (each with a discharge volume of 45 in^3), plus a 800 m-long (2625–ft long), 48–channel, towed hydrophone. The program will consist of approximately 2700 km (1678 mi) of surveys, including turns. Water depths within the seismic survey areas are 1600–5100 m (1750–5577 yd). The GI guns will be operated on a small grid for approximately 49 hours at each of 5 sites over a approximately 50–day period during May-August 2007, commencing between May 22 and June 19. There will be additional seismic operations associated with equipment testing, start-up, and repeat coverage of any areas where initial data quality is sub-standard.

In addition to the operations of the GI guns, a 3.5–kHz sub-bottom profiler , a Kongsberg-Simrad EM–120 multi-beam sonar, and a gravimeter will be used continuously throughout the cruise, and passive geophysical sensors will be deployed to conduct magnetic surveys at all times except during dredging.

Vessel Specifications

The *Roger Revelle* has a length of 83 m (272 ft), a beam of 16 m (52 ft), and a maximum draft of 5.2 m. The ship is powered by two 3,000 hp Propulsion General Electric motors and an 1180–hp Azimuthing jet bow thruster. An operation speed of 11.1 km/h (6 knots) is used during seismic acquisition. When not towing seismic survey gear, the *Roger Revelle* cruises at 22.2–23.1 km/h (12–12.5 knots) and has a maximum speed of 27.8 km/h (15 knots). It has a normal operating range of approximately 27,780 km (17,262 mi).

Acoustic Source Specifications

Seismic Airguns

The vessel *Roger Revelle* will tow a pair of GI airguns and an 800 m-long (2624–ft), 48–channel hydrophone streamer. Seismic pulses will be emitted at intervals of 6–10 seconds, which corresponds to a shot interval of approximatley 18.5–31 m (61–102 ft) (at a speed of 6 knots (11.1 km/h). The generator chamber of each GI gun, the one responsible for introducing the sound pulse into the ocean, is 45 in^3 (total air discharge approximately 90 in^3). The larger (105 in^3) injector chamber injects air into the previously-generated bubble to maintain its shape, and does not introduce more sound into the water. The two 45 in^3 GI guns will be towed 8 m (26 ft) apart side by side, 21 m (69 ft) behind the *Roger Revelle*, at a depth of 2 m (6.6 ft). The dominant frequency components are 0–188 Hz.

The sound pressure field of that GI gun variation has not been modeled, but that for two 45 in^3 Nucleus G guns (which actually have more energy than GI guns of the same size) has been modeled by the Lamont-Doherty Earth Observatory (L-DEO) in relation to distance and direction from the airguns. This source, which is directed downward, was found to have an output (0–peak) of 230.6 dB re 1 µPa m. The nominal downward-directed source levels indicated above do not represent actual sound levels that can be measured at any location in the water. Rather, they represent the level that would be found 1 m from a hypothetical point source emitting the same total amount of sound as is emitted by the combined GI guns. The actual received level at any location in the water near the GI guns will not exceed the source level of the strongest individual source. In this case, that will be about 224.6 dB re 1 µPa-m peak, or 229.8 dB re 1 µPa-m peak-to-peak. Actual levels experienced by any organism more than 1 m from either GI gun will be significantly lower.

A further consideration is that the rms (root mean square) received levels that are used as impact criteria for marine mammals are not directly comparable to the peak or peak to peak values normally used to characterize source levels of airgun arrays. The measurement units used to describe airgun sources, peak or peak-to-peak decibels, are always higher than the ''root mean square'' (rms) decibels referred to in biological literature. A measured received level of 160 dB rms in the far field would typically correspond to a peak measurement of approximately 170 to 172 dB, and to a peak-to-peak measurement of approximately 176 to 178 dB, as measured for the same pulse received at the same location (Greene 1997; McCauley *et al.*, 1998, 2000). The precise difference between rms and peak or peak-to-peak values depends on the frequency content and duration of the pulse, among other factors. However, the rms level is always lower than the peak or peak-to-peak level for an airgun-type source.

Bathymetric Sonar

The *Roger Revelle* will utilize the Kongsberg-Simrad EM120 multi-beam sonar, which operates at 11.25–12.6 kHz and is mounted in the hull. It operates in several modes, depending on water depth. In the proposed survey, it will be used in deep (>800–m (2625 ft)) water, and will operate in ''Deep'' mode. The beam width is 1° or 2° fore-aft and a total of 150° athwartship. Estimated maximum source levels are 239 and 233 dB at 1° and 2° beam widths, respectively. Each ''ping'' consists of nine successive fan-shaped transmissions, each ensonifying a sector that extends 1° or 2° fore-aft. In the ''Deep'' mode, the total duration of the transmission into each sector is 15 ms. The nine successive transmissions span an overall cross-track angular extent of about 150 degrees, with 16 ms gaps between the pulses for successive sectors. A receiver in the overlap area between two sectors would receive two 15–ms pulses separated by a 16–ms gap. The ''ping'' interval varies with water depth, from approximately 5 s at 1000 m (3280 ft) to 20 s at 4000 m (13120 ft).

Sub-bottom Profiler

The *Roger Revelle* will utilize the Knudsen Engineering Model 320BR sub-bottom profiler, which is a dual-frequency transceiver designed to operate at 3.5 and/or 12 kHz. It is used in conjunction with the multi-beam sonar to provide data about the sedimentary features that occur below the sea floor. The energy from the sub-bottom profiler is directed downward (in an 80–degree cone) via a 3.5–kHz transducer array mounted in the hull. The maximum power output of the

320BR is 10 kilowatts for the 3.5–kHz section and 2 kilowatts for the 12–kHz section. (The 12–kHz section is seldom used in survey mode on *Roger Revelle* because of overlap with the operating frequency of the Kongsberg Simrad EM–120 multi-beam sonar.)

The pulse length for the 3.5 kHz section of the 320BR is 0.8–24 ms, controlled by the system operator in regards to water depth and reflectivity of the bottom sediments, and will usually be 12 or 24 ms in this survey. The system produces one sound pulse and then waits for its return before transmitting again. Thus, the pulse interval is directly dependent upon water depth, and in this survey is 4.5–8 sec. Using the Sonar Equations and assuming 100 percent efficiency in the system (impractical in real world applications), the source level for the 320BR is calculated to be 211 dB re 1 µPa-m. In practice, the system is rarely operated above 80 percent power level.

Safety Radii

NMFS has determined that for acoustic effects, using acoustic thresholds in combination with corresponding safety radii is the most effective way to consistently apply measures to avoid or minimize the impacts of an action, and to quantitatively estimate the effects of an action. Thresholds are used in two ways: (1) to establish a mitigation shut-down or power down zone, i.e., if an animal enters an area calculated to be ensonified above the level of an established threshold, a sound source is powered down or shut down; and (2) to calculate take, in that a model may be used to calculate the area around the sound source that will be ensonified to that level or above, then, based on the estimated density of animals and the distance that the sound source moves, NMFS can estimate the number of marine mammals that may be ''taken''. NMFS believes that to avoid permanent physiological damage (Level A Harassment), cetaceans and pinnipeds should not be exposed to pulsed underwater noise at received levels exceeding, respectively, 180 and 190 dB re 1 µPa (rms). NMFS also assumes that cetaceans or pinnipeds exposed to levels exceeding 160 dB re 1 µPa (rms) may experience Level B Harassment.

Received sound levels have been modeled by L-DEO for a number of airgun configurations, including two 45–in^3 Nucleus G-guns, in relation to distance and direction from the airguns. The model does not allow for bottom interactions, and is most directly applicable to deep water. Based on the modeling, estimates of the maximum distances from the GI guns where sound levels of 190, 180, and 160 dB re 1 µPa (rms) are predicted to be received in deep (≤1000–m (3280–ft)) water are 10, 40, and 400 m (33, 131, and 1312 ft), respectively. Because the model results are for G guns, which have more energy than GI guns of the same size, those distances are overestimates of the distances for the 45–in^3 GI guns.

Empirical data concerning the 180- and 160- dB distances have been acquired based on measurements during the acoustic verification study conducted by L-DEO in the northern Gulf of Mexico from 27 May to 3 June 2003 (Tolstoy *et al.*, 2004). Although the results are limited, the data showed that radii around the airguns where the received level would be 180 dB re 1 µPa (rms) vary with water depth. Similar depth-related variation is likely in the 190–dB distances applicable to pinnipeds. Correction factors were developed for water depths 100–1000 m (328–3280 ft) and <100 m (328 ft). The proposed survey will occur in depths 1600–5100 m (5249–16732 ft), so the correction factors are not relevant here.

The empirical data indicate that, for deep water (>1000 m (3280 ft)), the L-DEO model tends to overestimate the received sound levels at a given distance (Tolstoy *et al.*, 2004). However, to be precautionary pending acquisition of additional empirical data, it is proposed that safety radii during airgun operations in deep water will be the values predicted by L-DEO's model (above). Therefore, the assumed 180- and 190–dB radii are 40 m and 10 m (131 and 33 ft), respectively.

Airguns will be shut down immediately when cetaceans or pinnipeds are detected within or about to enter the appropriate 180–dB (rms) or 190–dB (rms) radius, respectively.

Description of Marine Mammals in the Activity Area

Thirty-two species of cetacean, including 25 odontocete (dolphins and small and large toothed whales) species and seven mysticete (baleen whales) species, are thought to occur in the proposed seismic survey areas along the Ninety East Ridge in the northeastern Indian Ocean (Table 1). Several are listed under the U.S. Endangered Species Act (ESA) as Endangered: the sperm whale, humpback whale, blue whale, fin whale, and sei whale.

Although there have been several surveys of marine mammals in the Indian Ocean (e.g., Keller *et al.*, 1982; Leatherwood *et al.*, 1984; Eyre 1995; Baldwin *et al.*, 1998; de Boer 2000; de Boer *et al.*, 2003), data on the occurrence, distribution, and abundance of odontocetes and mysticetes in the northeastern Indian Ocean, encompassing the proposed seismic survey area along the Ninety East Ridge, are limited or lacking. Commercial whaling severely depleted all the large whale populations in this region, and subsequently, in 1979, the International Whaling Commission declared the Indian Ocean north of 55° S. latitude a whale sanctuary. The majority of recent detailed information on whales within the Indian Ocean Sanctuary (IOS) comes from

(1) A United Nations Environment Programme (UNEP) Report summarizing cetacean research in the western IOS (Leatherwood and Donovan 1991);

(2) A compilation of sightings for the entire IOS produced by the Whale and Dolphin Conservation Society (de Boer *et al.*, 2003); and

(3) A review of marine mammals records in India (Sathasivam 2004); and

(4) A series of research cruises within the IOS (Keller *et al.*, 1982; Leatherwood *et al.*, 1984; Corbett 1994; Eyre 1995; Ballance and Pitman 1998; de Boer 2000).

Because the proposed survey area spans such a wide range of latitudes (approximately 5° N.-25° S.), tropical and temperate species are found there. The survey area is all in deep-water habitat but is close to oceanic island habitats (i.e., Andaman, Nicobar, and Cocos (Keeling) Islands), so both coastal and oceanic species might be encountered, although species that stay in very shallow water (e.g., Indian hump-backed dolphin, Irrawaddy dolphin, and finless porpoise) would not. Abundance and density estimates of cetaceans found in areas other than the northeastern and central Indian Ocean are provided for reference only, and are not necessarily the same as those in the survey area. Table 1 also shows the estimated abundance of the marine mammals likely to be encountered during the *Roger Revelle*'s cruise. Additional information regarding the distribution of these species and how the estimated densities were calculated may be found in SIO's application.

Species	Habitat	Occurrence	Rqstd Take
Mysticetes			
Humpback whale (Megaptera novaeangliae)*	Mainly nearshore waters and banks	Common	5(0)**
Minke whale (Balaenoptera acutorostrata)	Pelagic and coastal	Uncommon	5
Antarctic minke whale (Balaenoptera bonaerensis)	Coastal and oceanic	Uncommon	5
Bryde's whale (Balaenoptera edeni)	Pelagic and coastal	Very common	5
Sei whale (Balaenoptera borealis) *	Primarily offshore, pelagic	Uncommon	5(0)**
Fin whale (Balaenoptera physalus)*	Continental slope, mostly pelagic	Common	5(0)**
Blue whale (Balaenoptera musculus)*	Pelagic and coastal	Very common	5(1)**
Odontocetes			
Sperm whale (Physeter macrocephalus)*	Usually pelagic and deep seas	Common	5(1)**
Pygmy sperm whale (Kogia breviceps)	Deep waters off the shelf	Common	5
Dwarf sperm whale (Kogia sima)	Deep waters off the shelf	Common	5
Cuvier's beaked whale (Ziphius cavirostris)	Pelagic	Common	5
Shepherd's beaked whale (Tasmacetus shepherdi))	Pelagic	Rare	5
Longman's beaked whale (Indopacetus pacificus)	Pelagic	Common?	1
Southern bottlenose whale (Hyperoodon planifrons)	Pelagic	Uncommon	5
True's beaked whale (Mesoplodon mirus)	Pelagic	Rare	5
Gray's beaked whale (Mesoplodon grayi)	Pelagic	Uncommon	5
Ginkgo-toothed whale (Mesoplodon ginkgodens)	Pelagic	Common	5
Blainville's beaked whale (Mesoplodon densirostris)	Pelagic	Very common	5
Rough-toothed dolphin (Steno bredanensis)	Deep water	Uncommon	69
Bottlenose dolphin (Tursiops truncatus)	Coastal and oceanic, shelf break	Common	129
Pantropical spotted dolphin (Stenella attenuata)	Coastal and pelagic	Uncommon	65
Spinner dolphin (Stenella longirostris)	Coastal and pelagic	Abundant	215
Striped dolphin (Stenella coeruleoalba)	Off continental shelf	Common	86
Fraser's dolphin (Lagenodelphis hosei)	Waters >1000 m	Rare	22
Common dolphin (Delphinus delphis)	Shelf and pelagic, seamounts	Very common	151
Risso's dolphin (Grampus griseus)	Waters >1000 m, seamounts	Very common	151
Melon-headed whale (Peponocephala electra)	Oceanic	Very common	50
Pygmy killer whale (Feresa attenuata)	Deep, pantropical waters	Common	25
False killer whale (Pseudorca crassidens)	Pelagic	Common	15
Killer whale (Orcinus orca)	Widely distributed	Common	5
Long-finned pilot whale (Globicephala melas)	Mostly pelagic	Rare	30

Species	Habitat	Occurrence	Rqstd Take
Short-finned pilot whale (Globicephala macrorhynchus)	Mostly pelagic, high-relief topography	Very common	15

Table 1. Species expected to be encountered (and potentially harassed) during SIO's Indian Ocean cruise
*Species are listed as endangered under the Endangered Species Act
**Parenthetical numbers represent numbers of takes NMFS proposes to authorize (we may not authorize take ofspecies, or take of numbers of species, that we are not exempted pursuant to our internal ESA consultation)

Potential Effects on Marine Mammals

Potential Effects of Airguns

The effects of sounds from airguns might include one or more of the following: tolerance, masking of natural sounds, behavioral disturbance, and temporary or permanent hearing impairment (Richardson *et al.*, 1995). Given the small size of the GI guns planned for the present project, effects are anticipated to be considerably less than would be the case with a large array of airguns. It is very unlikely that there would be any cases of temporary or, especially, permanent hearing impairment. Also, behavioral disturbance is expected to be limited to relatively short distances.

Tolerance

Numerous studies have shown that pulsed sounds from airguns are often readily detectable in the water at distances of many kilometers. For a summary of the characteristics of airgun pulses, see Appendix A of SIO's application. However, it should be noted that most of the measurements of airgun sounds that have been reported concerned sounds from larger arrays of airguns, whose sounds would be detectable considerably farther away than the GI guns planned for use in the present project.

Numerous studies have shown that marine mammals at distances more than a few kilometers from operating seismic vessels often show no apparent response-see Appendix A (e) of SIO's application. That is often true even in cases when the pulsed sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. Although various baleen whales, toothed whales, and (less frequently) pinnipeds have been shown to react behaviorally to airgun pulses under some conditions, at other times mammals of all three types have shown no overt reactions. In general, pinnipeds and small odontocetes seem to be more tolerant of exposure to airgun pulses than are baleen whales. Given the relatively small and low-energy airgun source planned for use in this project, mammals (and sea turtles) are expected to tolerate being closer to this source than might be the case for a larger airgun source typical of most seismic surveys.

Masking

Masking effects of pulsed sounds (even from large arrays of airguns) on marine mammal calls and other natural sounds are expected to be limited, although there are very few specific data on this. Some whales are known to continue calling in the presence of seismic pulses. Their calls can be heard between the seismic pulses (e.g., Richardson *et al.*, 1986; McDonald *et al.*, 1995; Greene *et al.*, 1999; Nieukirk *et al.*, 2004). Although there has been one report that sperm whales cease calling when exposed to pulses from a very distant seismic ship (Bowles *et al.*, 1994), a recent study reports that sperm whales off northern Norway continued calling in the presence of seismic pulses (Madsen *et al.*, 2002c). That has also been shown during recent work in the Gulf of Mexico (Tyack *et al.*, 2003). Given the small source planned for use here, there is even less potential for masking of baleen or sperm whale calls during the present study than in most seismic surveys. Masking effects of seismic pulses are expected to be negligible in the case of the smaller odontocete cetaceans, given the intermittent nature of seismic pulses and the relatively low source level of the airguns to be used here. Also, the sounds important to small odontocetes are predominantly at much higher frequencies than are airgun sounds. Masking effects, in general, are discussed further in Appendix A (d) of SIO's application.

Disturbance Reactions

Disturbance includes a variety of effects, including subtle changes in behavior, more conspicuous changes in activities, and displacement. Disturbance is one of the main concerns in this project. Reactions to sound, if any, depend on species, state of maturity, experience, current activity, reproductive state, time of day, and many other factors. If a marine mammal responds to an underwater sound by changing its behavior or moving a small distance, the response may or may not rise to the level of harassment, let alone affect the stock or the species as a whole. Alternatively, if a sound source displaces marine mammals from an important feeding or breeding area, effects on the stock or species could potentially be more than negligible. Given the many uncertainties in predicting the quantity and types of impacts of noise on marine mammals, it is common practice to estimate how many mammals are likely to be present within a particular distance of industrial activities, or exposed to a particular level of industrial sound. This practice potentially overestimates the numbers of marine mammals that are affected in some biologically important manner.

The sound criteria used to estimate how many marine mammals might be disturbed to some biologically-important degree by a seismic program are based on behavioral observations during studies of several species. However, information is lacking for many species. Detailed studies have been done on humpback, gray, and bowhead whales, and on ringed seals. Less detailed data are available for some other species of baleen whales, sperm whales, and small toothed whales. Most of those studies have focused on the impacts resulting from the use of much larger airgun sources than those planned for use in the present project. Thus, effects are expected to be limited to considerably smaller distances and shorter periods of exposure in the present project than in most of the previous work concerning marine mammal reactions to airguns.

Baleen Whales – Baleen whales generally tend to avoid operating airguns, but avoidance radii are quite variable. Whales are often reported to show no overt reactions to pulses from large arrays of airguns at distances beyond a few kilometers, even though the airgun pulses remain well above ambient noise levels out to much longer distances. However, as reviewed in Appendix A (e) of SIO's application, baleen whales exposed to strong noise pulses from airguns often react by deviating from their normal migration route and/or interrupting their feeding activities and moving away from the sound source. In the case of the migrating gray and bowhead whales, the observed changes in behavior appeared

to be of little or no biological consequence to the animals. They simply avoided the sound source by displacing their migration route to varying degrees, but within the natural boundaries of the migration corridors.

Studies of gray, bowhead, and humpback whales have determined that received levels of pulses in the 160–170 dB re 1 µPa rms range seem to cause obvious avoidance behavior in a substantial fraction of the animals exposed. In many areas, seismic pulses from large arrays of airguns diminish to those levels at distances ranging from 4.5–14.5 km (2.8–9 mi) from the source. A substantial proportion of the baleen whales within those distances may show avoidance or other strong disturbance reactions to the airgun array. Subtle behavioral changes sometimes become evident at somewhat lower received levels, and recent studies, reviewed in Appendix A (e) of SIO's application, have shown that some species of baleen whales, notably bowheads and humpbacks, at times show strong avoidance at received levels lower than 160–170 dB re 1 µPa rms. Reaction distances would be considerably smaller during the present project, in which the 160–dB radius is predicted to be approximately 0.40 km (0.9 mi), as compared with several kilometers when a large array of airguns is operating.

Humpback whales summering in southeast Alaska did not exhibit persistent avoidance when exposed to seismic pulses from a 1.64–L (100 in^3) airgun (Malme *et al.*, 1985). Some humpbacks seemed ''startled'' at received levels of 150–169 dB re 1 µPa on an approximate rms basis. Malme *et al.* (1985) concluded that there was no clear evidence of avoidance, despite the possibility of subtle effects, at received levels up to 172 re 1 µPa (approximately rms). More detailed information on responses of humpback whales to seismic pulses during studies in Australia can be found in Appendix A (a) of SIO's application.

Malme *et al.* (1986, 1988) studied the responses of feeding eastern gray whales to pulses from a single 100 in3 airgun off St. Lawrence Island in the northern Bering Sea. They estimated, based on small sample sizes, that 50 percent of feeding gray whales ceased feeding at an average received pressure level of 173 dB re 1 µPa on an (approximate) rms basis, and that 10 percent of feeding whales interrupted feeding at received levels of 163 dB. Those findings were generally consistent with the results of experiments conducted on larger numbers of gray whales that were migrating along the California coast.

Data on short-term reactions (or lack of reactions) of cetaceans to impulsive noises do not necessarily provide information about long-term effects. It is not known whether impulsive noises affect reproductive rate or distribution and habitat use in subsequent days or years. However, gray whales continued to migrate annually along the west coast of North America despite intermittent seismic exploration and much ship traffic in that area for decades (Appendix A in Malme *et al.*, 1984). Bowhead whales continued to travel to the eastern Beaufort Sea each summer despite seismic exploration in their summer and autumn range for many years (Richardson *et al.*, 1987). In any event, the brief exposures to sound pulses from the present small airgun source are highly unlikely to result in prolonged effects.

Toothed Whales – Little systematic information is available about reactions of toothed whales to noise pulses. Few studies similar to the more extensive baleen whale/seismic pulse work summarized above have been reported for toothed whales. However, systematic work on sperm whales is underway (Tyack *et al.*, 2003).

Seismic operators sometimes see dolphins and other small toothed whales near operating airgun arrays, but in general there seems to be a tendency for most delphinids to show some limited avoidance of seismic vessels operating large airgun systems. However, some dolphins seem to be attracted to the seismic vessel and floats, and some ride the bow wave of the seismic vessel even when large arrays of airguns are firing. Nonetheless, there have been indications that small toothed whales sometimes tend to head away, or to maintain a somewhat greater distance from the vessel, when a large array of airguns is operating than when it is silent (e.g., Goold, 1996; Calambokidis and Osmek, 1998; Stone, 2003). Similarly, captive bottlenose dolphins and beluga whales exhibit changes in behavior when exposed to strong pulsed sounds similar in duration to those typically used in seismic surveys (Finneran *et al.*, 2000, 2002). However, the animals tolerated high received levels of sound (pk-pk level >200 dB re 1 µPa) before exhibiting aversive behaviors. With the presently-planned small airgun system, such levels would only be found within a few meters of the airguns.

There are no specific data on the behavioral reactions of beaked whales to seismic surveys. A few beaked whale sightings have been reported from seismic vessels (Stone, 2003), however, based on limited observations most beaked whales tend to avoid approaching vessels of other types (e.g., Kasuya, 1986; Wursig *et al.*, 1998). Several beaked whale strandings have been associated with naval mid-frequency sonar exercises, however, the sounds produced by seismic airguns are quite different from tactical sonar (see Appendix A (g) of SIO's application). The strandings mentioned above are apparently at least in part a disturbance response, although auditory or other injuries may also be a factor. Whether beaked whales would ever react similarly to seismic surveys is unknown (see ''Strandings and Mortality'', below).

Sperm whales have been reported to show avoidance reactions to standard vessels not emitting airgun sounds, and it is to be expected that they would tend to avoid an operating seismic survey vessel. There were some limited early observations suggesting that sperm whales in the Southern Ocean and Gulf of Mexico might be fairly sensitive to airgun sounds from distant seismic surveys. However, more extensive data from recent studies in the North Atlantic suggest that sperm whales in those areas show little evidence of avoidance or behavioral disruption in the presence of operating seismic vessels (McCall Howard, 1999; Madsen *et al.*, 2002c; Stone, 2003).

Odontocete reactions to large arrays of airguns are variable and, at least for small odontocetes, seem to be confined to a smaller radius than has been observed for mysticetes. Thus, behavioral reactions of odontocetes to the small airgun source to be used here are expected to be very localized, probably to distances <0.40 km (.25 mi).

Pinnipeds – Pinnipeds are not likely to show a strong avoidance reaction to the small airgun source that will be used. Visual monitoring from seismic vessels, usually employing larger sources, has shown only slight (if any) avoidance of airguns by pinnipeds, and only slight (if any) changes in behavior-see Appendix A (e) of SIO's application. Those studies show that pinnipeds frequently do not avoid the area within a few hundred meters of operating airgun arrays, even for arrays much larger than the one to be used here (e.g., Harris *et al.*, 2001). However, initial telemetry work suggests that avoidance and other behavioral reactions to small airgun sources may be stronger than evident to date from visual studies of pinniped reactions to airguns (Thompson *et al.*, 1998). Even if reactions of the species occurring in the present study area are as strong as those evident in the telemetry study, reactions are expected to be confined to relatively

small distances and durations, with no long-term effects on pinnipeds.

Additional details on the behavioral reactions (or the lack thereof) by all types of marine mammals to seismic vessels can be found in Appendix A (e) of SIO's application.

Hearing Impairment and Other Physical Effects

Temporary or permanent hearing impairment is a possibility when marine mammals are exposed to very strong sounds, but there has been no specific documentation of this for marine mammals exposed to sequences of airgun pulses. Current NMFS policy regarding exposure of marine mammals to high-level sounds is that cetaceans and pinnipeds should not be exposed to impulsive sounds of 180 and 190 dB re 1 μPa (rms), respectively. Those criteria have been used in defining the safety (shut-down) radii planned for the proposed seismic survey. The precautionary nature of these criteria is discussed in Appendix A (f) of SIO's application, including the fact that the minimum sound level necessary to cause permanent hearing impairment is higher, by a variable and generally unknown amount, than the level that induces barely-detectable temporary threshold shift (TTS) (which NMFS' criteria are based on) and the level associated with the onset of TTS is often considered to be a level below which there is no danger of permanent damage. NMFS is presently developing new noise exposure criteria for marine mammals that take account of the now-available data on TTS in marine (and terrestrial) mammals.

Because of the small size of the airgun source in this project (two 45–in^3 GI guns), along with the planned monitoring and mitigation measures, there is little likelihood that any marine mammals will be exposed to sounds sufficiently strong to cause hearing impairment. Several aspects of the planned monitoring and mitigation measures for this project are designed to detect marine mammals occurring near the two GI airguns (and multi-beam bathymetric sonar), and to avoid exposing them to sound pulses that might, at least in theory, cause hearing impairment. In addition, many cetaceans are likely to show some avoidance of the area with high received levels of airgun sound (see above). In those cases, the avoidance responses of the animals themselves will reduce or (most likely) avoid any possibility of hearing impairment.

Non-auditory physical effects may also occur in marine mammals exposed to strong underwater pulsed sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage. It is possible that some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds. However, as discussed below, there is no definitive evidence that any of these effects occur even for marine mammals in close proximity to large arrays of airguns. It is especially unlikely that any effects of these types would occur during the present project given the small size of the source, the brief duration of exposure of any given mammal, and the planned monitoring and mitigation measures (see below). The following subsections discuss in somewhat more detail the possibilities of TTS, permanent threshold shift (PTS), and non-auditory physical effects.

Temporary Threshold Shift (TTS) – TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity recovers rapidly after exposure to the noise ends. Only a few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound.

For toothed whales exposed to single short pulses, the TTS threshold appears to be, to a first approximation, a function of the energy content of the pulse (Finneran *et al.*, 2002). Given the available data, the received level of a single seismic pulse might need to be approximately 210 dB re 1 μPa rms (approximately 221–226 dB pk-pk) in order to produce brief, mild TTS. Exposure to several seismic pulses at received levels near 200–205 dB (rms) might result in slight TTS in a small odontocete, assuming the TTS threshold is (to a first approximation) a function of the total received pulse energy. Seismic pulses with received levels of 200–205 dB or more are usually restricted to a radius of no more than 100 m (328 ft) around a seismic vessel operating a large array of airguns. Such levels would be limited to distances within a few meters of the small GI-gun source to be used in this project.

For baleen whales, there are no data, direct or indirect, on levels or properties of sound that are required to induce TTS. However, no cases of TTS are expected given the small size of the source, and, as mentioned previously, there is a strong likelihood that baleen whales would avoid the approaching GI gun (or vessel), with the sound source operating, before being exposed to levels high enough for there to be any possibility of TTS.

In pinnipeds, TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound have not been measured. Initial evidence from prolonged exposures suggested that some pinnipeds may incur TTS at somewhat lower received levels than do small odontocetes exposed for similar durations (Kastak *et al.*, 1999; Ketten *et al.*, 2001; cf. Au *et al.*, 2000). However, more recent indications are that TTS onset in the most sensitive pinniped species studied (harbor seal) may occur at a similar sound exposure level as in odontocetes (Kastak *et al.*, 2004).

A marine mammal within a radius of 100 m (328 ft) around a typical large array of operating airguns might be exposed to a few seismic pulses with levels of 205 dB, and possibly more pulses if the mammal moved with the seismic vessel. (As noted above, most cetacean species tend to avoid operating airguns, although not all individuals do so.) In addition, ramping up airgun arrays, which is standard operational protocol for large airgun arrays, provides an opportunity for cetaceans to move away from the seismic source and to avoid being exposed to the full acoustic output of the airgun array. However, several of the considerations that are relevant in assessing the impact of typical seismic surveys with arrays of airguns are not directly applicable here:

(1) The planned GI gun source is much smaller, with correspondingly smaller radii within which received sound levels could exceed any particular level of concern.

(2) With a large airgun array, it is unlikely that cetaceans would be exposed to airgun pulses at a sufficiently high level for a sufficiently long period to cause more than mild TTS, given the relative movement of the vessel and the marine mammal. In this project, the gun source is much smaller, so the radius of influence and duration of exposure to strong pulses is much smaller, especially in deep and intermediate-depth water.

(3) With a large array of airguns, TTS would be most likely in any odontocetes that bow-ride or otherwise linger near the airguns. In the present project, the

anticipated 180–dB distance in deep water is 40 m (131 ft), and the waterline at the bow of the *Roger Revelle* will be approximately 97 m (318 ft) ahead of the GI gun.

To avoid injury, NMFS has determined that cetaceans and pinnipeds should not be exposed to pulsed underwater noise at received levels exceeding, respectively, 180 and 190 dB re 1 µPa (rms). The predicted 180- and 190–dB distances for the GI guns operated by SIO are 40 m (131 ft) and 10 m (33 ft), respectively, in water depths >1000 m (3280 ft). [Those distances actually apply to operations with two 45–in^3 G guns, and smaller distances would be expected for the two 45–in^3 GI guns to be used here.] These sound levels are the received levels above which, in the view of a panel of bioacoustics specialists convened by NMFS, one cannot be certain that there will be no injurious effects, auditory or otherwise, to marine mammals. More recent TTS data imply that, at least for dolphins, TTS is unlikely to occur unless the dolphins are exposed to airgun pulses notably stronger than 180 dB re 1 µPa rms. However NMFS utilizes a precautionary approach of requiring shut down at received levels above which we cannot be certain there will be no injurious effects to the most sensitive species.

Permanent Threshold Shift (PTS) – When PTS occurs, there is physical damage to the sound receptors in the ear. In some cases, there can be total or partial deafness, while in other cases, the animal has an impaired ability to hear sounds in specific frequency ranges. There is no specific evidence that exposure to pulses of airgun sound can cause PTS in any marine mammal, even with large arrays of airguns. However, given the possibility that mammals close to an airgun array might incur TTS, there has been further speculation about the possibility that some individuals occurring very close to airguns might incur PTS. Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage in terrestrial mammals. Relationships between TTS and PTS thresholds have not been studied in marine mammals, but are assumed to be similar to those in humans and other terrestrial mammals. PTS might occur at a received sound level 20 dB or more above that inducing mild TTS if the animal were exposed to the strong sound for an extended period, or to a strong sound with rather rapid rise time-see Appendix A (f) of SIO's application.

It is highly unlikely that marine mammals could receive sounds strong enough to cause permanent hearing impairment during a project employing two 45–in^3 GI guns. In the present project, marine mammals are unlikely to be exposed to received levels of seismic pulses strong enough to cause TTS, as they would probably need to be within a few meters of the airguns for that to occur. Given the higher level of sound necessary to cause PTS, it is even less likely that PTS could occur. In fact, even the levels immediately adjacent to the airguns may not be sufficient to induce PTS, especially since a mammal would not be exposed to more than one strong pulse unless it swam immediately alongside an airgun for a period longer than the inter-pulse interval (6–10 s). Baleen whales generally avoid the immediate area around operating seismic vessels. The planned monitoring and mitigation measures, including visual monitoring, ramp ups, and shut downs of the airguns when mammals are seen within the ''safety radii'', will minimize the already-minimal probability of exposure of marine mammals to sounds strong enough to induce PTS.

Non-auditory Physiological Effects – Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to strong underwater sound include stress, neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage. There is no evidence that any of these effects occur in marine mammals exposed to sound from airgun arrays (even large ones) and there have been no direct studies of the potential for airgun pulses to elicit any of those effects. NMFS does not anticipate that marine mammals would experience any of these effects in response to being exposed to the airguns in this proposed study, especially considering the small size of the airguns. If any such effects do occur, they would probably be limited to unusual situations when animals might be exposed at close range for unusually long periods.

Exposure of laboratory animals, wildlife, and humans to strong noise often results in significant increases in adrenal activity, including cortisol and/or catecholamine release and related measures of stress (see Appendix A of SIO's application). However, it is doubtful that any single marine mammal would be exposed to strong seismic sounds for sufficiently long that significant physiological stress would develop. That is especially so in the case of the present project where the airguns are small, the ship's speed is relatively fast (5–8 knots or 9.3–14.8 km/h), and each survey does not encompass a large area.

Gas-filled structures in marine animals have an inherent fundamental resonance frequency. If stimulated at that frequency, the ensuing resonance could cause damage to the animal. A workshop (Gentry [ed.] 2002) was held to discuss whether the stranding of beaked whales in the Bahamas in 2000 (Balcomb and Claridge, 2001; NOAA and USN, 2001) might have been related to air cavity resonance or bubble formation in tissues caused by exposure to noise from naval sonar. A panel of experts concluded that resonance in air-filled structures was not likely to have caused this stranding. Opinions were less conclusive about the possible role of gas (nitrogen) bubble formation/growth in the Bahamas stranding of beaked whales.

Until recently, it was assumed that diving marine mammals are not subject to the bends or air embolism. However, a short paper concerning beaked whales stranded in the Canary Islands in 2002 suggests that cetaceans might be subject to decompression injury in some situations (Jepson *et al.*, 2003). If so, that might occur if they ascend quickly when exposed to aversive sounds. However, the interpretation that the effect was related to decompression injury is unproven (Piantadosi and Thalmann 2004; Fernandez *et al.*, 2004). Even if that effect can occur during exposure to mid-frequency sonar, there is no evidence that this type of effect occurs in response to airgun sounds. It is especially unlikely in the case of the proposed survey, involving only two GI guns.

In general, little is known about the potential for seismic survey sounds to cause auditory impairment or other physical effects in marine mammals. Available data suggest that such effects, if they occur at all, would be limited to short distances and probably to projects involving large arrays of airguns. However, the available data do not allow for meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in those ways. Marine mammals that show behavioral avoidance of seismic vessels, including most baleen whales, some odontocetes, and some pinnipeds, are especially unlikely to incur auditory impairment or other physical effects. Also, the planned mitigation measures, including ramp ups and shut downs, will reduce any such effects that might otherwise occur.

Strandings and Mortality

Marine mammals close to underwater detonations of high explosives can be killed or severely injured, and their auditory organs are especially

susceptible to injury (Ketten *et al.*, 1993; Ketten 1995). Airgun pulses are less energetic and have slower rise times, and there is no proof that they can cause serious injury, death, or stranding even in the case of large airgun arrays. However, the association of several strandings of beaked whales with naval exercises and, in one case, an L-DEO seismic survey, has raised the possibility that beaked whales exposed to strong pulsed sounds may be especially susceptible to injury and/or behavioral reactions that can lead to stranding. Appendix A (g) of SIO's application provides additional details.

Seismic pulses and mid-frequency sonar pulses are quite different. Sounds produced by airgun arrays are broadband with most of the energy below 1 kHz. Typical military mid-frequency sonars operate at frequencies of 2–10 kHz, generally with a relatively narrow bandwidth at any one time. Thus, it is not appropriate to assume that there is a direct connection between the effects of military sonar and seismic surveys on marine mammals. However, evidence that sonar pulses can, in special circumstances, lead to physical damage and mortality (NOAA and USN 2001; Jepson *et al.*, 2003), even if only indirectly, suggests that caution is warranted when dealing with exposure of marine mammals to any high-intensity pulsed sound.

In May 1996, 12 Cuvier's beaked whales stranded along the coasts of Kyparissiakos Gulf in the Mediterranean Sea. That stranding was subsequently linked to the use of low- and medium-frequency active sonar by a North Atlantic Treaty Organization (NATO) research vessel in the region (Frantzis 1998). In March 2000, a population of Cuvier's beaked whales being studied in the Bahamas disappeared after a U.S. Navy task force using mid-frequency tactical sonars passed through the area; some beaked whales stranded (Balcomb and Claridge, 2001; NOAA and USN, 2001).

In September 2002, a total of 14 beaked whales of various species stranded coincident with naval exercises in the Canary Islands (Martel n.d.; Jepson *et al.*, 2003; Fernandez *et al.*, 2003). Also in Sept. 2002, there was a stranding of two Cuvier's beaked whales in the Gulf of California, Mexico, when the L-DEO vessel *Maurice Ewing* was operating a 20–gun, 8490–in^3 array in the general area. The link between the stranding and the seismic surveys was inconclusive and not based on any physical evidence (Hogarth, 2002; Yoder, 2002). Nonetheless, that plus the incidents involving beaked whale strandings near naval exercises suggests a need for caution in conducting seismic surveys in areas occupied by beaked whales.

The present project will involve a much smaller sound source than used in typical seismic surveys. That, along with the monitoring and mitigation measures that are planned, are expected to minimize any possibility for strandings and mortality.

Potential Effects of Other Acoustic Devices

Bathymetric Sonar Signals

A multi-beam bathymetric sonar (Simrad EM120, 11.25–12.6 kHz) will be operated from the source vessel during much of the planned study. Sounds from the multi-beam sonar are very short pulses. Most of the energy in the sound pulses emitted by the multi-beam is at moderately high frequencies, centered at 12 kHz. The beam is narrow (1° or 2°) in fore-aft extent, and wide (150°) in the cross-track extent. Each ping consists of nine successive transmissions (segments) at different cross-track angles. Any given mammal at depth near the track line would be in the main beam for only a fraction of a second.

Tactical Navy sonars that have been linked to avoidance reactions and stranding of cetaceans (1) generally are more powerful than the Simrad EM120, (2) have a longer pulse duration, and (3) are directed close to omnidirectionally, vs. downward for the Simrad EM120. The area of possible influence of the Simrad EM120 is a much smaller narrow band oriented in the cross-track direction below the source vessel. Marine mammals that encounter the Simrad EM120 at close range are unlikely to be subjected to repeated pulses because of the narrow fore-aft width of the beam, and will receive only limited amounts of pulse energy because of the short pulses. In assessing the possible impacts of the 15.5 kHz Atlas Hydrosweep (a similar model), Boebel *et al.* (2004) noted that the critical sound pressure level at which TTS may occur is 203.2 dB re 1 μPa (rms). The critical region included an area of 43 m (141 ft) in depth, 46 m (151 ft) wide athwartship, and 1 m (3.3 ft) fore-and-aft (Boebel *et al.*, 2004).

Behavioral reactions of free-ranging marine mammals to military and other sonars appear to vary by species and circumstance. Observed reactions have included silencing and dispersal by sperm whales (Watkins *et al.*, 1985), increased vocalizations and no dispersal by pilot whales (Rendell and Gordon, 1999), and the previously-mentioned beachings by beaked whales. However, all of those observations are of limited relevance to the present situation. Pulse durations from those sonars were much longer than those of the SIO multi-beam sonar, and a given mammal would have received many pulses from the naval sonars. During SIO's operations, the individual pulses will be very short, and a given mammal would not receive many of the downward-directed pulses as the vessel passes by.

Captive bottlenose dolphins and a white whale exhibited changes in behavior when exposed to 1 s pulsed sounds at frequencies similar to those that will be emitted by the multi-beam sonar used by SIO, and to shorter broadband pulsed signals. Behavioral changes typically involved what appeared to be deliberate attempts to avoid the sound exposure (Schlundt *et al.*, 2000; Finneran *et al.*, 2002). The relevance of those data to free-ranging odontocetes is uncertain, and in any case, the test sounds were quite different in either duration or bandwidth as compared with those from a bathymetric sonar.

Because of the shape of the beam, NMFS believes it unlikely that marine mammals will be exposed to the bathymetric sonar at levels at or above those likely to cause harassment. Further, NMFS believes that the brief exposure of cetaceans or pinnipeds to one pulse, or small numbers of signals, from the multi-beam bathymetric sonar system are not likely to result in the harassment of marine mammals.

Sub-bottom Profiler Signals

A sub-bottom profiler will be operated from the source vessel at all times during the planned study. Sounds from the sub-bottom profiler are very short pulses, occurring for 12 or 24 ms once every 4.5–8 seconds. Most of the energy in the sound pulses emitted by this sub-bottom profiler is at mid frequencies, centered at 3.5 kHz. The beam width is approximately 80o (cone-shaped) and is directed downward.

The sub-bottom profiler on the *Roger Revelle* has a stated maximum source level of 211 dB re 1 μPa m (see section I of SIO's application). Thus, the received level would be expected to decrease to 180 dB and 160 dB approximately 35 m and 350 m below the transducer, respectively, assuming spherical spreading. Corresponding distances in the horizontal plane would be substantially lower, given the directionality of this source.

Marine mammal behavioral reactions to other pulsed sound sources are discussed above, and responses to the sub-bottom profiler are likely to be similar to those for other pulsed sources

if received at the same levels. However, the pulsed signals from the sub-bottom profiler are weaker than those from both the multi-beam sonar and the two GI guns. Behavioral responses are not expected unless marine mammals are very close to the source, e.g., within approximately 350 m below the vessel, or a lesser distance to the side. It is unlikely that the sub-bottom profiler produces pulse levels strong enough to cause hearing impairment or other physical injuries even in an animal that is (briefly) in a position near the source.

The sub-bottom profiler is usually operated simultaneously with other higher-power acoustic sources. Many marine mammals will move away in response to the approaching higher-power sources or the vessel itself before the mammals would be close enough for there to be any possibility of effects from the less intense sounds from the sub-bottom profiler. In the case of mammals that do not avoid the approaching vessel and its various sound sources, mitigation measures that would be applied to minimize effects of the higher-power sources would further reduce or eliminate any minor effects of the sub-bottom profiler.

Because of the shape of the conical beam and the power of the source, NMFS believes it unlikely that marine mammals will be exposed to the bathymetric sonar at levels at or above those likely to cause harassment. Further, NMFS believes that the brief exposure of cetaceans or pinnipeds to small numbers of signals from the multi-beam bathymetric sonar system are not likely to result in the harassment of marine mammals.

Estimated Take by Incidental Harassment

All anticipated takes would be ''takes by harassment'', involving temporary changes in behavior. The proposed mitigation measures are expected to minimize the possibility of injurious takes. (However, as noted earlier, there is no specific information demonstrating that injurious ''takes'' would occur even in the absence of the planned mitigation measures.) In the sections below, we describe methods to estimate ''take by harassment'', and present estimates of the numbers of marine mammals that might be affected during the proposed seismic survey in the northeast Indian Ocean. The estimates are based on the best available data concerning marine mammal densities (numbers per unit area) and estimates of the size of the area where effects potentially could occur.

Because there is very little information on marine mammal densities in the proposed survey area, densities were used from two of Longhurst's (2007) biogeographic provinces in the ETP that are oceanographically similar to the two provinces in which the seismic activities will take place (see further, below).

SIO's application presents two types of estimates: estimates of the number of potential ''exposures'', and estimates of the number of different individual marine mammals that might potentially be exposed to sound levels ≥160 dB re 1 μPa (rms). The distinction between ''exposures'' and ''number of different individuals exposed'' is marginally relevant in this project, because the plan does not call for repeated GI gun operations through the same or adjacent waters, and the 2 GI guns that will be used ensonify a relatively small area. Estimates of the number of exposures are considered precautionary overestimates of the actual numbers of different individuals potentially exposed to seismic sounds, because in all likelihood, exposures represent repeated exposures of some of the same individuals as discussed in the sections that follow. Because of their precautionary nature, the fact that they are the numbers SIO requested authorization for, and the fact that they differ only slightly from the estimated number of individuals, NMFS will use the estimated number of exposures for the take estimate.

The following estimates are based on a consideration of the number of marine mammals that might be disturbed appreciably by operations with the 2 GI guns to be used during approximately 2700 line-km of surveys at five sites on the Ninety East Ridge in the northeastern Indian Ocean. The anticipated radii of influence of the multi-beam sonar and sub-bottom profiler are less than those for the GI guns. It is assumed that, during simultaneous operations of the multi-beam sonar and airguns, any marine mammals close enough to be affected by the sonar would already be affected by the airguns. No animals are expected to exhibit more than short-term and inconsequential responses to the multi-beam sonar and sub-bottom profiler, given their characteristics (e.g., narrow downward-directed beam) and other considerations described previously. Therefore, no additional allowance is included for animals that might be affected by those sources. Any effects of the multi-beam sonar and sub-bottom profiler during times when they are operating but the airguns are silent are not considered.

Few systematic aircraft- or ship-based surveys have been conducted for marine mammals in offshore waters of the Indian Ocean, and the species of marine mammals that occur there are not well known. The density estimates used in this assessment are from two sources, as noted above. The most comprehensive and recent density data available for cetaceans of the ETP are from 1986 1996 NMFS ship surveys reported by Ferguson and Barlow (2001).

(1) Some of those waters are in Longhurst's (2007) Pacific Equatorial Divergence Province (PEQD), which is similar to the Indian Monsoon Gyres Province (MONS), in which 3 of the 5 proposed seismic surveys in the northeastern Indian Ocean will occur. The similarities are that they are both high-nitrate, low-chlorophyll regions of the oceans that support relatively large populations of yellowfin, bigeye, and skipjack tuna. SIO used the 1986 1996 data from blocks 162–170, 202–209, and 213–216 of Ferguson and Barlow (2001) for the species group density estimates given in Table 3 of SIO's application (and used to calculate the take estimates in Table 1 here).

(2) Some of the surveys conducted by Ferguson and Barlow (2001) in the ETP are in Longhurst's (2007) North Pacific Tropical Gyre Province (NPTG), which is similar to the Indian South Subtropical Gyre Province (ISSG), in which 2 of the 5 proposed seismic surveys will occur. The similarities are that they are both low-nitrate, low-chlorophyll regions of the oceans that support relatively large bigeye and yellowfin tuna populations. SIO used the 1986 1996 data from blocks 105, 106, 111, 112, and 125 131 of Ferguson and Barlow (2001) to compute the species group densities in Table 4 of their application (and used to calculate the take estimates in Table 1 here).

The species that will be encountered during the Indian Ocean survey will be different than those sighted during the surveys in the ETP. However, the overall abundance of species groups with generally similar habitat requirements are expected to be roughly similar. No density data were available for any cetacean species in the proposed seismic survey area. Thus, data from offshore areas of the ETP to estimate the densities of beaked whales, delphinids, small whales, and mysticetes in the northeastern Indian Ocean were used. SIO then estimated the relative abundance of individual species within the species groups on a scale of 1 (rare) to 10 (abundant) using various surveys and other information from areas near the study area, and general information on species such as latitudinal ranges,

water depth preferences, and group sizes (see Column 1 in Tables 3 and 4 of SIO's application). Finally, SIO estimated the density of each species expected to occur in the survey area from the densities for species groups in Tables 3 and 4 of their application by multiplying their relative abundance/ the relative abundance for all species in the species group times the density for the species group.

Tables 3 and 4 in SIO's application give the average and maximum densities for each species group of marine mammals reported in the PEQD and NPTG provinces of the ETP, corrected for effort, based on the densities reported in Ferguson and Barlow (2001). The densities from those studies had been corrected, by the original authors, for both detectability bias and availability bias. Detectability bias is associated with diminishing sightability with increasing lateral distance from the track line [f(0)]. Availability bias refers to the fact that there is less-than 100 percent probability of sighting an animal that is present along the survey track line, and it is measured by g(0).

It should be noted that the following estimates of ''takes by harassment'' assume that the seismic surveys will be undertaken and completed; in fact, the planned number of line-kms has been increased by 25 percent to accommodate lines that may need to be repeated, equipment testing, etc. As is typical on offshore ship surveys, inclement weather, equipment malfunctions, and other survey priorities (rock dredging, magnetic surveys) may cause delays and may limit the number of useful line-kms of seismic operations that can be undertaken. Furthermore, any marine mammal sightings within or near the designated safety zones will result in the shut down of seismic operations as a mitigation measure. Thus, the following estimates of the numbers of marine mammals potentially exposed to 160–dB sounds are precautionary, and probably overestimate the actual numbers of marine mammals that might be involved. The estimates assume that there are no conflicts in survey priorities or weather, equipment, or mitigation delays, which is unlikely, particularly given the complexity of the tasks and equipment involved.

There is some uncertainty about the representativeness of the data and the assumptions used in the take calculations. However, the approach used here is believed to be the best available approach. Also, to provide some allowance for the uncertainties, ''maximum estimates'' as well as ''best estimates'' of the numbers potentially affected have been derived. Best and maximum estimates are based on the average and maximum estimates of densities reported in the selected datasets that were used from Ferguson and Barlow (2001) described above. SIO has requested authorization for the take of the maximum estimates and NMFS has analyzed the maximum estimate for it's effect on the species or stock.

The potential number of occasions when members of each species might be exposed to received levels ≥160 dB re 1 μPa (rms) was calculated by multiplying

- Its expected density, either ''average'' (i.e., best) or ''maximum'', corrected as described above, times
- The anticipated total line-kilometers of operations with the 2 GI guns (including turns and additional buffer line km to allow for repeating of lines due to equipment malfunction, bad weather, etc.), times
- The cross-track distances within which received sound levels are predicted to be ≥160 dB.

For the 2 GI guns, that cross track distance is 2x the predicted 160–dB radii of 400 m (1312 ft) in water depths >1000 m (3280 ft).

Based on that method, the ''best'' and ''maximum'' estimates of the number of marine mammal exposures to airgun sounds ≥160 dB re 1 μPa (rms) were obtained for each of the ecological provinces using the reported average and maximum densities from Tables 3 and 4 of SIO's application. The two estimates were then added to give totals. Of the five endangered cetacean species that could be present, the best and maximum estimates show that only one blue whale and one sperm whale may be exposed to such noise levels (Table 5 of SIO's application). The vast majority of the best and maximum exposures to seismic sounds ≥160 dB would involve delphinids. Maximum estimates of exposures for the species with the highest numbers are, in descending order, spinner dolphin (215 exposures), common and Risso's dolphins (151 exposures), and bottlenose dolphin (129 exposures). Estimates for other species are lower (Table 1).

The far right column in Table 1, ''Requested Take Authorization'', shows the numbers for which ''take authorization'' is requested. The requested take authorization numbers are calculated as indicated above based on the maximum densities reported by Ferguson and Barlow (2001) in any of the survey blocks included in the average density estimates. For those species for which very low numbers to none are estimated to be exposed to seismic sounds ≥160 dB, SIO included allowance for encountering one group based on the mean group size. Where group sizes are less than five, SIO assigned a group size of five. However, for endangered species, NMFS only plans to authorize take for one sperm whale and one blue whale.

The best and maximum estimates are based on 160–dB distances predicted from the acoustic model applied by L-DEO. Based on the empirical calibration data collected in the Gulf of Mexico in 2003 for L-DEO's 2 GI guns in deep water (510 m (1673 ft)), actual 160–dB distances in deep water are likely to be less than predicted (Tolstoy *et al.*, 2004). Additionally, the requested take is based on maximum exposure estimates (based on maximum density estimates). Given these considerations, the predicted numbers of marine mammals that might be exposed to sounds ≥160 dB may be somewhat overestimated.

The stock structures of the marine mammals present in the Indian Ocean have not been identified by NMFS; therefore, NMFS must make the necessary findings based on the species as a whole. The species anticipated to be affected during the proposed activities are wide-ranging species. Though worldwide abundance (or abundance outside of that estimated for the U.S. stocks) has not been estimated, localized surveys in the west tropical Indian Ocean and elsewhere have been conducted. Since the take estimates proposed in this document fall largely within 6 percent (all but common dolphin (21 percent) and rough-toothed dolphin (14 percent)) of the numbers estimated to be present during a localized survey of the west tropical Indian Ocean, and the species range far beyond the Indian Ocean (i.e., the abundance of the species is notably larger), NMFS believes that the estimated take numbers for these are small relative both to the worldwide abundance of these species and to numbers taken in other activities that have been authorized for incidental take of these species.

Potential Effects on Habitat

The proposed airgun operations will not result in any permanent impact on habitats used by marine mammals, or to the food sources they use. The main impact issue associated with the proposed activities will be temporarily elevated noise levels and the associated direct effects on marine mammals, as discussed above.

One of the reasons for the adoption of airguns as the standard energy source for marine seismic surveys was that they (unlike the explosives used in the distant past) do not result in any

appreciable fish kill. However, the existing body of information relating to the impacts of seismic on marine fish and invertebrate species is very limited. The various types of potential effects of exposure to seismic on fish and invertebrates can be considered in three categories: (1) pathological, (2) physiological, and (3) behavioral. Pathological effects include lethal and sub-lethal damage to the animals, physiological effects include temporary primary and secondary stress responses, and behavioral effects refer to changes in exhibited behavior of the fish and invertebrates. The three categories are interrelated in complex ways. For example, it is possible that certain physiological and behavioral changes could potentially lead to the ultimate pathological effect on individual animals (i.e., mortality).

The available information on the impacts of seismic surveys on marine fish and invertebrates provides limited insight on the effects only at the individual level. Ultimately, the most important knowledge in this area relates to how significantly seismic affects animal populations.

The following sections provide an overview of the information that exists on the effects of seismic surveys on fish and invertebrates. The information comprises results from scientific studies of varying degrees of soundness and some anecdotal information.

Pathological Effects – In water, acute injury and death of organisms exposed to seismic energy depends primarily on two features of the sound source: (1) the received peak pressure, and (2) the time required for the pressure to rise and decay (Hubbs and Rechnitzer, 1952 in Wardle *et al.*, 2001). Generally, the higher the received pressure and the less time it takes for the pressure to rise and decay, the greater the chance of acute pathological effects. Considering the peak pressure and rise/decay time characteristics of seismic airgun arrays used today, the pathological zone for fish and invertebrates would be expected to be within a few meters of the seismic source (Buchanan *et al.*, 2004). For the proposed survey, any injurious effects on fish would be limited to very short distances, especially considering the small source planned for use in this project (two 45–in^3 GI guns).

Matishov (1992) reported that some cod and plaice died within 48 hours of exposure to seismic pulses 2 m (6.5 ft) from the source. No other details were provided by the author. On the other hand, there are numerous examples of no fish mortality as a result of exposure to seismic sources (Falk and Lawrence 1973; Holliday *et al.*, 1987; La Bella *et al.*, 1996; Santulli *et al.*, 1999; McCauley *et al.*, 2000a, 2000b; Bjarti, 2002; IMG, 2002; McCauley *et al.*, 2003; Hassel *et al.*, 2003).

There are examples of damage to fish ear structures from exposure to seismic airguns (McCauley *et al.*, 2000a, 2000b, 2003), but it should be noted the experimental fish were caged and exposed to high cumulative levels of seismic energy. Atlantic salmon were exposed within 1.5 m (4.9 ft) of underwater explosions (Sverdrup *et al.*, 1994). Compared to airgun sources, explosive detonations are characterized by higher peak pressures and more rapid rise and decay times, and are considered to have greater potential to damage marine biota. In spite of this, no salmon mortality was observed immediately after exposure or during the seven-day monitoring period following exposure.

Some studies have also provided some information on the effects of seismic exposure on fish eggs and larvae (Kostyuchenko, 1972; Dalen and Knutsen, 1986; Holliday *et al.*, 1987; Matishov, 1992; Booman *et al.*, 1996; Dalen *et al.*, 1996). Overall, impacts appeared to be minimal and any mortality was generally not significantly different from the experimental controls. Generally, any observed larval mortality occurred after exposures within 0.5 3 m (1.6–9.8 ft) of the airgun source. Matishov (1992) did report some retinal tissue damage in cod larvae exposed at 1 m (3.3 ft) from the airgun source. Saetre and Ona (1996) applied a 'worst-case scenario' mathematical model to investigate the effects of seismic energy on fish eggs and larvae, and concluded that mortality rates caused by exposure to seismic are so low compared to natural mortality that the impact of seismic surveying on recruitment to a fish stock must be regarded as insignificant.

The pathological impacts of seismic energy on marine invertebrate species have also been investigated. Christian *et al.* (2003) exposed adult male snow crabs, egg-carrying female snow crabs, and fertilized snow crab eggs to energy from seismic airguns. Neither acute nor chronic (12 weeks after exposure) mortality was observed for the adult male and female crabs. There was a significant difference in development rate noted between the exposed and unexposed fertilized eggs. The egg mass exposed to seismic energy had a higher proportion of less-developed eggs than the unexposed mass. It should be noted that both egg masses came from a single female and that any measure of natural variability was unattainable. However, a result such as this does point to the need for further study.

Pearson *et al.* (1994) exposed Stage II larvae of the Dungeness crab to single discharges from a seven-airgun seismic array and compared their mortality and development rates with those of unexposed larvae. For immediate and long-term survival and time to molt, this field experiment did not reveal any statistically-significant differences between the exposed and unexposed larvae, even those exposed within 1 m (3.3 ft) of the seismic source.

Bivalves of the Adriatic Sea were also exposed to seismic energy and subsequently assessed (LaBella *et al.*, 1996). No effects of the exposure were noted.

To date, there have not been any well-documented cases of acute post-larval fish or invertebrate mortality as a result of exposure to seismic sound under normal seismic operating conditions. Sub-lethal injury or damage has been observed, but generally as a result of exposure to very high received levels of sound, significantly higher than the received levels generated by the single GI gun sound source to be used in the proposed study. Acute mortality of eggs and larvae have been demonstrated in experimental exposures, but only when the eggs and larvae were exposed very close to the seismic sources and the received pressure levels were presumably very high. Limited information has not indicated any chronic mortality as a direct result of exposure to seismic.

*Physiological Effect*s – Biochemical responses by marine fish and invertebrates to acoustic stress have also been studied, although in a limited way. Studying the variations in the biochemical parameters influenced by acoustic stress might give some indication of the extent of the stress and perhaps forecast eventual detrimental effects. Such stress could potentially affect animal populations by reducing reproductive capacity and adult abundance.

McCauley *et al.* (2000a, 2000b) used various physiological measures to study the physiological effects of exposure to seismic energy on various fish species, squid, and cuttlefish. No significant physiological stress increases attributable to seismic energy were detected. Sverdrup *et al.* (1994) found that Atlantic salmon subjected to acoustic stress released primary stress hormones, adrenaline and cortisol, as a biochemical response although there were different patterns of delayed increases for the different indicators. Caged European sea bass were exposed to seismic energy and numerous

biochemical responses were indicated. All returned to their normal physiological levels within 72 hours of exposure.

Stress indicators in the haemolymph of adult male snow crabs were monitored after exposure of the animals to seismic energy (Christian *et al.*, 2003). No significant differences between exposed and unexposed animals were found in the stress indicators (e.g., proteins, enzymes, cell type count).

Primary and secondary stress responses of fish after exposure to seismic energy all appear to be temporary in any studies done to date. The times necessary for these biochemical changes to return to normal are variable depending on numerous aspects of the biology of the species and of the sound stimulus.

Summary of Physical (Pathological and Physiological) Effects – As indicated in the preceding general discussion, there is a relative lack of knowledge about the potential physical (pathological and physiological) effects of seismic energy on marine fish and invertebrates. Available data suggest that there may be physical impacts on egg, larval, juvenile, and adult stages at very close range. Considering typical source levels associated with commercial seismic arrays, close proximity to the source would result in exposure to very high energy levels. Again, this study will employ a sound source that will generate low energy levels. Whereas egg and larval stages are not able to escape such exposures, juveniles and adults most likely would avoid it. In the case of eggs and larvae, it is likely that the numbers adversely affected by such exposure would not be that different from those succumbing to natural mortality. Limited data regarding physiological impacts on fish and invertebrates indicate that these impacts are short term and are most apparent after exposure at close range.

The proposed seismic program for 2007 is predicted to have negligible to low physical effects on the various life stages of fish and invertebrates for its short duration (approximately 49 hours at each of five sites on the Ninety East Ridge) and 2700–km extent. Therefore, physical effects of the proposed program on the fish and invertebrates would be not significant.

Fish and Invertebrate Acoustic Detection and Production – Hearing in fishes was first demonstrated in the early 1900s through studies involving cyprinids (Parker, 1903 and Bigelow, 1904 in Kenyon *et al.*, 1998). Since that time, numerous methods have been used to test auditory sensitivity in fishes, resulting in audiograms of over 50 species. These data reveal great diversity in fish hearing ability, mostly attributable to various peripheral modes of coupling the ear to internal structures, including the swim bladder. However, the general auditory capabilities of <0.2 percent of fish species are known so far.

For many years, studies of fish hearing have reported that the hearing bandwidth typically extends from below 100 Hz to approximately 1 kHz in fishes without specializations for sound detection, and up to approximately 7 kHz in fish with specializations that enhance bandwidth and sensitivity. Recently there have been suggestions that certain fishes, including many clupeiforms (herring, shads, anchovies, etc.) may be capable of detecting ultrasonic signals with frequencies as high as 126 kHz (Dunning *et al.*, 1992; Nestler *et al.*, 1992). Studies on Atlantic cod, a non-clupeiform fish, suggested that this species could detect ultrasound at almost 40 kHz (Astrup and M hl, 1993).

Mann *et al.* (2001) showed that the American shad is capable of detecting sounds up to 180 kHz. They also demonstrated that the gulf menhaden is also able to detect ultrasound, whereas other species such as the bay anchovy, scaled sardine, and Spanish sardine only detect sounds with frequencies up to approximately 4 kHz.

Among fishes, at least two major pathways for sound transmission to the ear have been identified. The first and most primitive is the conduction of sound directly from the water to tissue and bone. The fish's body takes up the sound's acoustic particle motion and subsequent hair cell stimulation occurs because of the difference in inertia between the hair cells and their overlying otoliths. These species are known as 'hearing generalists' (Fay and Popper, 1999). The second sound pathway to the ears is indirect. The swim bladder or other gas bubble near the ears expands and contracts in volume in response to sound pressure fluctuations, and the motion is then transmitted to the otoliths. While present in most bony fishes, the swim bladder is absent or reduced in many other fish species. Only some species of fish with a swim bladder appear to be sound-pressure sensitive via this indirect pathway to the ears; they are called 'hearing specialists'. Hearing specialists have some sort of connection with the inner ear, either via bony structures known as Weberian ossicles, extensions of the swim bladder, or a swim bladder more proximate to the inner ear. Hearing specialists' sound-pressure sensitivity is high and their upper frequency range of detection is extended above those species that hear only by the direct pathway. Typically, most fish detect sounds of frequencies up to 2,000–Hz but, as indicated, others have detection ranges that extend to much higher frequencies.

Fish also possess lateral lines that detect water movements. The essential stimulus for the lateral line consists of differential water movement between the body surface and the surrounding water. The lateral line is typically used in concert with other sensory information, including hearing (Sand, 1981; Coombs and Montgomery, 1999).

Elasmobranchs (sharks and skates) lack any known pressure-to-displacement transducers such as swim bladders. Therefore, they presumably must rely on the displacement sensitivity of their mechanoreceptive cells. Unlike acoustic pressure, the kinetic stimulus is inherently directional but its magnitude rapidly decreases relative to the pressure component as it propagates outward from the sound source in the near field. It is believed that elasmobranches are most sensitive to low frequencies, those <1 kHz (Corwin 1981).

Because they lack air-filled cavities and are often the same density as water, invertebrates detect underwater acoustics differently than fish. Rather than being pressure sensitive, invertebrates appear to be most sensitive to particle displacement. However, their sensitivity to particle displacement and hydrodynamic stimulation seem poor compared to fish. Decapods, for example, have an extensive array of hair-like receptors both within and upon the body surface that could potentially respond to water- or substrate-borne displacements. They are also equipped with an abundance of proprioceptive organs that could serve secondarily to perceive vibrations. Crustaceans appear to be most sensitive to sounds of low frequencies, those <1000 Hz (Budelmann, 1992; Popper *et al.*, 2001).

Many fish and invertebrates are also capable of sound production. It is believed that these sounds are used for communication in a wide range of behavioral and environmental contexts. The behaviors most often associated with acoustic communication include territorial behavior, mate finding, courtship, and aggression. Sound production provides a means of long-distance communication and communication when underwater visibility is poor (Zelick *et al.*, 1999).

Behavioral Effects – Because of the apparent lack of serious pathological

and physiological effects of seismic energy on marine fish and invertebrates, most concern now centers on the possible effects of exposure to seismic surveys on the distribution, migration patterns, and catchability of fish. There is a need for more information on exactly what effects such sound sources might have on the detailed behavior patterns of fish and invertebrates at different ranges. Studies investigating the possible effects of seismic energy on fish and invertebrate behavior have been conducted on both uncaged and caged animals. Studies of change in catch rate regard potential effects of seismic energy on larger spatial and temporal scales than are typical for close-range studies that often involve caged animals (Hirst and Rodhouse, 2000). Hassel *et al.* (2003) investigated the behavioral effects of seismic pulses on caged sand lance in Norwegian waters. The sand lance did exhibit responses to the seismic, including an increase in swimming rate, an upwards vertical shift in distribution, and startle responses. Normal behaviors were resumed shortly after cessation of the seismic source. None of the observed sand lance reacted by burying into the sand.

Engas *et al.* (1996) assessed the effects of seismic surveying on Atlantic cod and haddock behavior using acoustic mapping and commercial fishing techniques. Results indicated that fish abundance decreased at the seismic survey area, and that the decline in abundance and catch rate lessened with distance from the survey area. Fish abundance and catch rates had not returned to pre-shooting levels five days after cessation of shooting. In other airgun experiments, catch per unit effort (CPUE) of demersal fish declined when airgun pulses were emitted, particularly in the immediate vicinity of the seismic survey (Dalen and Raknes, 1985; Dalen and Knutsen, 1986; L kkeborg, 1991; Skalski *et al.*, 1992). Reductions in the catch may have resulted from a change in behavior of the fish. The fish schools descended to near the bottom when the airgun was firing, and the fish may have changed their swimming and schooling behavior. Fish behavior returned to normal minutes after the sounds ceased.

Marine fish inhabiting an inshore reef off the coast of Scotland were monitored by telemetry and remote camera before, during, and after airgun firing (Wardle *et al.*, 2001). Although some startle responses were observed, the seismic gun firing had little overall effect on the day-to-day behavior of the resident fish.

Other species involved in studies that have indicated fish behavioral responses to underwater sound include rockfish (Pearson *et al.*, 1992), Pacific herring (Schwarz and Greer, 1984), and Atlantic herring (Blaxter *et al.*, 1981). The responses observed in these studies were relatively temporary. What is not known is the effect of exposure to seismic energy on fish and invertebrate behaviors that are associated with reproduction and migration.

Studies on the effects of sound on fish behavior have also been conducted using caged or confined fish. Such experiments were conducted in Australia using fish, squid, and cuttlefish as subjects (McCauley *et al.* (2000a,b). Common observations of fish behavior included startle response, faster swimming, movement to the part of the cage furthest from the seismic source (i.e., avoidance), and eventual habituation. Fish behavior appeared to return pre-seismic state 15 30 min after cessation of seismic shooting. Squid exhibited strong startle responses to the onset of proximate airgun firing by releasing ink and/or jetting away from the source. The squid consistently made use of the 'sound shadow' at the surface, where the sound intensity was less than at 3–m (9.8 ft) depth. These Australian experiments provided more evidence that fish and invertebrate behavior will be modified at some received sound level. Again, the behavioral changes seem to be temporary.

Christian *et al.* (2003) conducted an experimental commercial fishery for snow crab before and after the area was exposed to seismic shooting. Although the resulting data were not conclusive, no drastic decrease in catch rate was observed after seismic shooting commenced. Another behavioral investigation by Christian *et al.* (2003) involved caging snow crabs, positioning the cage 50 m (164 ft) below a seven-gun array, and observing the immediate responses of the crabs to the onset of seismic shooting by remote underwater camera. No obvious startle behaviors were observed. Anecdotal information from Newfoundland, Canada, indicated that snow crab catch rates showed a significant reduction immediately following a pass by a seismic survey vessel. Other anecdotal information from Newfoundland indicated that a school of shrimp showing on a fishing vessel sounder shifted downwards and away from a nearby seismic source. Effects were temporary in both the snow crab and shrimp anecdotes (Buchanan *et al.*, 2004).

Summary of Behavioral Effects – As is the case with pathological and physiological effects of seismic on fish and invertebrates, available information is relatively scant and often contradictory. There have been well-documented observations of fish and invertebrates exhibiting behaviors that appeared to be responses to exposure to seismic energy (i.e., startle response, change in swimming direction and speed, and change in vertical distribution), but the ultimate importance of those behaviors is unclear. Some studies indicate that such behavioral changes are very temporary, whereas others imply that fish might not resume pre-seismic behaviors or distributions for a number of days. There appears to be a great deal of inter- and intra-specific variability. In the case of finfish, three general types of behavioral responses have been identified: startle, alarm, and avoidance. The type of behavioral reaction appears to depend on many factors, including the type of behavior being exhibited before exposure, and proximity and energy level of sound source.

During the proposed study, only a small fraction of the available habitat would be ensonified at any given time, and fish species would return to their pre-disturbance behavior once the seismic activity ceased. The proposed seismic program is predicted to have negligible to low behavioral effects on the various life stages of the fish and invertebrates during its short duration (approximately 49 hours at each of 5 sites on the Ninety East Ridge) and 2700–km extent.

Changes in behavior in fish near the airguns might have short-term impacts on the ability of cetaceans to feed near the survey area. However, only a small fraction of the available habitat would be ensonified at any given time, and fish species would return to their pre-disturbance behavior once the seismic activity ceased. Thus, the proposed survey would have little impact on the abilities of marine mammals to feed in the area where seismic work is planned. Some of the fish that do not avoid the approaching airguns (probably a small number) may be subject to auditory or other injuries.

Zooplankters that are very close to the source may react to the shock wave. These animals have an exoskeleton and no air sacs. Little or no mortality is expected. Many crustaceans can make sounds and some crustaceans and other invertebrates have some type of sound receptor. However, the reactions of zooplankters to sound are not known. Some mysticetes feed on concentrations of zooplankton. A reaction by zooplankton to a seismic impulse would only be relevant to whales if it caused a concentration of zooplankton to scatter. Pressure changes of sufficient magnitude to cause this type of reaction would probably occur only very close to

the source. Impacts on zooplankton behavior are predicted to be negligible, and this would translate into negligible impacts on feeding mysticetes.

Because of the reasons noted above and the nature of the proposed activities (small airguns and limited duration), the proposed operations are not expected to have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or their populations or stocks.

Monitoring

Either dedicated marine mammal observers (MMOs) or other vessel-based personnel will watch for marine mammals near the seismic source vessel during all daytime and nighttime airgun operations. GI airgun operations will be suspended when marine mammals are observed within, or about to enter, designated safety radii where there is a possibility of significant effects on hearing or other physical effects. At least one dedicated vessel-based MMO will watch for marine mammals near the seismic vessel during daylight periods when shooting is being conducted, and two MMOs will watch for marine mammals for at least 30 min prior to start-up of airgun operations. Observations of marine mammals will also be made and recorded during any daytime periods without airgun operations. At night, the forward-looking bridge watch of the ship's crew will look for marine mammals that the vessel is approaching, and execute avoidance maneuvers; the 180dB/190dB safety radii around the airguns will be continuously monitored by an aft-looking member of the scientific party, who will call for shutdown of the guns if mammals are observed within the safety radii. Nighttime observers will be aided by (aft-directed) ship's lights and night vision devices (NVDs).

Observers will be appointed by SIO with NMFS concurrence. Two observers will be on the vessel, and both will have gone through NOAA/NMFS training for marine mammal observations. Observers will be on duty in shifts usually of duration no longer than two hours. Use of two simultaneous observers prior to start up will increase the detectability of marine mammals present near the source vessel, and will allow simultaneous forward and rearward observations. Bridge personnel additional to the dedicated marine mammal observers will also assist in detecting marine mammals and implementing mitigation requirements, and before the start of the seismic survey will be given instruction in how to do so.

The *Roger Revelle* is a suitable platform for marine mammal observations, and has been used for that purpose during the routine CalCOFI (California Cooperative Oceanic Fisheries Investigations). Observing stations will be at the 02 level, with observers' eyes approximately 10.4 m (34 ft) above the waterline: one forward on the 02 deck commanding a forward-centered, approximately 240° view, and one atop the aft hangar, with an aft-centered view that includes the 60–m radius area around the airguns. The eyes of the bridge watch will be at a height of approximately 15 m (49 ft); marine mammal observers will repair to the enclosed bridge and adjoining aft steering station during any inclement weather (unlikely at this place and season), and as necessary to use the 50 X ''big-eye'' binoculars that are mounted there.

Standard equipment for marine mammal observers will be 7 X 50 reticle binoculars and optical range finders. At night, night vision equipment will be available. The observers will be in wireless communication with ship's officers on the bridge and scientists in the vessel's operations laboratory, so they can advise promptly of the need for avoidance maneuvers or airgun power-down or shut-down.

The vessel-based monitoring will provide data required to estimate the numbers of marine mammals exposed to various received sound levels, to document any apparent disturbance reactions, and thus to estimate the numbers of mammals potentially ''taken'' by harassment. It will also provide the information needed in order to shut down the GI airguns at times when mammals are present in or near the safety zone. When a mammal sighting is made, the following information about the sighting will be recorded:

(1) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from seismic vessel, sighting cue, apparent reaction to seismic vessel (e.g., none, avoidance, approach, paralleling, etc.), and behavioral pace.

(2) Time, location, heading, speed, activity of the vessel (shooting or not), sea state, visibility, cloud cover, and sun glare.

The data listed under (2) will also be recorded at the start and end of each observation watch and during a watch, whenever there is a change in one or more of the variables.

All mammal observations and airgun shutdowns will be recorded in a standardized format. Data will be entered into a custom database using a notebook computer when observers are off duty. The accuracy of the data entry will be verified by computerized data validity checks as the data are entered, and by subsequent manual checking of the database. Those procedures will allow initial summaries of data to be prepared during and shortly after the field program, and will facilitate transfer of the data to statistical, graphical, or other programs for further processing and archiving.

Results from the vessel-based observations will provide:

- The basis for real-time mitigation (airgun shut down).
- Information needed to estimate the number of marine mammals potentially taken by harassment, which must be reported to NMFS.
- Data on the occurrence, distribution, and activities of marine mammals in the area where the seismic study is conducted.
- Information to compare the distance and distribution of marine mammals relative to the source vessel at times with and without seismic activity.
- Data on the behavior and movement patterns of marine mammals seen at times with and without seismic activity.

Mitigation

For the proposed seismic surveys in the Northeastern Indian Ocean during May August 2007, SIO will deploy two GI airguns as an energy source, with a total discharge volume of 90 in3. The energy from the airguns will be directed mostly downward. The small size of the airguns to be used during the proposed study will reduce the potential for effects relative to those that might occur with a large airgun arrays.

In addition to marine mammal monitoring, the following mitigation measures will be adopted during the proposed seismic program, provided that doing so will not compromise operational safety requirements. Although power-down procedures are often standard operating practice for seismic surveys, it will not be used here because powering down from two guns to one gun would make only a small difference in the 180- or 190–dB radius – probably not enough to allow continued one-gun operations if a mammal came within the safety radius for two guns. Mitigation measures that will be adopted are:

(1) Speed or course alteration;

(2) Ramp-up and shut-down procedures; and

(3) Night operations;

Speed or Course Alteration – If a marine mammal is detected outside the

safety radius and, based on its position and the relative motion, is likely to enter the safety radius, the vessel's speed and/or direct course may, when practical and safe, be changed in a manner that also minimizes the effect to the planned science objectives. The marine mammal activities and movements relative to the seismic vessel will be closely monitored to ensure that the animal does not approach within the safety radius. If the animal appears likely to enter the safety radius, further mitigative actions will be taken, i.e. either further course alterations or shut down of the airguns.

Shut-down Procedures - If a marine mammal is detected outside the safety radius but is likely to enter the safety radius, and if the vessel's course and/or speed cannot be changed to avoid having the animal enter the safety radius, the airguns will be shut down before the animal is within the safety radius (10 m (33 ft) for pinnipeds (190–dB isopleth) or 40 m (131 ft) for cetaceans (180–dB isopleth)). Likewise, if a marine mammal is already within the safety radius when first detected, the airguns will be shut down immediately.

Airgun activity will not resume until the animal has cleared the safety radius. The animal will be considered to have cleared the safety radius if it is visually observed to have left the safety radius, or if it has not been seen within the radius for 15 min (small odontocetes and pinnipeds) or 30 min (mysticetes and large odontocetes, including sperm, pygmy sperm, dwarf sperm, beaked, and bottlenose whales).

Ramp-up Procedures – A ''ramp-up'' procedure will be followed when the airguns begin operating after a period without airgun operations. The two GI guns will be added in sequence 5 minutes apart. During ramp-up procedures, the safety radius for the two GI guns will be maintained.

Night Operations – At night, vessel lights and/or night vision devices (NVDs) could be useful in sighting some marine mammals at the surface within a short distance from the ship (within the safety radii for the two GI guns in deep water). Start up of the airguns will only occur in situations when the entire safety radius is visible with vessel lights and NVDs.

Reporting

A report will be submitted to NMFS within 90 days after the end of the cruise. The end of the northeastern Indian Ocean cruise is predicted to occur between July 16 and August 13, 2007. The report will describe the operations that were conducted and the marine mammals that were detected near the operations. The report will be submitted to NMFS, providing full documentation of methods, results, and interpretation pertaining to all monitoring. The 90–day report will summarize the dates and locations of seismic operations, marine mammal sightings (dates, times, locations, activities, associated seismic survey activities), and estimates of the amount and nature of potential ''take'' of marine mammals by harassment or in other ways.

Endangered Species Act

Under section 7 of the Endangered Species Act (ESA) the NSF has begun consultation on this proposed seismic survey. NMFS will also consult on the issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of the IHA.

National Environmental Policy Act (NEPA)

NSF prepared an Environmental Assessment of a Planned Low-Energy Marine Seismic Survey by the Scripps Institution of Oceanography in the Northeast Indian Ocean, May July 2007. NMFS will either adopt NSF's EA or conduct a separate NEPA analysis, as necessary, prior to making a determination on the issuance of the IHA.

Preliminary Determinations

NMFS has preliminarily determined that the impact of conducting the seismic survey in the northeast Indian Ocean may result, at worst, in a temporary modification in behavior (Level B Harassment) of small numbers of 29 species of cetaceans. Further, this activity is expected to result in a negligible impact on the affected species or stocks. The provision requiring that the activity not have an unmitigable adverse impact on the availability of the affected species or stock for subsistence uses does not apply for this proposed action.

For reasons stated peviously in this document, this determination is supported by: (1) the likelihood that, given sufficient notice through relatively slow ship speed and rampup, marine mammals are expected to move away from a noise source that is annoying prior to its becoming potentially injurious; (2) the fact that marine mammals would have to be closer than 40 m from the vessel to be exposed to levels of sound (180 dB) believed to have even a minimal chance of causing TTS; and (3) the likelihood that marine mammal detection ability by trained observers is high at that short distance from the vessel. As a result, no take by injury or death is anticipated and the potential for temporary or permanent hearing impairment is very low and will be avoided through the incorporation of the proposed mitigation measures.

While the number of potential incidental harassment takes will depend on the distribution and abundance of marine mammals in the vicinity of the survey activity, the number of potential harassment takings is estimated to be small, less than a few percent of any of the estimated population sizes, and has been mitigated to the lowest level practicable through incorporation of the measures mentioned previously in this document.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to SIO for conducting a low-energy seismic survey in the Indian Ocean from May - August, 2007, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: April 4, 2007.

David Cottingham,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010207B]

Small Takes of Marine Mammals Incidental to Specified Activities; Seismic Surveys in the Beaufort and Chukchi Seas off Alaska

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

ACTION: Notice of receipt of application and proposed incidental take authorization; request for comments.

SUMMARY: NMFS has received an application from Shell Offshore, Inc. (SOI) for an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals, by harassment, incidental to conducting open-water offshore exploratory drilling on Outer Continental Shelf (OCS) oil lease blocks in the Beaufort Sea off Alaska. Under the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to

issue an IHA to SOI to incidentally take, by Level B harassment, small numbers of several species of marine mammals between mid-July and November, 2007, incidental to conducting this drilling program.

DATES: Comments and information must be received no later than May 10, 2007.

ADDRESSES: Written comments on the application should be addressed to P. Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning the contact listed here. The mailbox address for providing email comments is *PR1.010207B @noaa.gov*. Comments sent via e-mail, including all attachments, must not exceed a 10–megabyte file size. A copy of the application (containing a list of the references used in this document) may be obtained by writing to this address or by telephoning the contact listed here and are also available at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#iha*.

Documents cited in this document, that are not available through standard public library access methods, may be viewed, by appointment, during regular business hours at this address.

FOR FURTHER INFORMATION CONTACT: Kenneth Hollingshead, Office of Protected Resources, NMFS, (301) 713–2289 or Brad Smith, NMFS, Alaska Regional Office 907–271–3023.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

Open Water Exploration Drilling

SOI is planning to utilize two drilling units during the 2007 open water season in order to drill priority exploration targets on their U.S. Minerals Management Services (MMS) OCS leases in the U.S. Beaufort Sea. The highest priority exploratory targets for 2007 are located offshore of Pt. Thomson and Flaxman Island, on the leaseholds referred to as Sivulliq and Olympia, in Camden Bay. However, given the locations of open water conditions during 2007 and permit/authorization stipulations, SOI may elect to re-prioritize well locations on one, or more of their OCS leases (see Figure 1 in SOI's IHA application). Re-prioritizing of drilling prospects due to ice may cause drilling to occur at other Beaufort Sea OCS leases held by SOI, but only those that have been pre-cleared to the satisfaction of MMS. It is anticipated that the drilling vessels will each drill up to two wells during the open water season of 2007.

The drilling units proposed for SOI's 2007 OCS drilling program include the semi-submersible drill ship, the *Kulluk*, and a floating drill ship, the *Frontier Discoverer* (*Discoverer*). Both the *Kulluk* and *Discoverer* will be mobilized into the Beaufort Sea as soon as ice conditions permit. Each will be accompanied by up to two Arctic-class, foreign-flagged, ice management vessels which will also serve duty as anchor tenders, and other drill ship support tasks. These ice management vessels are: the *M/V Jim Kilabuk*, the *M/V Vladimir Ignatjuk*, the *M/V Kapitan Dranitsyn*, the *M/V Fennica-Nordica*,; and the *M/V Tor Viking*.

Additional support vessels, such as the *M/V Peregrine* and aircraft will also be used during the drilling season, assisting with crew change support and provision re-supply. Oil spill response vessels (OSRV) will accompany the drill ships, at all times while drilling occurs through prospective hydrocarbon-bearing zones. Projected dates for arrivals of OSRVs on location in the Beaufort Sea will be known around the end of April/May 2007. An ice-class, purpose built OSRV is being constructed for SOI and will be deployed in the Beaufort Sea for this drilling program. Potential OSRV support includes the *Arctic Endeavor* barge and associated tug; and an OSR tanker that will be staged in proximity to both drilling units. Specifications for the *Kulluk*, *Discoverer* and prospective ice management vessels are included in SOI's IHA application.

The *Kulluk* is currently moored in McKinley Bay, Yukon Territory, Canada. Ice management support (*Ignatjuk* and *Fennica-Nordica*) for the *Kulluk* are projected to enter the Beaufort Sea during mid-late June 2007 traveling west to east toward McKinley Bay. The *Kulluk* is projected to be towed into the Alaskan Beaufort Sea during July 2007 by one of the arctic class ice management vessels, which travel through the Chukchi and Beaufort Seas before arriving in McKinley Bay for mobilization. The *Discoverer* is currently docked in Singapore and will travel to Kotzebue for re-supply before mobilizing into the Beaufort Sea, accompanied by ice management vessels. The *Dranitsyn* will provide ice management support for the *Discoverer*. Both ships are expected to depart Kotzebue in early July before entering the Beaufort Sea.

These vessels will traverse the Alaskan Beaufort from west to east and are projected to begin the traverse before July 1, 2007. These vessels should free the *Kulluk* and ready it for mobilization to the Alaskan Beaufort Sea by late July or early August 2007. The *Tor Viking* is projected to enter the Beaufort Sea during mid-late June 2007 and arrive on location of the Sivulliq prospect in late June. The *Kilabuk* will provide support and supply to the *Kulluk*. Toward the

end of July, an additional ice management vessel (the *Dranitsyn*) will escort the *Discoverer* from the Bering Sea northward through the Chukchi and Beaufort Seas to drilling prospects where ice conditions allow safe operating access. At the conclusion of open water operations around the end of October 2007, SOI expects to demobilize both the *Kulluk* and the *Discoverer* before the end of November 2007. The *Kulluk* will be accompanied by two ice management vessels back to the Canadian Beaufort Sea (McKinley Bay), while two ice management vessels will accompany the *Discoverer* west through the Beaufort Sea and south through the Chukchi Sea.

Pre-Feasibility Geotechnical Borehole Drilling

To obtain geotechnical data for pre-feasibility analyses of shallow sub-sea sediments, SOI plans to drill as many as eight boreholes, each up to 400 ft (122 m) in depth. SOI notes that these boreholes will be completed at depths more than one mile (1.6 km) above any of the prospective subsurface hydrocarbon- bearing zones in the Sivulliq prospect (see Figure 1 in SOI's application). Three potential development locations will be investigated at Sivulliq, deeper locations along a prospective pipeline access corridor will also be investigated. This operation is expected to take approximately one week per borehole.

The geotechnical survey component of the program will be conducted by a vessel typically over 200 ft (61 m) in length, with a moon-pool and drilling rig approximately at mid-ships, A-frame at the stern, helideck above the bow/bridge and accommodations for about 40 technical staff and crew. A typical geotechnical coring vessel is illustrated in Attachment A of SOI's MMPA application.

The geotechnical drilling is expected to begin during July 2007. Including weather, ice conditions and logistics/resupply it is anticipated that geotechnical borings may require up to 8 weeks within a 12–week time-frame finished by the end of October 2007. The proposed geotechnical locations include the Sivulliq prospect and the Pt. Thomson to Sivulliq prospective pipeline access corridor.

Marine Mammals

A total of three cetacean species (bowhead, gray, and beluga whales), three species of pinnipeds (ringed, spotted, and bearded seal), and one marine carnivore (polar bear) are known to occur in or near the proposed drilling areas in the U.S. Beaufort Sea. Other extralimital species that occasionally occur in very small numbers in this portion of the U.S. Beaufort Sea include the harbor porpoise and killer whale. However, because of their rarity in this area, they are not expected to be exposed to, or affected by, any activities associated with the drilling, and are not discussed further. The polar bear is under the jurisdiction of the U.S. Fish and Wildlife Service (USFWS) and is not discussed further in this document. The species and numbers of marine mammals likely to be found within this portion of the Beaufort Sea are listed in Table 4–1 in SOI's IHA application.

A description of the biology and distribution of the marine mammal species under NMFS' jurisdiction can be found in SOI's IHA application, MMS' 2006 PEA for Arctic seismic activities, the NMFS/MMS Draft Programmatic EIS for Arctic Seismic in the Beaufort and Chukchi seas and several other documents (e.g., MMS Final EA for Lease Sale 202, Army Corps of Engineers for the Northstar Project, 1999). Information on these species can be found also in the NMFS Stock Assessment Reports. The 2006 Alaska Stock Assessment Report is available at: *http://www.nmfs.noaa.gov/pr/sars/region.htm* Please refer to these documents for information on these potentially affected marine mammal species.

Potential Effects of Seismic Surveys on Marine Mammals

Disturbance by drilling sounds is the principal means of taking by this activity. Drilling vessels, support vessels including ice management vessels, and aircraft may provide a potential second source of noise. The physical presence of vessels and aircraft could also lead to non-acoustic effects on marine mammals involving visual or other cues.

As outlined in previous NMFS documents, the effects of noise on marine mammals are highly variable, and can be categorized as follows (based on Richardson *et al.*, 1995):

(1) The noise may be too weak to be heard at the location of the animal (i.e., lower than the prevailing ambient noise level, the hearing threshold of the animal at relevant frequencies, or both);

(2) The noise may be audible but not strong enough to elicit any overt behavioral response;

(3) The noise may elicit reactions of variable conspicuousness and variable relevance to the well being of the marine mammal; these can range from temporary alert responses to active avoidance reactions such as vacating an area at least until the noise event ceases;

(4) Upon repeated exposure, a marine mammal may exhibit diminishing responsiveness (habituation), or disturbance effects may persist; the latter is most likely with sounds that are highly variable in characteristics, infrequent and unpredictable in occurrence, and associated with situations that a marine mammal perceives as a threat;

(5) Any anthropogenic noise that is strong enough to be heard has the potential to reduce (mask) the ability of a marine mammal to hear natural sounds at similar frequencies, including calls from conspecifics, and underwater environmental sounds such as surf noise;

(6) If mammals remain in an area because it is important for feeding, breeding or some other biologically important purpose even though there is chronic exposure to noise, it is possible that there could be noise-induced physiological stress; this might in turn have negative effects on the well-being or reproduction of the animals involved; and

(7) Very strong sounds have the potential to cause temporary or permanent reduction in hearing sensitivity. In terrestrial mammals, and presumably marine mammals, received sound levels must far exceed the animal's hearing threshold for there to be any temporary threshold shift (TTS) in its hearing ability. For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound. Received sound levels must be even higher for there to be risk of permanent hearing impairment. In addition, intense acoustic or explosive events may cause trauma to tissues associated with organs vital for hearing, sound production, respiration and other functions. This trauma may include minor to severe hemorrhage.

The only anticipated impacts to marine mammals associated with drilling activities are from propagation of sounds from the drilling units and associated support vessels and aircraft. SOI and NMFS believe that any impacts on the whale and seal populations of the Beaufort Sea activity area are likely to be short term and transitory arising from the temporary displacement of individuals or small groups from locations they may occupy at the times they are exposed to intermittent drilling sounds at the 120–190 db received levels. As noted in SOI's IHA application, it is highly unlikely that animals will be exposed to sounds of such intensity and duration as to physically damage their auditory mechanisms. In the case of bowhead

whales that displacement might well take the form of a deflection of the swim paths of migrating bowheads away from (seaward of) received noise levels greater than 160 db (Richardson *et al.*, 1999). This study and other studies conducted to test the hypothesis of the deflection response of bowheads have determined that bowheads return to the swim paths they were following at relatively short distances after their exposure to the received sounds (SOI, 2006). To date, no evidence has been obtained that bowheads so exposed have incurred injury to their auditory mechanisms. Additionally, while there is no conclusive evidence that exposure to sounds exceeding 160 db have displaced bowheads from feeding activity (Richardson and Thomson, 2002), there is some information that intermittent sounds (e.g., oil drilling and vessel propulsion sounds) may cause a deflection in the migratory path of whales (Malme *et al.*, 1983, 1984), but possibly not when the acoustic source is not in the direct migratory path (Tyack and Clark, 1998).

There is no evidence that seals are more than temporarily displaced from ensonified zones and no evidence that seals have experienced physical damage to their auditory mechanisms even within ensonified zones.

Distance Effects of Open Water Drilling on Marine Mammals

The only type of incidental taking requested in SOI's IHA application is that of takes by noise harassment. The principal sources of project-created noise will be those resulting from the *Kulluk* and *Discoverer* and their support vessels, especially ice management vessels. Although the bulk of the activity will be centered in the area of drilling, potential exposures, or impacts to marine mammals also will occur as the drilling vessels, and ice management vessels mobilize through the Beaufort and Chukchi Seas.

Noise propagation studies were performed on the *Kulluk* (Hall *et al.*, 1994) in the Kuvlum prospect drill sites, approximately 6 mi (9.6 km) east of SOI's Sivulliq prospect that SOI is proposing to drill during 2007. Acoustic recording devices were established at 10–m (33–ft) and 20–m (65.6–ft) depths below water surface at varying distances from the *Kulluk* and decibel (dB) levels were recorded during drilling operations. There were large differences between sound propagation between the different water depths. At 10 m (33 ft) water depth, the 120–db threshold had a 0.7–km (0.4–mi) radius around the *Kulluk*, and the 105–db threshold had an 8.5–km (5.3–mi) radius. At a depth of 20 m (66 ft) below water surface, the 120–db threshold had a radius of 8.5 km (5.3 mi) and the 105–db threshold had a radius of 100 km (62.1 mi). There is no definitive explanation for the large differences in propagation at the different levels. Possible explanations include the presence of an acoustic layer due to melting ice during the sound studies and/or sound being channeled into the lower depths due to the seafloor topography (SOI, 2006). However, new sound propagation studies will be performed on the *Kulluk*, *Discoverer*, ice management, and support vessels once these vessels are at their locations for drilling in the Beaufort Sea.

Numbers of Marine Mammals Expected to Be Taken

Using the marine mammal density estimates presented in Table 6–1 (see IHA application), SOI provided estimates of the numbers of potential marine mammal sound exposures in Table 6–2. Average expected abundances for bowhead whales were derived from the Miller *et al.* (2002) feeding study in which total proportion of the population ''moving through'' was estimated for the depth isopleths in which drilling operations are expected to occur. These estimates are based on the 160 dB re 1 microPa (rms) criteria for most cetaceans, because this range is assumed to be the sound source level at which marine mammals may change their behavior sufficiently to be considered ''taken by harassment.'' The proportion of bowhead whales that might occur within the area potentially ensonified by the 160 dB criterion was estimated from Richardson and Thomson (2002) in which average migrating distribution across the 0–20, 20–40, 40–200 and >200 m (65.6 ft, 131 ft, 656 ft respectively) isopleths are estimated to be 25, 27, 37, and 10 percent of the population respectively. As the majority of the operations related to the 2007 drilling program will occur within the 20–40 m (65.6–131 ft) depth isopleth, SOI estimates that the average expected number of bowheads in this area would be 3,480 individuals. As a conservative estimate of potential bowheads present was twice that number, or a maximum estimate of 6,960 individual bowheads.

Hall *et al.* (1994) utilized measurements from sonobuoys deployed at distances of 20, 27, and 34 km (65.6, 88.6, 111.5 ft) from active drilling operations to estimate that combined activities including drilling, geotechnical boring, vessel transit, and ice management activities may reach 160 dB at a distance of 200 m (656 ft) from the source. Although no single source produced measured sound in excess of 160 dB, this 200–m (656–ft) distance was selected by SOI as a conservative estimate of potential sound propagation from drilling related sources. Although planned operating procedures will limit the number of sound sources that will be operating during any portion of the bowhead migration, the additional conservative assumption is made that 10 sources could simultaneously operate at a level to cumulatively produce 160 dB at 200 m (656 ft). Therefore, the total 160 dB ensonified area would be 2 km (1.2 mi), or approximately 7 percent of the 29–km (18–mi) wide 20–40 m (65.6–131 ft) isopleth. Seven percent of the bowhead whales present in the 20–40 m (65.6–131 ft) isopleth would be 244 animals at the average density estimate and 488 animals at the maximum density estimate.

Based on the findings by Malme *et al.* (1983, 1984) for intermittent low-frequency noise exposures on a low-frequency hearing specialist (gray whales), NMFS requested SOI prepare an estimation of sound exposures to the level of 120 dB rms. Although the biological significance of this 120–dB sound level is subject to debate (as indicated by later research (Tyack and Clark, 1998), if the LF source was removed from the direct migratory path, gray whales ignored the signal), several related studies report (discussed next) that migrating bowhead whales react to and, possibly avoid, sound levels in excess of 120 dB. As such, estimation of exposures to 120 dB levels is included in this discussion.

SOI points out that one difficulty with NMFS' 120–dB criterion for intermittent noise is an inconsistency between field observations of migrating bowhead avoidance behavior associated with sound measurements and sound measurements and modeling that is independent of whale observations. The majority of observations (in the Beaufort Sea) upon which the 120–dB criterion are based are derived from aerial monitoring programs around both drilling and seismic sources. Closest observed proximity of bowhead whales to operating drilling or icebreaking operations vary between 3 km (1.86 mi) (Hall *et al.*, 1994), 11 km (6.8 mi) (LGL & Greeneridge, 1987) and 19 km (11.8 mi) (Ljungblad *et al.*,1987). SOI notes that there is some consistency, however, in estimation of the distance of deflection from drilling/ice management activities being in the range of 10–20 km (6.2–12.4 mi) from the source. Sound measurements acquired in the proximity of observed whales tend to be

approximately 120 dB leading to the conclusion that migrating bowheads tend to avoid sound levels in excess of 120 dB (Richardson *et al.*, 1995). Similar conclusions have been drawn from observations around operating seismic vessels (LGL, 2005).

Projection of sound propagation from measurements of sound around drilling operations and seismic operations and modeled sound propagation (Hall *et al.*, 1994) yielded estimations of the 120–dB isopleth well beyond the 20 km (12.4 mi) distance. For example, Hall *et al.* (1994) estimated the 120–dB isopleth for combined drilling/ice management operations to be in excess of 100 km (62 mi) from the source(s). While subsistence hunters report changes in migrating bowhead whale behavior at distance as far as 35 mi (56 km) from operating seismic vessels, extrapolation of avoidance to greater distances is not generally reported.

For the purpose of estimation of relevant exposures for bowhead whales, a reasonably conservative distance of 30 km (18.6 mi) zone of potential exposure around drilling operations would produce exposures within the 0–20, 20–40, and 40–200 m (65.6 ft, 131 ft, 656 ft respectively) depth zones. As a result, it is possible that exposures to sound levels in excess of 120 dB could be experienced by as much as 65 percent of the population (8,378 individuals).

For all other species, the average expected abundance was estimated by multiplying the reported densities (Table 6–1 in the IHA application) for each species times a potential operational area of 840 km2 (operational is the area in which primary drilling activities will occur, i.e. 29–km (18–mi) width of the 20–m - 40–m (65.6–ft - 131–ft) depth isopleth squared). Maximum expected abundances for all species were estimated by multiplying average expected abundance times two. Average and expected exposures were then calculated by multiplying the abundance times the expected portion of the operational area expected to be ensonified greater than 160 dB (i.e. 0.069).

Ringed seals would be the most prevalent marine mammal species encountered at each of the two proposed drilling areas. Pinnipeds are not likely to react to sounds unless they are ≤170 dB re 1 microPa (rms), and Moulton and Lawson (2002) indicated that most pinnipeds exposed to 170 dB do not visibly react. Under this IHA, SOI has requested a take authorization for all pinnipeds using the maximum density between 170 and 179 dB instead of the 160 dB threshold. SOI's decision to use the lower estimated number is based on the theory that surveys for pinnipeds within the Beaufort Sea, and elsewhere, are based on on-ice counts which will overestimate the number of potential exposures (i.e., only a portion of the animals are in the water, and therefore, could be exposed). Spotted and bearded seals may be encountered in much small numbers than ringed seals, but also have the potential for some exposure.

Potential Impact of the Activity on the Species or Stock

SOI states that the only anticipated impacts to marine mammals associated with drilling activities would be behavioral reactions to noise propagation from the drilling units and associated support vessels. NMFS notes however, that in addition to these sources of anthropogenic sounds, additional disturbance to marine mammals may result from aircraft overflights and the resulting visual disturbance by the drilling vessels themselves. SOI and NMFS believe, however, that the impacts would be temporary and result in only short term displacement of seals and whales from within ensonified zones produced by such noise sources. Any impacts on the whale and seal populations of the Beaufort Sea activity area are likely to be short term and transitory arising from the temporary displacement of individuals or small groups from locations they may occupy at the times they are exposed to drilling sounds at the 160–190 db (or lower) received levels. As noted, it is highly unlikely that animals will be exposed to sounds of such intensity and duration as to physically damage their auditory mechanisms. In the case of bowhead whales that displacement might well take the form of a deflection of the swim paths of migrating bowheads away from (seaward of) received noise levels greater than 160 db (Richardson *et al.*, 1999). Studies conducted to test the hypothesis of the deflection response of bowheads have determined that bowheads return to the swim paths they were following at relatively short distances after their exposure to the received sounds (SOI, 2006). There is no evidence that bowheads so exposed have incurred injury to their auditory mechanisms. Additionally, there is no conclusive evidence that exposure to sounds exceeding 160 db have displaced bowheads from feeding activity (Richardson and Thomson, 2002). Finally, there is no indication that seals are more than temporarily displaced from ensonified zones and no evidence that seals have experienced physical damage to their auditory mechanisms even within ensonified zones.

Potential Effects of Drilling Sounds and Related Activities on Subsistence Needs

SOI notes that there could be an adverse impact on the Inupiat bowhead subsistence hunt if the whales were deflected seaward (further from shore) in the traditional hunting areas north of Pt. Thomson in Camden Bay. The impact would be that whaling crews would necessarily be forced to travel greater distances to intercept westward migrating whales thereby creating a safety hazard for whaling crews and/or limiting chances of successfully striking and landing bowheads. This potential impact is proposed to be mitigated by the application of mitigation procedures described later in this document and implemented by a Conflict Avoidance Agreement (CAA) between the SOI, the Alaska Eskimo Whaling Commission (AEWC) and the whaling captains' associations of Kaktovik, Nuiqsut and Barrow. SOI believes that the proposed mitigation measures will minimize adverse effects on whales and whalers. (see Mitigation later in this document). As a result, there should not be an unmitigable adverse impact on the availability of the marine mammal species, particularly bowhead whales, for subsistence uses.

Potential Impact On Habitat

SOI states that the proposed drilling and related activities will not result in any permanent impact on habitats used by marine mammals, or to their prey sources. Any effects would be temporary and of short duration at any one location. The effects of the planned drilling activities are expected to be negligible. It is estimated that only a small portion of the animals utilizing the areas of the proposed activities would be temporarily displaced from that habitat. During the period of drilling activities (late-July or early-August through October 2007), most marine mammals would be dispersed throughout the Beaufort Sea area. The peak of the bowhead whale migration through the Beaufort Sea typically occurs in October, and efforts to reduce potential impacts during this time will be discussed with the affected whaling communities. Starting in late- August, bowheads may travel in proximity to the drilling activity and some might be displaced seaward by the planned activities. The numbers of cetaceans and pinnipeds subject to displacement are small in relation to abundance estimates for the affected mammal stocks.

In addition, SOI states that feeding does not appear to be an important

activity by bowheads migrating through the eastern and central part of the Alaskan Beaufort Sea in most years. In the absence of important feeding areas, the potential diversion of a small number of bowheads is not expected to have any significant or long-term consequences for individual bowheads or their population. Bowheads, gray, or beluga whales are not predicted to be excluded from any significant habitat.

The proposed activities are not expected to have any habitat-related effects that would produce long-term affects to marine mammals or their habitat due to the limited extent of the acquisition areas and timing of the activities.

Proposed Mitigation and Monitoring Measures

SOI has proposed implementing a marine mammal mitigation and monitoring program (MMMMP) that will consist of monitoring and mitigation during the exploratory drilling activities. In conjunction with monitoring during SOI's seismic and shallow-hazard surveys (subject to an upcoming notice and review), monitoring will provide information on the numbers of marine mammals potentially affected by these activities and permit real time mitigation to prevent injury of marine mammals by industrial sounds or activities. These goals will be accomplished by conducting vessel- , aerial-, and acoustic-monitoring programs to characterize the sounds produced by the drilling and to document the potential reactions of marine mammals in the area to those sounds and activities. Acoustic modeling will be used to predict the sound levels produced by the shallow hazards and drilling equipment in the U.S. Beaufort Sea. For the drilling program, acoustic measurements will also be made to establish zones of influence (ZOIs) around the activities that will be monitored by observers. Aerial monitoring and reconnaissance of marine mammals and recordings of ambient sound levels, vocalizations of marine mammals, and received levels should they be detectable using bottom-founded acoustic recorders along the Beaufort Sea coast will be used to interpret the reactions of marine mammals exposed to the activities. The components of SOI's monitoring program is briefly described next. Additional information can be found in SOI's application.

Underwater Acoustics Program

Sounds produced during the drilling operation and by the shallow hazards equipment and other support vessels will be measured in the field during typical operations. These measurements will be used to establish disturbance radii for marine mammal groups within the project area. The objectives of SOI's planned work are: (1) to measure the distances from the various sound sources to broadband received levels of 170, 160, and 120 dB rms re 1 microPa (sounds are not expected to reach 180 dB), and (2) to measure the radiated vessel sounds vs. distance for the source and support vessels. The measurements will be made at the beginning of the specific activity (i.e., shallow hazards survey activity and drilling activity) and all safety and disturbance radii will be reported within 72 hours of completing the measurements. For the drilling operation, a subsequent mid-season assessment will be conducted to measure sound propagation from combined drilling operations during ''normal'' operations. For drilling activities, the primary radii of concern will be the 160–dB disturbance radii (although measurements will be made to the 180–dB isopleth). In addition to reporting the radii of specific regulatory concern, distances to other sound isopleths down to 120 dB (if measurable) will be reported in increments of 10 dB. The distance at which received sound levels become ≤ 120 dB for continuous sound (which occurs during drilling activities as opposed to impulsive sound which occurs during seismic activities) is sometimes considered to be a zone of potential disturbance for some cetacean species by NMFS. SOI plans to use vessel-based marine mammal observers (MMOs) to monitor the 160–dB disturbance radii around the seismic sound sources and, if necessary, to implement mitigation measures for the 190- and 180–dB safety radii. The MMOs will also monitor the 120–dB zone around the drilling ships. An aerial survey program will be implemented to monitor the 120–dB zone around the drilling activities in the Beaufort Sea in 2007. These two monitoring and mitigation programs are discussed next.

SOI plans to use a qualified acoustical contractor to measure the sound propagation of the vessel-based drilling rigs during periods of drilling activity, and the drill ships and support vessels while they are underway at the start of the field season. Noise from ships with ice-breaking capabilities will be measured during periods of ice-breaking activity. These measurements will be used to determine the sound levels produced by various equipment and to establish any safety and disturbance radii if necessary. Bottom-founded hydrophones similar to those used in 2006 for measurements of vessel-based seismic sound propagation will likely be used to determine the levels of sound propagation from the drill rigs and associated vessels. An initial sound source analysis will be supplied to NMFS and the drilling operators within 72 hours of completion of the measurements, if possible. A detailed report on the methodology and results of these tests will be provided to NMFS as part of the 90 day report following completion of the drilling program.

Acoustic Monitoring Program

SOI plans to develop an acoustic component of the MMMMP to further understand, define, and document sound characteristics and propagation within the broader Beaufort Sea and potential deflections of bowhead whales from anticipated migratory pathways in response to vessel-based drilling activities. Of particular interest for this investigatory component is the east-west extent of deflection (i.e., how far east of a sound source do bowheads begin to deflect and how far to the west beyond the sound source does deflection persist). Of additional interest is the extent of offshore deflection that occurs. Currently, insufficient information is available on how vessel-based drilling noise similar to that proposed by SOI in the Beaufort Sea in 2007 may impact migrating bowhead whales.

Determining the potential effects of drilling noise on migration bowhead whales will be complicated by the presence of ice-breaking and other support vessels that may contribute significantly to underwater sound levels. Miles *et al.* (1987) reported higher sound pressure levels (SPLs) from ice-breakers underway in open water than from vessel-based drilling activity. SPLs from dredging activity, a working tug, and an icebreaker pushing ice were also greater than those produced by vessel-based drilling activity. However, sounds produced during drilling activity are relatively continuous while ice management vessel sounds are considered to be intermittent, and there is some concern that continuous and intermittent sounds may result in behavioral reactions (at least in mysticete whales) at a greater distance than impulse sound (i.e., seismic) of the same intensity.

Acoustic localization methods provide a possible alternative to aerial surveys for addressing these questions. As compared with aerial surveys, acoustic methods have the advantage of providing a vastly larger number of whale detections, and can operate day or night, independent of visibility, and

to some degree independent of ice conditions and sea state-all of which prevent or impair aerial surveys. However, acoustic methods depend on the animals to call, and to some extent assume that calling rate is unaffected by exposure to industrial noise. Bowheads do call frequently in the fall, but there is some evidence that their calling rate may be reduced upon exposure to industrial sounds, complicating interpretation. Also, acoustic methods require development and deployment of instruments that are stationary (preferably mounted on the bottom) to record and localize the whale calls. According to SOI, acoustic methods would likely be more effective for studying impacts related to a stationary sound source, such as a drilling rig that is operating within a relatively localized area, than for a moving sound source such as that produced by a seismic source vessel.

In addition, SOI plans to conduct a study in 2007 similar to the one conducted for seismic in 2006 in the Chukchi Sea to determine the effect of drilling noise and noise from support vessels and seismic activities on migrating bowhead whales. An acoustic ''net'' array was used during the 2006 field season in the Chukchi Sea. It was designed to (1) collect information on the occurrence and distribution of beluga whales that may be available to subsistence hunters near villages located on the Chukchi Sea coast, and (2) measure the ambient noise levels near these villages and record received levels of sounds from seismic survey activities should they be detectable. The basic components of this effort consisted of bottom-founded equipment for long-duration passive acoustic recording. A suite of autonomous seafloor recorders was deployed in a ''net'' array extending from nearshore to approximately 50 miles offshore. During the 2007 drilling program, SOI proposes to deploy bottom-founded acoustic recorders around SOI's drilling activities that have the ability of recording calling whales. Figure 1 in SOI's IHA application shows potential locations of the bottom-founded recorders and an array layout in relation to the drilling site. The actual locations of the bottom-founded recorders will depend on specifications of recording equipment chosen for the project, and on the acoustical characteristics of the environment, which are yet to be determined. The results of these data will be used to determine the extent of deflection of migrating bowhead whales from the sound sources produced by the vessel-based drill rig.

Aerial Survey Monitoring Program

SOI proposes to conduct an aerial survey program in support of its dual seismic exploration and drilling programs in the Beaufort Sea during summer and fall of 2007. The objectives of the aerial survey will be to: (1) advise operating vessels as to the presence of marine mammals in the general area of operations; (2) monitor the area east of the seismic activity to ensure that large numbers of bowhead mothers and calves do not enter the area where they would be ensonified by seismic sounds ≥120 dB re 1microPa, which might displace them from feeding areas or their preferred migratory routes, (3) collect and report data on the distribution, numbers, movement and behavior of marine mammals near the seismic and drilling operations with special emphasis on migrating bowhead whales; (4) support regulatory reporting and Inupiat communications related to the estimation of impacts of seismic and drilling operations on marine mammals; (5) monitor the accessibility of bowhead whales to Inupiat hunters; and, (6) document how far west of seismic and drilling activities bowhead whales travel before they return to their normal migration paths, and if possible, to document how far east of seismic and drilling operations the deflection begins.

For additional information on SOI's aerial survey design and other information, please refer to SOI's IHA application.

Vessel-based Marine Mammal Monitoring Program

The vessel-based operations will be the core of SOI's MMMMP. The MMMMP will be designed to ensure that disturbance to marine mammals and subsistence hunts is minimized, that effects on marine mammals are documented, and to collect baseline data on the occurrence and distribution of marine mammals in the study area. Those objectives will be achieved, in part, through the vessel-based monitoring and mitigation program.

The MMMMP will be implemented by a team of experienced MMOs, including both biologists and Inupiat personnel, approved in advance by NMFS. The MMOs will be stationed aboard the drilling vessels and associated support vessels throughout the drilling period. The duties of the MMOs will include watching for and identifying marine mammals; recording their numbers, distances, and reactions to the drilling operations; initiating mitigation measures when appropriate; and reporting the results. Reporting of the results of the vessel-based monitoring program will include the estimation of the number of ''takes.''

Drilling activities are expected to occur during August and October 2007. The dates and operating areas will depend upon ice and weather conditions, along with SOI's arrangements with agencies and stakeholders. Vessel-based monitoring for marine mammals will be performed throughout the period of drilling operations. The vessel-based work will provide: (1) the basis for real-time mitigation, (2) information needed to estimate the ''take'' of marine mammals by harassment, which must be reported to NMFS and USFWS, (3) data on the occurrence, distribution, and activities of marine mammals in the areas where the drilling program is conducted, (4) information to compare the distances, distributions, behavior, and movements of marine mammals relative to the source vessels at times with and without drilling or ice-management activity, (5) a communication channel to Inupiat whalers and the Whaling Coordination Center, and (6) employment and capacity building for local residents, with one objective being to develop a larger pool of experienced Inupiat MMOs.

All MMOs will be provided training through a program approved by NMFS, as described later. At least one observer on each vessel will be an Inupiat who will have the additional responsibility of communicating with the Inupiat community and (during the whaling season) directly with Inupiat whalers. Details of the vessel-based marine mammal monitoring program are described in the IHA application.

Mitigation Measures During Drilling Activities

SOI's proposed offshore drilling program incorporates both design features and operational procedures for minimizing potential impacts on marine mammals and on subsistence hunts. The design features and operational procedures are described in the IHA application and are summarized below. Survey design features to reduce impacts include: (1) timing and locating some drilling support activities to avoid interference with the annual fall bowhead whale hunts from Kaktovik, Nuiqsut (Cross Island), and Barrow; (2) conducting pre-season modeling and early season field assessments to establish the appropriate 180 dB and 190 dB safety zones (if necessary), and the 160 and 120 dB behavior radii; and (3) vessel-based (and aerial) monitoring to implement appropriate mitigation (and to assess the effects of project activities on marine mammals).

Under current NMFS guidance ''safety radii'' for marine mammals around acoustic sources are customarily defined as the distances within which received pulse levels are ≥180 dB re 1 microPa (rms) for cetaceans and ≥190 dB re 1 microPa (rms) for pinnipeds. These safety criteria are based on an assumption that lower received levels will not injure these animals or impair their hearing abilities, but that higher received levels might have a potential for such effects. Mitigation measures as discussed below would be implemented if marine mammals are observed within or about to enter these safety radii. However, Greene (1987) reported SPLs ranging from 130–136 dB (rms) at 0.2 km (656 ft) from the *Kulluk* during drilling activities (drilling, tripping, and cleaning) in the Arctic. Higher received levels up to 148 dB (rms) were recorded for supply vessels that were underway and for icebreaking activities. As a result, SOI believes that the exploratory drilling and the activities of the support vessels are not likely to produce sound levels sufficient to cause temporary hearing loss or permanent hearing damage to any marine mammals. Consequently, standard mitigation as described later in this document for seismic activities including shut down of any drilling activity should not be necessary (unless sound monitoring tests described elsewhere in this document indicate SPLs at or greater than 180 dB). If testing indicates SPLs will reach or exceed 180 dB or 190 dB, then appropriate mitigation measures would be implemented by SOI to avoid potential Level A harassment of cetaceans (at or above 180 dB) or pinnipeds (at or above 190 dB). Mitigation measures may include reducing drilling or ice management noises, whichever is appropriate. However, SOI plans to use MMOs onboard the drill ships and the various support and supply vessels to monitor marine mammals and their responses to industry activities. In addition, an acoustical program and an aerial survey program which are discussed in previous sections will be implemented to determine potential impacts of the drilling program on marine mammals.

Marine Mammal Observers

The observer(s) (MMOs and Inupiat) will watch for marine mammals from the best available vantage point on the operating source vessel, which is usually the bridge or flying bridge. The observer(s) will scan systematically with the naked eye and 7 50 reticle binoculars, supplemented with night-vision equipment when needed (see below). Personnel on the bridge will assist the marine mammal observer(s) in watching for pinnipeds and whales. The observer(s) will give particular attention to the areas around the vessel. When a mammal sighting is made, the following information about the sighting will be recorded: (1) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from seismic vessel, apparent reaction to seismic vessel (e.g., none, avoidance, approach, paralleling, etc.), closest point of approach, and behavioral pace; (2) time, location, heading, speed, and activity of the vessel, sea state, ice cover, visibility, and sun glare; (3) the positions of other vessel(s) in the vicinity of the source vessel. This information will be recorded by the MMOs at times of whale (but not seal) sightings.

The ship's position, heading, and speed, the seismic state (e.g., number and size of operating airguns), and water temperature, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables. Distances to nearby marine mammals will be estimated with binoculars containing a reticle to measure the vertical angle of the line of sight to the animal relative to the horizon. Observers may use a laser rangefinder to test and improve their abilities for visually estimating distances to objects in the water. However, previous experience showed that this Class 1 eye-safe device was not able to measure distances to seals more than about 70 m (230 ft) away. However, it was very useful in improving the distance estimation abilities of the observers at distances up to about 600 m (1968 ft)-the maximum range at which the device could measure distances to highly reflective objects such as other vessels. Experience indicates that humans observing objects of more-or-less known size via a standard observation protocol, in this case from a standard height above water, quickly become able to estimate distances within about plus or minus 20 percent when given immediate feedback about actual distances during training.

In addition to routine MMO duties, Inupiat observers will be encouraged to record comments about their observations into the ''comment'' field in the database. Copies of these records will be available to the Inupiat observers for reference if they wish to prepare a statement about their observations. If prepared, this statement would be included in the 90–day and final reports documenting the monitoring work.

Mitigation for Subsistence Uses

The *Kulluk* and *Discoverer*, and all support vessels and aircraft will operate in accordance with the conditions of a CAA currently being negotiated with the AEWC. SOI notes that the CAA for SOI's drilling activity will incorporate all appropriate measures and procedures regarding the timing and areas of the operator's planned activities (i.e., times and places where effects of drilling operations will be monitored and prospectively mitigated to avoid potential conflicts with active subsistence whaling and sealing); communications system between operator's vessels and whaling and hunting crews (i.e., the communications centers will be located in strategic areas); provision for marine mammal observers/Inupiat communicators aboard all project vessels; conflict resolution procedures; and provisions for rendering emergency assistance to subsistence hunting crews. The CAA will also provide guidance toward mitigating any potential adverse effects on the bowhead whale subsistence hunts by member of the villages of Kaktovik and Nuiqsut.

Reporting

The results of the 2007 SOI vessel-based monitoring, including estimates of take by harassment, will be presented in the ''90 day'' and final technical report(s)'' usually required by NMFS under IHAs. SOI proposes that these technical report(s) will include: (1) summaries of monitoring effort: total hours, total distances, and distribution through study period, sea state, and other factors affecting visibility and detectability of marine mammals; (2) analyses of the effects of various factors influencing detectability of marine mammals: sea state, number of observers, and fog/glare; (3) species composition, occurrence, and distribution of marine mammal sightings including date, water depth, numbers, age/size/gender categories, group sizes, and ice cover; (4) sighting rates of marine mammals versus operational state (and other variables that could affect detectability); (5) initial sighting distances versus operational state; (6) closest point of approach versus seismic state; (7) observed behaviors and types of movements versus operational state; (8) numbers of sightings/individuals seen versus operational state; (9) distribution around the drilling vessel and support vessels versus operational state; and (10) estimates of take based on (a) numbers

of marine mammals directly seen within the relevant zones of influence (160 dB, 180 dB, 190 dB (if SPLs of that level are measured)), and (b) numbers of marine mammals estimated to be there based on sighting density during daytime hours with acceptable sightability conditions.

Comprehensive Report

Following the 2007 open water season, a comprehensive report describing the proposed acoustic, vessel-based, and aerial monitoring programs will be prepared. The comprehensive report will describe the methods, results, conclusions and limitations of each of the individual data sets in detail. The report will also integrate (to the extent possible) the studies into a broad based assessment of industry activities and their impacts on marine mammals in the Beaufort Sea during 2007. The report will form the basis for future monitoring efforts and will establish long term data sets to help evaluate changes in the Beaufort Sea ecosystem. The report will also incorporate studies being conducted in the Chukchi Sea and will attempt to provide a regional synthesis of available data on industry activity in offshore areas of northern Alaska that may influence marine mammal density, distribution and behavior.

This comprehensive report will consider data from many different sources including two relatively different types of aerial surveys; several types of acoustic systems for data collection (net array, passive acoustic monitoring, vertical array, and other acoustical monitoring systems that might be deployed), and vessel based observations. Collection of comparable data across the wide array of programs will help with the synthesis of information. However, interpretation of broad patterns in data from a single year is inherently limited. Much of the 2007 data will be used to assess the efficacy of the various data collection methods and to establish protocols that will provide a basis for integration of the data sets over a period of years.

Plan of Cooperation (POC)

SOI notes in its IHA application that POC meetings occurred in Barrow and Nuiqsut on October 16 and 17, 2006, and follow-up meetings are planned for the period May or June 2007 in these communities. SOI conducted a meeting with the Kaktovik Inupiat Corporation in Kaktovik on November 28, 2006, and will continue efforts with public and private organizations to hold additional meetings as needed in Kaktovik during 2007. Following these meetings, a POC report will be prepared.

SOI also notes in its application that negotiations were initiated beginning September 2006 with the AEWC to create a drilling CAA between SOI, and the subsistence hunting communities of Barrow, Nuiqsut, and Kaktovik for the 2007 drilling program activities. The drilling CAA will cover both the proposed Beaufort Sea exploratory and geotechnical drilling programs. SOI and other industry participant operators, with AEWC, attended public meetings and meet with the whaling captains in the communities of Kaktovik, Nuiqsut, and Barrow between January 29–February 1, 2007. These meetings initiated information exchanges with the communities on the potential, proposed open water seismic and drilling programs for 2007. Additional engagements with AEWC and the whaling captains of Kaktovik, Nuiqsut, and Barrow will occur between these meetings and onset of open water activities in June/July of 2007.

If requested, post-season meetings will also be held to assess the effectiveness of the 2007 drilling CAA, to address how well conflicts (if any) were resolved; and to receive recommendations on any changes (if any) might be needed in the implementation of future CAAs.

Endangered Species Act (ESA)

NMFS has issued a biological opinion regarding the effects of oil-and-gas activities in the Arctic Ocean on ESA-listed species and critical habitat under the jurisdiction of NMFS. That biological opinion concluded that oil-and-gas exploration activities are not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. A copy of the Biological Opinion is available upon request (see **ADDRESSES**). NMFS will also consult on the issuance of this IHA under section 101(a)(5)(D) of the MMPA to SOI for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

National Environmental Policy Act (NEPA)

The information provided in the Environmental Assessment (EA) on the Proposed OCS Lease Sale 202 Beaufort Sea Planning Area by the MMS in August 2006 led MMS to determine that implementation of either the preferred alternative or other alternatives identified in the EA would not have a significant impact on the human environment. Therefore, an Environmental Impact Statement was not prepared by MMS. Preliminarily, NMFS has determined that the proposed action discussed in this document is not substantially different from the 2006 action. A final decision on whether to adopt the MMS EA as its own and issue a Finding of No Significant Impact, or to prepare its own NEPA document will be made by NMFS prior to making a final decision on the proposed issuance of an IHA to SOI for this activity.

Preliminary Conclusions

Based on the information provided in SOI's application and other referenced documentation, NMFS has preliminarily determined that the impact of SOI conducting an exploratory drilling program in the U.S. Beaufort Sea in 2007 will have no more than a negligible impact on marine mammals. NMFS has preliminarily determined that the short-term impact of conducting exploratory drilling by two drilling vessels and by supporting vessels, including ice management vessels in the U.S. Beaufort Sea may result, at worst, in a temporary modification in behavior by certain species of marine mammals, including vacating the immediate vicinity around the activity due to noise from the activity.

While behavioral and avoidance reactions may be made by these species in response to the resultant noise, this behavioral change is expected to have a negligible impact on the animals. While the number of potential incidental harassment takes will depend on the distribution and abundance of marine mammals (which vary annually due to variable ice conditions and other factors) in the area of drilling operations, the number of potential harassment takings is estimated to be small (as indicated in Table 6–2 in SOI's application). In addition, no take by death and/or serious injury is anticipated or would be authorized; there is a very low potential for an oil spill to result from the drilling activity, and the potential for temporary or permanent hearing impairment is low due to the low SPLs associated with drilling and ice management activities. Also, Level B harassment takings are likely to be avoided through the incorporation of the monitoring and mitigation measures mentioned in this document and required by the authorization. No rookeries, mating grounds, areas of concentrated feeding, or other areas of special significance for marine mammals occur within or near the planned area of operations during the season of operations.

At this time NMFS is unable to make a preliminary determination that SOI's proposed drilling program will not have an unmitigable adverse impact on

subsistence uses of bowhead whales. As SOI notes in its IHA application, there could be an adverse impact on the Inupiat bowhead subsistence hunt if the whales were deflected seaward (further from shore) in the traditional hunting areas north of Pt. Thomson in Camden Bay. NMFS believes that this could result in whaling crews being forced to travel greater distances to intercept westward migrating whales thereby creating a significant safety hazard for whaling crews (with a potential loss of life), limiting chances of successfully striking and landing bowheads, and/or not landing bowheads quickly before decomposition and spoilage occurs. Prior to issuing an IHA for activities that take place in Arctic waters, NMFS must ensure that the taking by the activity will not have an unmitigable adverse impact on subsistence uses of marine mammals. In 50 CFR 216.103, NMFS has defined an ''unmitigable adverse impact'' to mean:

an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

While SOI states that the potential impact will be mitigated by the application of mitigation procedures described in its application and implemented by a CAA between the SOI, the AEWC and the whaling captains' associations of Kaktovik, Nuiqsut and Barrow, the IHA application does not contain suggested measures to mitigate impacts on the fall bowhead subsistence hunt. NMFS presumes that SOI preferred to not make these measures public while it continued discussions with the AEWC and affected whaling captains (see Plan of Cooperation). Mitigation measures suggested publically include warm shutdown of drilling operations during the subsistence hunt and moving the drilling structures either further offshore or behind the barrier islands. Therefore, while SOI believes that the mitigation measures that will be implemented will minimize any adverse effects on whales and whalers, NMFS has not been provided an opportunity to make a similar determination. In its application, SOI states that it would provide results of its discussion of measures to reduce impacts to subsistence uses for bowhead whales this spring. NMFS encourages SOI to complete its negotiations quickly to ensure NMFS being able to make the determinations necessary under the MMPA within the time frames provided by the MMPA.

Therefore, provided the mitigation measures contained in the CAA are agreed upon by the involved parties (which does not include NMFS) and provided publically during the public comment period, NMFS proposes to issue an IHA to SOI for conducting an offshore drilling program in the U.S. Beaufort Sea in 2007, provided the previously mentioned monitoring and reporting requirements are incorporated. NMFS has preliminarily determined that the proposed activity would result in the harassment of small numbers of marine mammals; would have no more than a negligible impact on the affected marine mammal stocks; and, subject to development of mitigation measures during discussions with interested parties, would not have an unmitigable adverse impact on the availability of species or stocks for subsistence uses.

Dated: April 4, 2007.

P. Michael Payne,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–6753 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040507D]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Ad Hoc Sector Omnibus Committee (Committee) in April, 2007, to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: The meeting will be held on Thursday, April 26, 2007, at 9:30 a.m.

ADDRESSES: The meeting will be held at the Sheraton Ferncroft, 50 Ferncroft Road, Danvers, MA 01923; telephone: (978) 777–2500; fax: (978) 750–7959.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Committee will continue development of sector programs and operational guidelines addressing the specific terms of reference issues provided by the Council.

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

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: April 5, 2007.

Tracey L. Thompson,

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

[FR Doc. E7–6715 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040507C]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Salmon Bycatch Workgroup will meet in Anchorage, AK.

DATES: The meeting will be held on Friday, April 27, 2007, from 9 a.m. to 3 p.m.

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

Council address: North Pacific Fishery Management Council, 605 W.

4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff, telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The Workgroup will receive background information on salmon bycatch patterns, stock of origin information and methodology for establishment of previous catch limits for salmon species in the Bering Sea Aleutian Island trawl fisheries. Plans for development of Workgroup recommendations for options of catch limits (hard caps and trigger caps) by species during the May Workgroup meeting.

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

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: April 5, 2007.

Tracey L. Thompson,

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

[FR Doc. E7–6714 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040507E]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council will hold a meeting of its Rock Shrimp Advisory Panel and Golden Crab Advisory Panel, in Charleston, SC.

DATES: The meetings will take place May 1–3, 2007. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held at the Town and Country Inn, 2008 Savannah Highway, Charleston, SC 29407; telephone: (800) 334–6660 or (843) 571–1000; fax: (843) 766–9444.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer; telephone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net*.

SUPPLEMENTARY INFORMATION: Members of the Rock Shrimp Advisory Panel will meet from 1:30 p.m. - 5 p.m. on May 1, 2007, and from 8:30 a.m. - 12 noon on May 2, 2007.

The Rock Shrimp Advisory Panel will meet jointly with the Golden Crab Advisory Panel from 1:30 p.m. - 5 p.m. on May 2, 2007. The Golden Crab Advisory Panel will meet from 8:30 a.m. - 5 p.m. on May 3, 2007.

Both the Rock Shrimp and Golden Crab Advisory Panels (APs) will receive the following presentations: (1) an overview of the Council's Fishery Ecosystem Plan (FEP), (2) deepwater coral habitats in the South Atlantic Region, and (3) Vessel Monitoring Systems and electronic logbooks currently in use by the Gulf of Mexico shrimp fishery. Following the presentations, advisory panel members will discuss and provide recommendations on the development of allowable gear zones and designations of deepwater coral areas as Habitat Areas of Particular Concern (HAPCs) as alternatives to be included in the Council's Comprehensive Amendment to the FEP. The Rock Shrimp AP and Golden Crab AP will meet jointly to discuss common fishing areas.

In addition, the Rock Shrimp AP will provide recommendations regarding the current ''Use it or Lose it'' provision for the rock shrimp fishery. The provision, created as part of a limited access program for the rock shrimp fishery through Amendment 5 to the Shrimp Fishery management Plan (FMP) for the South Atlantic Region, states that if a limited access rock shrimp permit is ''not active'' during a 48 month period (4 calendar years) it will not be renewed and criteria will be applied to put the permit back in the limited access rock shrimp fishery. A rock shrimp limited access permit is defined as inactive when the vessel it is attached to has less than 15,000 pounds of documented rock shrimp harvest from the exclusive economic zone (EEZ) within the South Atlantic Council's area of jurisdiction in a calendar year. The Rock Shrimp AP will also provide a description of the rock shrimp fishery and the royal red shrimp fishery for inclusion in the FEP. The Golden Crab AP will provide a description of the golden crab fishery for the FEP as well.

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

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for‘ auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meetings.Note: The times and sequence specified in this agenda are subject to change.

Dated: April 5, 2007.

Tracey L. Thompson,

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

[FR Doc. E7–6716 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D.040407A]

Marine Mammals; File No. 984–1814–01

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

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that Dr. Terrie Williams, Department of Ecology and Evolutionary Biology, Center for Ocean Health - Long Marine Laboratory, University of California, 100 Shaffer Road, Santa Cruz, CA, 95060 has been issued an amendment to scientific research Permit No. 984–1814.

ADDRESSES: The amendment and related documents are available for review

upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

FOR FURTHER INFORMATION CONTACT: Kate Swails or Tammy Adams, (301)713–2289.

SUPPLEMENTARY INFORMATION: On February 15, 2007, notice was published in the **Federal Register** (72 FR 7419) that an amendment of Permit No. 984–1814, issued June 21, 2006 (71 FR 37060), had been requested by the above-named individual. The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 984–1814 authorized the permit holder to capture up to 20 adult Weddell seals (*Leptonychotes weddellii*) and disturb up to 30 adult and 10 juvenile seals annually in McMurdo Sound, Antarctica. The animals have a data logger/video system attached, muscle biopsies and blood samples collected, and blubber thickness measured. The permit also authorizes up to 3 research-related mortalities per year. The amendment changes the field season for this project from five August to December field seasons over 5 years to three back to back field seasons over the course of two research years. Researchers will capture 50 Weddell seals annually for 2 years instead of 20 annually over the course of 5 years. Researchers will attach data logger/video systems to 24 adult seals and another 24 seals will have time-depth recorders attached annually. Researchers will measure metabolic rates of all captured seals using open-flow respirometry.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: April 5, 2007.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–6752 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 030507C]

Marine Mammals; File No. 373–1868

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

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that the Point Reyes Bird Observatory (PRBO) Conservation Science (Dr. William J. Sydeman, Responsible Party), 3820 Cypress Drive, # 11 Petaluma, CA 94954 has been issued a permit to conduct scientific research on pinnipeds in California.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

FOR FURTHER INFORMATION CONTACT: Jaclyn Daly or Amy Sloan, (301)713–2289.

SUPPLEMENTARY INFORMATION: On November 6, 2006, notice was published in the **Federal Register** (71 FR 64943) that a request for a scientific research permit to take harbor seals (Phoca vitulina richardsi), northern elephant seals (*Mirounga angustirostris*), California sea lions (*Zalophus californianus*), and northern fur seals (Callorhinus ursinus) had been submitted by the above-named organization. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

A permit has been issued to PRBO to conduct scientific research on pinnipeds. A maximum of 300 harbor seals and 3,050 elephant seals will be captured or handled per year over a five year period, and an estimated 300 elephant seals, 5,150 harbor seals, 600 California sea lions, and five northern fur seals per year will be incidentally disturbed during pinniped research operations.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: April 4, 2007.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–6755 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Patent and Trademark Financial Transactions

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 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 11, 2007.

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

- *E-mail: Susan.Fawcett@uspto.gov.* Include ''0651–0043 comment'' in the subject line of the message.
- *Fax:* 571–273–0112, marked to the attention of Susan Fawcett.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tamara McClure, Office of Finance, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–6345; or by e-mail to *Tamara.McClure@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Under 35 U.S.C. 41 and 15 U.S.C. 1113, the USPTO charges fees for processing and other services related to patents, trademarks, and information products. Customers may submit payments to the USPTO by several methods, including by credit card,

deposit account, and electronic funds transfer (EFT). The provisions of 35 U.S.C. 41 and 15 U.S.C. 1113 are implemented in 37 CFR 1.16–1.28, 2.6–2.7, and 2.206–2.209.

The USPTO is developing a pilot program that will allow customers to access and manage their financial activity records online. Customers will be able to create a Financial Profile through the USPTO Web site by registering a username and password, providing contact information, and specifying the types of notifications and alerts they would like to receive. After establishing a Financial Profile, customers may then add the relevant account information to the profile in order to track their credit card, deposit account, and EFT transactions with the USPTO.

In the future, customers will also be able to use their Financial Profiles to perform transactions with the USPTO by using their previously stored account information. The Financial Profiles are being added to this information collection.

II. Method of Collection

By mail, facsimile, hand delivery, or electronically to the USPTO. Information for Financial Profiles will be collected electronically through the USPTO Web site.

III. Data

OMB Number: 0651–0043.

Form Number(s): PTO–2038, PTO–2231, PTO–2232, PTO–2233, PTO–2234, PTO–2236.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 1,929,205 responses per year, including 500 responses per year for Financial Profiles.

Estimated Time Per Response: The USPTO estimates that it will take the public approximately two to four minutes (0.03 to 0.07 hours) to prepare and submit the existing items in this collection. The USPTO estimates that it will take the public approximately six minutes (0.10 hours) to complete and submit a Financial Profile.

Estimated Total Annual Respondent Burden Hours: 58,166 hours per year, including 50 hours per year for Financial Profiles.

Estimated Total Annual Respondent Cost Burden: $2,617,470 per year. The USPTO expects that 75% of the submissions for this information collection will be prepared by fee administrators/coordinators and that 25% of the submissions will be prepared by paraprofessionals. Using those proportions and the estimated rates of $30 per hour for fee administrators/coordinators and $90 per hour for paraprofessionals, the USPTO estimates that the average rate for all respondents will be approximately $45 per hour. Using this estimated rate of $45 per hour, the USPTO estimates that the respondent cost burden for submitting the information in this collection will be approximately $2,617,470 per year, including $2,250 in respondent cost burden for the Financial Profiles.

Item	Estimated time for response (minutes)	Estimated annual responses	Estimated annual burden hours
Financial Profiles	6	500	50
Total	.....	500	50

Estimated Total Annual Non-hour Respondent Cost Burden: $237,168. This collection is currently approved with a total of $237,168 in annual (non-hour) cost burden in the form of service fees for deposit accounts and returned payments, postage costs for mailing submissions to the USPTO, and recordkeeping costs related to electronic credit card payments and electronic deposit account replenishments. There are no additional annual costs associated with the Financial Profiles.

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, e.g., 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 3, 2007.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E7–6731 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) 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: United States Patent and Trademark Office (USPTO).

Title: Post Allowance and Refiling.

Form Number(s): PTO/SB/44/50/51/51S/52/53/56/57/58 and PTOL–85B.

Agency Approval Number: 0651–0033.

Type of Request: Revision of a currently approved collection.

Burden: 68,245 hours annually.

Number of Respondents: 224,926 responses per year.

Avg. Hours Per Response: The USPTO estimates that it will take the public from approximately 1.8 minutes (0.03 hours) to two hours to read the instructions, gather the necessary information, prepare the appropriate form or other document, and submit the information to the USPTO.

Needs and Uses: The USPTO is required by 35 U.S.C. 131 and 151 to examine applications and issue them as patents when appropriate. The applicant must then pay the required issue fee to receive the patent and avoid abandonment of the application. The USPTO can also correct errors in patents

and reissue patents as appropriate. Under 37 CFR 1.510–1.570 and 37 CFR 1.902–1.997, the USPTO may grant requests for *ex parte* and *inter partes* reexamination proceedings. The public uses this collection to request corrections of errors in issued patents, to request reissue patents, to request reexamination proceedings, and to ensure that the necessary fees and documentation are submitted to the USPTO. The USPTO is adding two items to this information collection, an electronic version of the Issue Fee Transmittal (Form PTOL–85B) and a petition to request an extension of time in *ex parte* or *inter partes* reexamination proceedings. This petition is an existing requirement that was not previously covered in this collection.

Affected Public: Individuals or households, businesses or other for-profits, and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by any of the following methods:

• *E-mail: Susan.Fawcett@uspto.gov.* Include ''0651–0033 copy request'' in the subject line of the message.

• *Fax:* 571–273–0112, marked to the attention of Susan Fawcett.

• *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before May 10, 2007 to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

Dated: April 3, 2007.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E7–6735 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2007–0014]

Grant of Interim Extension of the Term of U.S. Patent No. 4,650,787; Sanvar®

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. 156(d)(5) for a third 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 23, 2007, 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 third 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, 2007), a third interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A third 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, 2008.

Dated: April 3, 2007.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E7–6698 Filed 4–9–07; 8:45 am]

BILLING CODE 3510–16–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 19 April 2007, at 10 a.m. in the Commission's offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street, NW., Washington, DC 20001–2728. Items of discussion affecting the appearance of Washington, DC, may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *http://www.cfa.gov*. Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address or call 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated in Washington, DC, 4 April 2007.

Thomas Luebke,

Secretary

[FR Doc. 07–1772 Filed 4–9–07; 8:45 am]

BILLING CODE 6330–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–HA–0022]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In accordance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary of Defense for Health Affairs announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed extension of 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received June 11, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection, please write TRICARE Management Activity, Office of General Counsel, 16401 E. Centretech Parkway, *Attn:* Helen Hilton, Aurora, CO 80011, or call TRICARE Management Activity, Office of General Counsel, at (303) 676–3542.

Title Associated With Form, and OMB Number: Statement of Personal Injury—Possible Third Party Liability, TRICARE Management Activity; DD Form 2527; OMB Number 0720–0003.

Needs and Uses: This information collection is completed by CHAMPUS beneficiaries suffering from personal injuries and receiving medical care at Government expense. The information is necessary in the assertion of the Government's right to recovery under the Federal Medical Care Recovery Act. The data is used in the evaluation and processing of these claims.

Affected Public: Individuals or households; Federal government.

Annual Burden Hours: 33,250.

Number of Respondents: 133,000.

Responses per Respondent: 1.

Average Burden per Response: 20 minutes.

Frequency: On occasion, only when a beneficiary is injured under circumstances creating possible liability in a third party.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The Federal Medical Recovery Act, 42 U.S.C. 2651–2653 as implemented by Executive Order No. 11060 and 28 CFR part 43 provides for recovery of the reasonable value of medical care provided by the United States to a person who is injured or suffers a disease under circumstances creating tort liability in some third person. DD Form 2527 is required for investigating and asserting claims in favor of the United States arising out of such incidents.

When a claim for CHAMPUS benefits is identified as involving possible third party liability and the information is not submitted with the claim, the TRICARE/CHAMPUS contractor requests that the injured party (or a designee) complete DD Form 2527. To protect the interests of the Government, the contractor suspends claims processing until the requested third party liability information is received. The contractor conducts a preliminary evaluation based upon the collection of information and refers the case to a designated appropriate legal officer of the Uniformed Services. The responsible Uniformed Services legal officer uses the information as a basis for asserting and settling the Government's claim. When appropriate, the information is forwarded to the Department of Justice as the basis for litigation.

Section 1 of the Form is used to collect general information, such as name, address and telephone numbers about the military sponsor and the injured beneficiary and the date, time and location where the injured occurred.

Section 2 of the Form is used to collect information about accidental injuries. Most of the investigations for third party liability involve motor vehicle accidents. Information about insurance coverage for the parties involved in the accident is collected. Section 2 of the Form is also used to collect information about accidents that do not involve motor vehicles. Information such as the type of accident, the place where the injury occurred, the name of the property owner where the injury occurred and cause of the injury is collected. The name and address of the employer is collected when the injury was work related.

Section 3 of the Form is used for miscellaneous information such as possible medical treatment at a Government hospital, the name and address of the beneficiary's attorney, and information regarding any possible releases or settlements with another party to the accident. It also contains the certification, date and signature of the beneficiary (or a designee).

Dated: April 3, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1757 Filed 4–9–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–HA–0029]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In accordance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary of Defense for Health Affairs announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed extension of 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received June 11, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection, please write to TRICARE Management Activity, Contract Operations Branch, 16401 E. Centretech Parkway, Attn: Kenneth Zimmerman, Aurora, CO 80011, or call TRICARE Management Activity, Contract Operations Branch, at (303) 676–3502.

Title Associated With Form, and OMB Number: TRICARE Retiree Dental Program Enrollment Form, OM Number 0720–0015.

Needs and Uses: This information collection is completed by Uniformed Services members entitled to retired pay and their eligible family members who are seeking enrollment in the TRICARE Retiree Dental Program (TRDP). The information is necessary to enable the DoD-contracted third party administrator of the program to identify the program's applicants, determine their eligibility for TRDP enrollment, establish the premium payment amount, and to verify by the applicant's signature that the applicant understands the benefits and rules of the program.

Affected Public: Individuals or household.

Annual Burden Hours: 17,833.

Number of Respondents: 71,332.

Responses per Respondent: 1.

Average Burden per Response: 15 minutes.

Frequency: Once, at time of initial application.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The TRICARE Retiree Dental Program (32 CFR 199.22) was implemented in 1998 based on the authority of 10 U.S.C. 1076c. Dental coverage under the program is available on a voluntary basis to retirees of the Uniformed Services entitled to retired pay and their family members. The initial Notice of Proposed rule and proposed information collection was published in the **Federal Register** (62 FR 34032) on June 24, 1997. No comments were received concerning the information collection requirements at that time.

The information collection requirements under this proposed extension are similar to those under the current collection. Information on the applicant, such as name, address, telephone numbers, retiree's social security numbers, is necessary for identification purposes, as is information on the family members to be enrolled. The form contains information on premium payment types of enrollments, and enrollment periods, and a certification statement for the applicant to sign and date. The primary change in the proposed extension of the information collection is the elimination of the requirement for information on the applicant's chosen premium payment methodology if the applicant is not entitled to retired pay (e.g., a surviving spouse). The third party administrator of the program has found it unnecessary to continue the collection of this information on the enrollment form.

Dated: April 2, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1758 Filed 4–9–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0032]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense (Personnel and Readiness), DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 11, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Under Secretary of Defense (Personnel and Readiness) (Military Personnel Policy) (Officer and Enlisted Personnel Management), ATTN: CDR Lesa Kirsch, USN, 4000 Defense Pentagon, Washington, DC 20301–4000 or call at (703) 697–4959.

Title, Associated Form, and OMB Control Number: Repatriation Automated Accounting and Reporting System, DD Form 2585, OMB Control Number 0704–0334.

Needs and Uses: This information collection is necessary for personnel accountability of all evacuees, regardless of nationality, who are processed through designated Repatriation Centers throughout the United States. The information obtained from the DD Form 2585 is entered into an automated system; a series of reports is accessible to DoD Components, Federal and State agencies and Red Cross, as required.

Affected Public: Individuals or households; Federal government.

Annual Burden Hours: 1,667.

Number of Respondents: 5,000.

Responses per Respondent: 1.

Average Burden per Response: 20 minutes.

Frequency: One-time.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Executive Order 12656 (Assignment of Emergency Preparedness Responsibilities) assigns Federal departments and agencies responsibilities during emergency situations. In its supporting role to the Departments of State and Health and Human Services (HHS), the Department of Defense will assist in planning for the protection, evacuation and repatriation of U.S. citizens in threatened areas overseas. The DD Form 2585, *Repatriation Processing Center Processing Sheet* has numerous functions, but it primarily used for personnel accountability of all evacuees who process through designated Repatriation Centers. During processing, evacuees are provided emergency human services, including food, clothing, lodging, family reunification, social services and financial assistance through federal entitlements, loans or emergency aid organizations. The information, once collected, is input into the Repatriation Automated Accounting and Reporting System, and is available to designated offices throughout Departments of Defense, State, Health and Human and Human Services, the American Red Cross and State government emergency planning offices for operational inquiries and reporting and future planning purposes.

Dated: April 2, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1759 Filed 4–9–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0031]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense (Personnel and Readiness), DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 11, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Manpower Data Center, ATTN: Dr. Timothy Elig, 1600 Wilson Boulevard, Suite 400, Arlington, VA 22209–2593, or call at (703) 696–5858.

Title Associated Form and OMB Control Number: Post-Election Voting Survey of Overseas Citizens and Post-Election Voting Survey of Local Election Officials; OMB Control Number 0704–0125.

Needs and Uses: The information collection requirement is necessary to meet a requirement of the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA) of 1986 [42 USC 1973ff]. UOCAVA requires a report to the President and Congress on the effectiveness of assistance under the Act, a statistical analysis of voter participation, and a description of State-Federal cooperation.

Affected Public: Individuals or households; State, local or tribal government.

Annual Burden Hours: 391 hours.

Number of Respondents: 2,343.

Responses per Respondent. 1.

Average Burden per Response: 10 minutes.

Frequency: Quadrennially.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

UOCAVA requires the States to allow Uniformed Services personnel, their family members, and overseas citizens to use absentee registration procedures and to vote by absentee ballot in general, special, primary, and runoff elections for Federal offices. The Act covers members of the Uniformed Services and the merchant marine to include the commissioned corps of the National Oceanic and Atmospheric Administration and Public Health Service, and their eligible dependents. Federal civilian employees overseas, and overseas U.S. citizens not affiliated with the Federal Government. Federal Voting Assistance Program (FVAP) conducts the post-election survey on a statistically random basis to determine participation rates that are representative of all citizens covered by the Act, measure State-Federal cooperation, and evaluate the effectiveness of the overall absentee voting program. The information collected is used for overall program evaluation, management and improvement, and to compile the congressionally-mandated report to the President and Congress.

Dated: April 2, 2007.

Patrica L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1760 Filed 4–9–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

U.S. Strategic Command Strategic Advisory Group

AGENCY: Department of Defense, USSTRATCOM.

ACTION: Notice of closed meeting.

SUMMARY: The Strategic Advisory Group (SAG) will meet in closed session on 8–10 May 2007. The mission of the SAG is to provide timely advice on scientific, technical, intelligence, and policy-related issues to the Commander, U.S. Strategic Command, during the development of the Nation's strategic war plans. Full development of the topics will require discussion of information classified in accordance with Executive Order 12958, dated April 17, 1995. Access to this information must be strictly limited to

personnel having requisite security clearances and specific need-to-know. Unauthorized disclosure of the information to be discussed at the SAG meeting could have exceptionally grave impact upon national defense.

In accordance with Section 10(d) of the Federal Advisory Committee Act (5 U.S.C. App.), it has been determined that this SAG meeting concerns matters listed in 5 U.S.C. Section 552b(c)(1), and that, accordingly, this meeting will be closed to the public.

DATES: 8–10 May 2007.

LOCATION: Offutt AFB, NE 68113–6030.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce Sudduth, USSTRATCOM/J030, (402) 294–4102.

SUPPLEMENTARY INFORMATION: Mr. Floyd March, Joint Staff, (703) 697–0610.

Dated: April 4, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–1754 Filed 4–9–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Task Force on the Future of Military Health Care

AGENCY: Department of Defense, Uniformed Services University of the Health Sciences.

ACTION: Quarterly Meeting Notice.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended) and the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended) announcement of the following meeting:

Name of Committee: Board of Regents of the Uniformed Services University of the Health Sciences.

Date of Meeting: May 18, 2007.

Location: Board of Regents Conference Room (D3001), Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Maryland 20814.

Time: 9 a.m. to 3 p.m.

Proposed Agenda: The actions that will take place include the approval of minutes from the Board of Regents Meeting held February 5, 2007; acceptance of administrative reports; approval of faculty appointments and promotions; and the awarding of post-baccalaureate degrees as follows: Doctor of Medicine, Masters of Science in Nursing, and masters and doctoral degrees in the biomedical sciences and public health. The President, USU; Dean, USU School of Medicine; Acting Dean, USU Graduate School of Nursing; and Director, Armed Forces Radiobiology Research Institute will also present reports. These actions are necessary for the University to remain an accredited medical school and to pursue its mission, which is to provide outstanding health care practitioners and scientists to the uniformed services.

SUPPLEMENTARY INFORMATION: Pursuant to Federal statute and regulations (5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, this meeting is open to the public. Interested persons may submit a written statement for consideration by the Board of Regents. Individuals submitting a written statement must submit their statement to the Designated Federal Officer at the address detailed above. If such statement is not received at least 10 calendar days prior to the meeting, it may not be provided to or considered by the Board of Regents until its next open meeting. The Designated Federal Officer will review all timely submissions with the Board of Regents Chair and ensure such submissions are provided to Board of Regents Members before the meeting. After reviewing the written comments, submitters may be invited to orally present their issues during an open portion of the May 2007 meeting or at a future meeting.

FOR FURTHER INFORMATION AND BASE ACCESS PROCEDURES CONTACT: Janet S. Taylor, Designated Federal Officer.

Dated: April 5, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–1783 Filed 4–6–07; 10:40 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Task Force on the Future of Military Health Care

AGENCY: Department of Defense.

ACTION: Notice of meeting; Correction.

SUMMARY: On March 30, 2007 (72 FR 15118) the Department of Defense published a notice on Department of Defense Task Force on the Future of Military Health Care. Pursuant to the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended) and 41 Code of Federal Regulations (CFR) 102–3.140 thorough 160, the Department of Defense announced the Department of Defense Task Force on the Future of Military Health Care's April 9 and 10, 2007 meeting in San Antonio, Texas

Following submission of that **Federal Register** notice the Task Force members, on March 28, 2007 changed the agenda for the scheduled meeting in San Antonio. Due to these changes and pursuant to 41 CFR 102–3.150, Department of Defense announces a Corrected Meeting Notice for the April 9–10, 2007 meeting of the Department of Defense Task Force on the Future of Military Health Care:

Name of Committee: Department of Defense Task Force on the Future of Military Health Care (hereafter referred to as the Task Force), a duly established subcommittee of the Defense Health Board.

Date of Meetings: April 9 and April 10, 2007

Date of Meeting: April 9, 2007.

Time of Meeting: 1 p.m.–7 p.m.

Place of Meetings:

1 p.m.–3 p.m. Preparatory Work Meeting (Closed to the Public). U.S. Army Institute of Surgical Research, 3400 Rawley E. Chambers Avenue, Brooke Army Medical Center, Fort Sam Houston, Texas, 78234–6315.

3:10 p.m.–5 p.m. Preparatory Work Meeting (Closed to the Public). Center for the Intrepid, 3851 Roger Brooke Drive, Fort Sam Houston, Texas, 78234.

5:30 p.m.–7 p.m. Town Hall Meeting, (Open to the Public). Sam Houston Club, Building 1395 Chaffee Road, Fort Sam Houston, Texas, 78234.

Purpose of Meetings: To obtain, review, and evaluate information related to the Task Force's congressionally-directed mission to examine matters relating to the future of military health care.

The Task Force's preparatory work meetings (1 p.m. to 3 p.m. and 3:10 to 5 p.m.) are convened solely to gather information, conduct research and analyze relevant issues and facts in preparation for an open meeting of the Task Force. As such, both of these meetings, pursuant to 41 CFR 102–3.160(a), are closed to the public.

The Town Hall Meeting, which is open to the public, will be held at the Sam Houston Club and the public is encouraged to attend. During this meeting, the public will have the opportunity to speak, in a Town Hall forum, to the Task Force members about the DoD military health care system.

Date of Meeting: April 10, 2007

Time of Meeting: 7:30 a.m.–5:30 p.m.

Place of Meeting: Hyatt Regency, Hill Country Resort, 9800 Hyatt Resort Drive, San Antonio, Texas, 78251.

7:30 a.m.–7:50 a.m. Administrative Work Meeting (Closed to the Public).

8 a.m.–5 p.m. Public Meeting (Open to the Public).

5:10 p.m.–5:30 p.m. Preparatory Work (Closed to the Public).

Purpose of Meeting: To obtain, review, and evaluate information related to the Task Force's congressionally-directed mission to examine matters relating to the future of military health care. The Task Force members will receive briefings on topics related to the delivery of military health care during the public meeting.

Agenda: Panel discussions with active, retired, Guard/reserve forces and spouses, concerning a variety of issues affecting the military healthcare system.

Prior to the public meeting the Task Force will conduct an Administrative Work Meeting from 7:30 a.m. to 7:50 a.m. to discuss solely administrative matters of the Task Force and to receive administrative information from the Department of Defense.

In addition, the Task Force, following its public meeting, will conduct a Preparatory Work Meeting from 5:10 p.m. to 5:30 p.m. to solely analyze relevant issues and facts in preparation for the Task Force's next meeting.

Both the Administrative and Preparatory Meetings will be held at the Hyatt Regency Hill Country Ballroom.

Both the Administrative Work Meeting and Preparatory Work Meeting, pursuant to 41 CFR 102–3.160(a) and (b), are closed to the public.

Additional information is available online at the Task Force Web site, *http://www.DoDfuturehealthcare.net*.

FOR FURTHER INFORMATION CONTACT: Colonel Christine Bader, Executive Secretary, Department of Defense Task Force on the Future of Military Health Care, TMA/Code: DHS, Five Skyline Place, Suite 810, 5111 Leesburg Pike, Falls Church, Virginia 22041–3206, (703) 681–3279, ext. 109 (*christine.bader@ha.osd.mil*).

SUPPLEMENTARY INFORMATION: Open sessions of the meeting will be limited by space accommodations. Any interested person may attend; however, seating is limited to the space available at the Sam Houston Club and the Hyatt Regency Hill Country.

Individuals or organizations wishing to submit written comments for consideration by the Task Force should provide their comments in an electronic (PDF Format) document to the Executive Secretary of the Department of Defense Task Force on the future of Military Health Care, *christine.bader@ha.osd.mil,* no later than April 6, 2007.

Pursuant to the FACA statute, FACA regulations and DoD policy, substantive changes to any previously announced Federal advisory committee meeting notice must be republished in the **Federal Register**. Rescheduling the visit to San Antonio, Texas to comply with the 15-calendar day requirement of the Sunshine Act and 41 CFR 102–3.150(a) would have an adverse impact on the Task Force's ability to comply with its congressionally-mandated mission. Accordingly, the Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Dated: April 5, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1784 Filed 4–6–07; 10:40 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Task Force on the Future of Military Health Care

AGENCY: DoD.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended) and 41 Code of Federal Regulations (CFR) 102–3.140 through 160, the Department of Defense announces the following committee meeting:

Name of Committee: Department of Defense Task Force on the Future of Military Health Care, a duly established subcommittee of the Defense Health Board.

Date of Meeting: April 25, 2007.

Time of Meeting: 12 p.m. to 4 p.m.

Place of Meeting: National Transportation Safety Board Conference Center, 429 L'Enfant Plaza, Washington, DC 20594.

Purpose of Meeting: To obtain, review, and evaluate information related to the Task Force's congressionally-directed mission to examine matters relating to the future of military health care. The Task Force members will receive briefings on topics related to the delivery of military health care during the public meeting.

Agenda: Discussion topics include Budget and finance issues related to the military healthcare system.

Prior to the public meeting the Task Force will conduct a Preparatory Work Meeting from 8:30 a.m.–11:45 a.m. to solely analyze relevant issues and facts in preparation for the Task Force's next public meeting. In addition, the Task Force, following its public meeting, will conduct an additional Preparatory Work Meeting from 4:10 p.m. to 4:40 p.m. to analyze relevant issues and facts in preparation for the Task Force's next public meeting. Both Preparatory Meetings will be held at the National Transportation Safety Board Conference Center, and pursuant to 41 Code of Federal Regulations, Part 102–3.160(a), both Preparatory Work Meetings are closed to the public.

Additional information and meeting registration is available online at the Task Force Web site: *www.DoDfuturehealthcare.net*

FOR FURTHER INFORMATION CONTACT: Colonel Christine Bader, Executive Secretary, Department of Defense Task Force on the Future of Military Health Care, TMA/Code:DHS, Five Skyline Place, Suite 810, 5111 Leesburg Pike, Falls Church, Virginia 22041–3206, (703) 681–3279, ext. 109 (*christine.bader@ha.osd.mil*).

SUPPLEMENTARY INFORMATION: Open sessions of the meeting will be limited by space accommodations. Any interested person may attend; however, seating is limited to the space available at the National Transportation Safety Board Conference Center. Individuals or organizations wishing to submit written comments for consideration by the Task Force should provide their comments in an electronic (PDF Format) document through the Task Force Web site (*http://www.DoDfuturehealthcare.net*) at the ''Contact Us'' page, no later than five (5) business days prior to the scheduled meeting.

Dated: April 5, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1785 Filed 4–6–07; 10:40 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Task Force on the Future of Military Health Care

AGENCY: DoD

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended) and 41 Code of Federal Regulations (CFR) 102–3.140 through 160, the Department of Defense announces the following committee meeting:

Name of Committee: Department of Defense Task Force on the Future of Military Health Care, a duly established subcommittee of the Defense Health Board.

Date of Meeting: April 18, 2007.

Time of Meeting: 9 a.m. to 4 p.m.

Place of Meeting: National Transportation Safety Board Conference Center, 429 L'Enfant Plaza, Washington, DC 20594.

Purpose of Meeting: To obtain, review, and evaluate information related to the Task Force's congressionally-directed mission to examine matters relating to the future of military health care. The Task Force members will receive briefings on topics related to the delivery of military health care during the public meeting.

Agenda: Discussion topics include: Efficiencies of the military healthcare system; outreach programs and mail order pharmacy issues.

Prior to the public meeting the Task Force will conduct an Administrative Work Meeting from 8:30 a.m. to 8:50 a.m. to discuss solely administrative matters of the Task Force, and to receive administrative information from the Department of Defense. In addition, the Task Force, following its public meeting, will conduct a Preparatory Work Meeting from 4:10 p.m. to 4:40 p.m. to solely analyze relevant issues and facts in preparation for the Task Force's next public meeting. Both the Administrative and Preparatory Meetings will be held at the National Transportation Safety Board Conference Center, and pursuant to 41 CFR 102–3.160(a) and (b), both the Administrative Work Meetings and the Preparatory Work Meetings are closed to the public.

Additional information and meeting registration is available online at the Task Force Web site: *www.DoDfuturehealthcare.net.*

FOR FURTHER INFORMATION CONTACT: Colonel Christine Bader, Executive Secretary, Department of Defense Task Force on the Future of Military Health Care, TMA/Code: DHS, Five Skyline Place, Suite 810, 5111 Leesburg Pike, Falls Church, Virginia 22041–3206, (703) 681–3279, ext. 109 (*christine.bader@ha.osd.mil*).

SUPPLEMENTARY INFORMATION: Open sessions of the meeting will be limited by space accommodations. Any interested person may attend; however, seating is limited to the space available at the National Transportation Safety Board Conference Center. Individuals or organizations wishing to submit written comments for consideration by the Task Force should provide their comments in an electronic (PDF Format) document through the Task Force Web site (*http://www.DoDfuturehealthcare.net*) at the ''Contact Us'' page, no later than five (5) business days prior to the scheduled meeting.

Due to scheduling difficulties the Task Force was unable to finalize its agenda in time to publish notice of its meeting in the **Federal Register** for the 15-calendar days required by 41 CFR 102–3.150(a). Accordingly, the Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Dated: April 5, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–1786 Filed 4–6–07; 10:40 am]

BILLING CODE 5007–06–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Notice of Availability for the Final Environmental Impact Statement for Hemet/San Jacinto Integrated Recharge and Recovery Project, Riverside County, CA

AGENCY: Department of the Army—U.S. Army Corps of Engineers, DoD.

ACTION: Notice of availability.

SUMMARY: The U.S. Army Corps of Engineers, Los Angeles District (Regulatory Division), in coordination with the Eastern Municipal Water District (EMWD), has completed a Final Environmental Impact Statement (EIS) for the Hemet/San Jacinto Integrated Recharge and Recovery Project. EMWD requires authorization pursuant to Section 404 of the Clean Water Act for 15.9 acres of fill into waters of the U.S.

FOR FURTHER INFORMATION CONTACT: Questions or comments concerning the Final EIS should be directed to Dr. Daniel P. Swenson, Regulatory Division, U.S. Army Corps of Engineers, P.O. Box 532711, Los Angeles, CA, 90053, (213) 452–3414. Comments should be submitted no later than May 10, 2007.

SUPPLEMENTARY INFORMATION: None.

Mark Durham,

Acting Chief, Regulatory Division.

[FR Doc. E7–6723 Filed 4–9–07; 8:45 am]

BILLING CODE 3710–KF–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 10, 2007.

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 5, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Vocational and Adult Education

Type of Review: New.

Title: National Research Center for Career and Technical Education.

Frequency: Annually.

Affected Public: Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 10.

Burden Hours: 3,600.

Abstract: Section 114(d)(4) of the Carl D. Perkins Career and Technical Education Act of 2006 (the Act), authorizes the Secretary, after consulting with the States, to establish a national research center for the purposes of conducting scientifically based research and evaluation, disseminations, and training activities. Further, section 114(d)(5) of the Act authorizes the Secretary to carry out technical assistance to States for the purpose of developing, improving, and identifying the most successful methods and techniques for providing career and technical education programs assisted under the Act. The Secretary plans to provide this technical assistance through the research center. The purpose of this information collection is to invite applications for a national research center competition that implements sections 114(d)(4) and (5) of the Act, under which the Secretary will award a cooperative agreement to establish a research center.

This information collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1890–0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection.

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 2287. 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., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. 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. E7–6703 Filed 4–9–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before June 11, 2007.

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.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 4, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: New.

Title: A Study of Differential Effects of ELL Training and Materials.

Frequency: On Occasion; Semi-Annually; Annually.

Affected Public: Individuals or household; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 1,368.

Burden Hours: 751.

Abstract: This study seeks to examine the impact on student achievement of a combination of a comprehensive English Language Learner (ELL) student program, On Our Way to English [OWE], and a professional development course, Responsive Instruction for Success in English [RISE]. Schools identified as having a high percentage of Spanish-speaking ELL students will be randomly assigned to either the treatment condition or a control group. All grade 1–5 classrooms at each school will participate in the condition assigned to the school. This study begins in 2007. OWE and RISE will be implemented in treatment schools during the 2007–2008 and 2008–2009 school years. Data on classroom practices, student activities, and student language and literacy will be collected each of these years. Intermediate and cumulative effects of the interventions will be analyzed using year-end data and data collected over the course of the study. Other analyses may explore education mechanisms that contribute to variation in the impact in achievement.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3303. 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., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. 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. E7–6704 Filed 4–9–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–384–000]

ANR Pipeline Company; Notice of Filing

April 4, 2007.

Take notice that on March 30, 2007, ANR Pipeline Company tendered for filing its Deferred Transportation Cost Adjustment filing.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 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 April 11, 2007.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6686 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER02–1175–003, ER98–4652–004]

Boralex Ft. Fairfield LP, Boralex Stratton Energy LP; Notice of Filing

April 4, 2007.

Take notice that on March 21, 2007, Boralex Ft. Fairfield LP and Boralex Stratton Energy LP each submit corrected FERC Electric Tariffs, designated as Revised Volume No. 1.

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 11, 2007.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6679 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–383–000]

CenterPoint Energy Gas Transmission Company; Notice of Tariff Filing and Crediting Revenue Report

April 4, 2007.

Take notice that on March 30, 2007, CenterPoint Energy Gas Transmission Company (CEGT) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following revised tariff sheets to be effective May 1, 2007:

Twelfth Revised Sheet No. 17
Eleventh Revised Sheet No. 18

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and

interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6685 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–390–000]

El Paso Natural Gas Company; Notice of Tariff and Transportation Service Agreements

April 4, 2007.

Take notice that on April 2, 2007, El Paso Natural Gas Company (El Paso) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1–A, Sixteenth Revised Sheet No. 2 and Seventh Revised Sheet No. 2A to become effective May 3, 2007.

The TSAs are being submitted for the Commission's information and review and have been listed on the tendered tariff sheets as non-conforming agreements.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6692 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL07–53–000]

FirstEnergy Generation Corp.; Notice of Filing

April 4, 2007.

Take notice that on April 2, 2007, FirstEnergy Generation Corp. submitted a petition requesting the Commission to disclaim jurisdiction over passive owner participants associated with a proposed sale and leaseback of existing generation.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on April 20, 2007.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6678 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–382–000]

Florida Gas Transmission Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

April 4, 2007.

Take notice that on March 30, 2007, Florida Gas Transmission Company, LLC (FGT) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the following tariff sheets become effective May 1, 2007:

Original Sheet No. 344
Sheet Nos. 345–449

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or

protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6684 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–380–000]

Horizon Pipeline Company, L.L.C.; Notice of Refund Report

April 4, 2007.

Take notice that on March 30, 2007, Horizon Pipeline Company, L.L.C. (Horizon) filed its Refund Report regarding the penalty revenues, for the period January 1, 2006 through December 31, 2006, that it refunded to its customers pursuant to Section 10.7 of the General Terms and Conditions of its FERC Gas Tariff, Original Volume No. 1.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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 April 11, 2007.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6682 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–387–000]

Kern River Gas Transmission Company; Notice of Report of Gas Compressor Fuel and Lost and Unaccounted-For Gas Factors for 2006

April 4, 2007.

Take notice that on March 30, 2007, Kern River Gas Transmission Company tendered a report supporting its gas compressor fuel and lost and unaccounted-for gas factors for 2006.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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 April 11, 2007.

Philis Posey,

Acting Secretary.

[FR Doc. E7–6689 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–385–000]

Mississippi Canyon Gas Pipeline, LLC; Notice of Tariff Filing and Non-Conforming Service Agreement

April 4, 2007.

Take notice that on March 30, 2007, Mississippi Canyon Gas Pipeline, LLC (Mississippi Canyon) as part of its FERC Gas Tariff, First Revised Volume No. 1, First Revised Sheet No. 157, to become effective April 1, 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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6687 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–379–000]

Natural Gas Pipeline Company of America; Notice of Proposed Change in FERC Gas Tariff

April 4, 2007.

Take notice that on March 30, 2007, Natural Gas Pipeline Company of America (Natural) tendered for filing are part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to become effective May 1, 2007.

Natural states that copies of the filing are being mailed to its customers and interested state regulatory agencies.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6681 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–386–000]

Northern Border Pipeline Company; Notice of Tariff Filing

April 4, 2007.

Take notice that on March 30, 2007, Northern Border Pipeline Company (Northern Border) tendered for filing to be part of its FERC Gas Tariff, First Revised Volume No. 1, Ninth Revised Sheet No. 99, to become effective May 1, 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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6688 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–378–000]

Pine Needle LNG Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

April 4, 2007.

Take notice that on March 30, 2007 Pine Needle LNG Company, LLC (Pine Needle) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Thirteenth Revised Sheet No. 4 to become effective May 1, 2007.

Pine Needle states that it is serving copies of the instant filing to its affected customers, interested state commissions and other interested parties.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6680 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–388–000]

Texas Gas Transmission, LLC; Notice of Tariff Filing and Non-Conforming Service Agreements

April 4, 2007.

Take notice that on April 2, 2007, Texas Gas Transmission, LLC, (Texas Gas) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets, to become effective April 1, 2007:

Second Revised Sheet No. 52
Original Sheet No. 52A
Ninth Revised Sheet No. 56

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6690 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–381–000]

Trailblazer Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

April 4, 2007.

Take notice that on March 30, 2007, Trailblazer Pipeline Company (Trailblazer) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Fifth Revised Sheet No. 8, to become effective May 1, 2007.

Trailblazer states that copies of this filing are being mailed to its customers and interested state commissions.

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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and

interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6683 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–389–000]

Wyoming Interstate Company, Ltd ; Notice of Proposed Changes in FERC Gas Tariff

April 4, 2007.

Take notice that on April 2, 2007, Wyoming Interstate Company, Ltd tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 2, Fifteenth Revised Sheet No. 38 to become effective May 3, 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 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6691 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

April 4, 2007.

Take notice that the Commission received the following electric rate filings.

Docket Numbers: ER07–113–002.

Applicants: Midwest Independent Transmission System Operator, Inc.; Transmission Owners of the Midwest Independent Transmission System Operator, Inc.; Midwest Stand-Alone Transmission Companies.

Description: Midwest Independent Transmission System Operator, Inc et al submit amendments to their compliance filing submitted on 1/29/07.

Filed Date: 3/23/2007.

Accession Number: 20070403–0267.

Comment Date: 5 p.m. Eastern Time on Friday, April 13, 2007.

Docket Numbers: ER07–562–001.

Applicants: Trans-Allegheny Interstate Line Company.

Description: Trans-Allegheny Interstate Line Company submits its response to the Commission deficiency letter of 3/21/07.

Filed Date: 3/30/2007.

Accession Number: 20070404–0104.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–608–001.

Applicants: Gerdau Ameristeel Energy, Inc.

Description: Gerdau Ameristeel Energy, Inc. submits an amended Electric Tariff No. 1.

Filed Date: 4/3/2007.

Accession Number: 20070403–5021.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 24, 2007.

Docket Numbers: ER07–685–000.

Applicants: Fitchburg Gas & Electric Light Company.

Description: Fitchburg Gas and Electric Co submits a compliance filing to reflect FERC's recently revised accounting and financial reporting requirements re Order 668.

Filed Date: 3/30/2007.

Accession Number: 20070403–0209.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–686–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits the Anza Wholesale Distribution Load Interconnection Facilities Agreement et al with Southwest Transmission Cooperative.

Filed Date: 3/30/2007.

Accession Number: 20070403–0211.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–687–000.

Applicants: New England Power Pool Participants Committee.

Description: The New England Power Pool Participants Committee submits counterpart signature pages of New England Power Pool Agreement dated as of 9/1/71 as amended & executed by Manchester Methane LLC *et al.*

Filed Date: 3/30/2007.

Accession Number: 20070403–0212.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–688–000.

Applicants: Entergy Arkansas, Inc.; Entergy Services, Inc.

Description: Entergy Services Inc., agent and on behalf of the Entergy Arkansas Inc. submits its Thirty-Seventh Amendment to the Power Coordination Interchange and Transmission Service Agreement etc.

Filed Date: 3/30/2007.

Accession Number: 20070403–0213.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–691–000.

Applicants: Consolidated Edison Co. of New York, Inc.

Description: Consolidated Edison Company of New York Inc. submits its Delivery Service Rate Schedule 96 and amendments to Economic Development

Delivery Service Rate Schedule, FERC Rate Schedule 92.

Filed Date: 3/30/2007.

Accession Number: 20070403–0214.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–693–000.

Applicants: Entergy Services, Inc.

Description: Entergy Services, Inc. acting as agent for the Entergy Operating Co's submits an executed Network Operating Agreement & an Network Integration Transmission Service Agreement with the City of Benton, AR.

Filed Date: 3/30/2007.

Accession Number: 20070403–0217.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Docket Numbers: ER07–695–000.

Applicants: PJM Interconnection L.L.C.

Description: PJM Interconnection LLC submits an executed Interconnection Service Agreement with PPL Shoreham Energy, LLC *et al.*

Filed Date: 3/30/2007.

Accession Number: 20070403–0210.

Comment Date: 5 p.m. Eastern Time on Friday, April 20, 2007.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES07–22–001.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, LLC submits an application for authority to continue to borrow funds from the Unsecured Notes for a revolving line of credit up to $50 million etc.

Filed Date: 3/30/2007.

Accession Number: 20070403–0208.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 11, 2007.

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 dockets(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.

Philis J. Posey,

Acting Secretary.

[FR Doc. E7–6720 Filed 4–9–07; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0079; FRL–8296–8]

Agency Information Collection Activities; Submission To OMB for Review and Approval; 8-hour Ozone National Ambient Air Quality Standard Implementation Rule, EPA ICR Number 2236.02, OMB Control Number 2060–0594

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before May 10, 2007.

ADDRESSES: Submit your comments, referencing docket ID number EPA–OAR–HQ–2003–0079, to (1) EPA online using *www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Air Docket, Mail Code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Butch Stackhouse, Air Quality Policy Division, Office of Air Quality Planning and Standards, Mail Code C539–01, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5208, facsimile number (919) 541–0824, electronic mail e-mail address: *stackhouse.butch@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On November 15, 2006 (71 FR 66515), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–OAR–HQ–2003–0079, which is available for public viewing online at *http://www.regulations.gov*, or in person viewing at the Air Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

Use EPA's electronic docket and comment system at *http://www.regulations.gov*, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether

submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov*, as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov*.

Title: 8-Hour Ozone National Ambient Air Quality Standard Implementation Rule.

ICR Numbers: EPA ICR Number 2236.02, OMB Control Number 2060–0594.

ICR Status: This ICR is scheduled to expire on April 30, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Paperwork Reduction Act requires the information found in this Information Collection Request (ICR) number 2236.02, to assess the burden (in hours and dollars) of the 8-hour Ozone National Ambient Air Quality Standard Implementation (NAAQS) Rule as well as the periodic reporting and recordkeeping necessary to maintain the rule. The rule was proposed June 2, 2003 (68 FR 32802) and promulgated in two Phases: Phase 1 published April 30, 2004 (69 FR 23951) and Phase 2 published November 29, 2005 (70 FR 71612). The preamble to the proposed and final regulation addressed the administrative burden in general terms. The preamble to the final Phase 2 rule stated that an ICR would be prepared (70 FR at 71692). The rule includes requirements that involve collecting information from States with areas that have been designated nonattainment for the 8-hour ozone NAAQS. The time period covered in this ICR is a three year period from May 1, 2007 through April 30, 2010. The information collection milestones include State submission of an attainment demonstration State Implementation Plan (SIP), a Reasonable Further Progress (RFP) SIP submission, and a Reasonable Available Control Technology (RACT) SIP. However, not all of the milestones and associated burden and administrative cost estimates apply to every designated nonattainment area. Areas with cleaner air quality have fewer requirements.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 9,511 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: State and local governments.

Estimated Number of Respondents: 30.

Frequency of Response: Annual.

Estimated Total Annual Hour Burden: 285,333.

Estimated Total Annual Cost: $17,400,000 includes $0 annualized capital or O&M costs.

Changes in the Estimates: There is no increase in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens.

Dated: April 2, 2007.

Robert Gunter,

Acting Director, Collection Strategies Division.

[FR Doc. E7–6707 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2006–0720; FRL–8296–9]

Agency Information Collection Activities; Submission To OMB for Review and Approval; Comment Request; NESHAP for Off-Site Waste and Recovery Operations (Renewal), EPA ICR Number 1717.05, OMB Control Number 2060–0313

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on May 31, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before May 10, 2007.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2006–0720, to (1) EPA online using www.regulations.gov (our preferred method), by e-mail to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, Mail Code 2201T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Compliance Assessment and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; e-mail address: *williams.learia@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 6, 2006 (71 *FR* 58853), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID Number EPA–HQ–OECA–2006–0720, which is available for online viewing at *http://www.regulations.gov*, or in person viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday,

excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket Center is (202) 566–1927.

Use EPA's electronic docket and comment system at *http://www.epa.gov*, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search, then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov*, as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov*.

Title: NESHAP for Off-Site Waste and Recovery Operations (Renewal).

ICR Numbers: EPA ICR Number 1717.05; OMB Control Number 2060–0313.

ICR Status: This ICR is scheduled to expire on May 31, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Off-Site Waste and Recovery Operations (40 CFR part 63, subpart DD) were proposed on October 13, 1994, and promulgated on July 1, 1996. These standards apply to hazardous air pollutants (HAP) emissions from selected facilities involved in waste management and recovery operations that are not subject to Federal air standards under other subparts in part 63 commencing construction, modification or reconstruction after the date of proposal if the facility is a ''major source'' of HAP emissions as defined in general provisions to 40 CFR part 63 or the facility has the potential to emit more than 10 tons per year for a single HAP or more than 25 tons per year for multiple HAP. In addition, subpart DD cross-references control requirements to be applied to specific types of affected sources: tanks-level 1, containers, surface impoundments, individual drain systems, oil-water separators and organic water separators, loading, transfer, and storage systems. This information is being collected to assure compliance with 40 CFR part 63, subpart DD. Organic HAP emissions are the pollutants regulated under this subpart.

Owners or operators of the affected facilities described must make one-time-only notifications. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Semiannual reports of excess emissions (or reports certifying that no exceedances have occurred) are required. These notifications, reports, and records are essential in determining compliance; and are required, in general, of all sources subject to NESHAP.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintain reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 63, subpart DD as authorized in section 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined not to be private.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average approximately 218 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Off-Site Waste and Recovery Operations.

Estimated Number of Respondents: 236.

Frequency of Response: Initially, on occasion, and semiannually.

Estimated Total Annual Hour Burden: 154,306 hours.

Estimated Total Costs: $9,928,473, which includes $0 annualized Capital Startup Costs, $5,000 annualized Operations & Maintenance (O&M) Costs and $9,923,473 annualized labor costs.

Changes in the Estimates: There is no change in the labor hours in this ICR compared to the previous ICR. This is due to two considerations. First, the regulations have not changed over the past three years and are not anticipated to change over the next three years. Secondly, the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden. There is a $5,000 correction to the burden cost to cover operations and maintenance costs for photocopying and postage which were not included in the previous ICR approval.

Dated: April 2, 2007.

Robert Gunter,

Acting Director, Collection Strategies Division.

[FR Doc. E7–6708 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0171; FRL–8296–7]

Agency Information Collection Activities; Submission To OMB for Review and Approval; Comment Request; Recordkeeping and Reporting Requirements Regarding the Sulfur Content of Motor Vehicle Gasoline Under the Tier 2 Rule (Renewal), EPA ICR Number 1907.04, OMB Control Number 2060–0437

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request for a renewal of an existing approved collection. This ICR is scheduled to expire on 4/30/07. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before May 10, 2007.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OAR–2003–0171, to (1) EPA online using www.regulations.gov (our preferred method), by e-mail to *a-and-r-docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Air and Radiation Docket and Information Center, Mail Code 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Marilyn Bennett, Office of Transportation and Air Quality, Mail Code 6406J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–343–9624; fax number: 202–343–2802; e-mail address: *bennett.marilyn@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On December 1, 2006, (71 FR 69558), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2003–0171, which is available for online viewing at www.regulations.gov, or in person viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742.

Use EPA's electronic docket and comment system at www.regulations.gov, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at www.regulations.gov as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov*.

Title: Recordkeeping and Reporting Requirements Regarding the Sulfur Content of Motor Vehicle Gasoline under the Tier 2 Rule (Renewal).

ICR Numbers: EPA ICR No. 1907.04, OMB Control Number 2060–0437.

ICR Status: This ICR is scheduled to expire on April 30, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9

Abstract: The requirements covered under this ICR are included in the final Tier 2 rule, published on the February 10, 2000 (65 FR 6698). A minor additional ICR requirement was added to the Tier 2 rule on June 12, 2002 (67 FR 40169).

The scope of the recordkeeping and reporting requirements for each type of party (e.g., refiners, importers, distributors, or retailers of gasoline), and therefore the cost to that party, reflects the party's opportunity to create, control or alter the sulfur content of gasoline. As a result, refiners and importers have significant requirements, which are necessary both for their own tracking and that of downstream parties, and for EPA enforcement, while parties downstream from the gasoline production or import point, such as retailers, have minimal burdens under the rule. Many of the reporting and recordkeeping requirements for refiners and importers regarding the sulfur content of gasoline on which the Tier 2 sulfur program relies currently exist under EPA's reformulated gasoline (RFG) and conventional gasoline (CG) anti-dumping programs. The ICR for the RFG/CG programs covered the majority of the start-up costs associated with the reporting of gasoline sulfur content. Consequently, much of the cost associated with the sulfur-control requirements under the sulfur program has already been accounted for under the ICR for the RFG/CG programs.

The information under this ICR will be collected by EPA's Compliance and Innovative Strategies Division (CISD), Office of Transportation and Air Quality, Office of Air and Radiation (OAR), and by EPA's Air Enforcement Division, Office of Regulatory Enforcement, Office of Enforcement and Compliance Assurance (OECA). The information collected will be used by EPA to evaluate compliance with the gasoline sulfur control requirements under the Tier 2 rule. This oversight by EPA is necessary to ensure attainment of the air quality goals of the Tier 2 program. Proprietary information will be submitted by refiners and importers for demonstrating compliance with the sulfur standards, and for establishing baseline sulfur levels under the credit trading and hardship programs associated with the rule. Confidentiality is handled in accordance with the Freedom of Information Act and EPA regulations at 40 CFR part 2.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average between 12 and 500 hours per respondent, depending on the information collection requirements of the particular party. The average number of hours per response is estimated to be approximately 1 hour. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and

review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Refiners, Importers, Gasoline Terminals, Pipelines, Users of R&D Gasoline.

Estimated Number of Respondents: 1,380.

Frequency of Response: On occasion, monthly and annually.

Estimated Total Annual Hour Burden: 38,573.

Estimated Total Annual Cost: $2,573,954, includes $0 annualized capital or O&M costs.

Changes in the Estimates: There is a decrease of 169 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens because some activities are no longer required under the rule.

Dated: April 2, 2007.

Robert Gunter,

Acting Director, Collection Strategies Division.

[FR Doc. E7–6711 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2006–0036; FRL–8296–6]

Agency Information Collection Activities; Submission To OMB for Review and Approval; Comment Request; NESHAP for Magnetic Tape Manufacturing Operations (Renewal); EPA ICR Number 1678.06, OMB Control Number 2060–0326

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on, or before May 10, 2007.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2006–0036, to (1) EPA online using www.regulations.gov (our preferred method), or by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 2201T , 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Leonard Lazarus, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: 202–564–6369; fax number: 202–564–0050; e-mail address: *lazarus.leonard@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 5, 2006, **Federal Register** (71 FR 58853) EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Additional comments regarding this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2006–0036, which is available for public viewing online at *http://www.regulations.gov,* in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1927.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit, or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. When in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically, or in paper, will be made available for public viewing at *http://www.regulations.gov,* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NESHAP for Magnetic Tape Manufacturing Operations (40 CFR Part 63, Subpart EE).

ICR Numbers: EPA ICR Number 1678.06, OMB Control Number 2060–0326.

ICR Status: This ICR is scheduled to expire on May 31, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct, or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register**, or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Owners or operators of magnetic tape manufacturing operations must make the following one-time-only reports: notification of the date of construction or reconstruction; notification of the anticipated and actual dates of startup; notification of any physical, or operational change to an existing facility which may increase the regulated pollutant emission rate; notification of the date of the initial performance test; and the results of the initial performance test. Owners, or operators also are required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility. Each owner, or operator of an affected magnetic tape coating operation shall install, calibrate, maintain, and operate a monitoring device that continuously measures control device efficiency. Recordkeeping requirements include records of the freeboard ratio, compliance monitoring system (CMS) maintenance and calibration, performance tests, material balance calculation, and hazardous air pollutant (HAP) usage.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 200 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose, or provide information to, or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit, or otherwise disclose the information.

Respondents/Affected Entities: Owners or operators of magnetic tape manufacturing operations.

Estimated Number of Respondents: 6.

Frequency of Response: Initially, on occasion, semiannually, quarterly.

Estimated Total Annual Hour Burden: 3,395.

Estimated Total Annual Cost: $264,722, which includes $11,000 annualized capital cost, $36,000 O&M costs, and $217,722 labor costs.

Changes in the Estimates: There is no change in the labor hours, or cost in this ICR compared to the previous ICR. This is due to two considerations. First, the regulations have not changed during the past three years and are not anticipated to change in the next three years. Second, the growth rate for the industry is very low, negative, or non-existent, so there is no significant change in the overall burden. Because there are no changes in the regulatory requirements and there is no significant industry growth, the labor hours and cost figures in the previous ICR are used in this ICR, and there is no change in burden to industry.

Dated: March 30, 2007.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. E7–6712 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8297–1]

Science Advisory Board Staff Office; Notification of a Public Meeting of the Science Advisory Board Committee on Valuing the Protection of Ecological Systems and Services (C–VPESS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public meeting of the SAB Committee on Valuing the Protection of Ecological Systems and Services (C–VPESS) to discuss a draft committee report related to valuing the protection of ecological systems and services.

DATES: A public meeting of the C–VPESS will be held from 8:30 a.m. to 5:30 p.m. (Eastern Time) on May 1, 2007 and from 8:30 a.m. to 2 p.m. (Eastern Time) on May 2, 2007.

ADDRESSES: The meeting will take place at the SAB Conference Center, 1025 F Street, NW., Suite 3700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning this public teleconference may contact Dr. Angela Nugent, Designated Federal Officer (DFO), via telephone at: (202) 343–9981 or e-mail at: *nugent.angela@epa.gov.* General information concerning the EPA Science Advisory Board can be found on the EPA Web site at: *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: Background on the SAB C–VPESS and its charge was provided in 68 FR 11082 (March 7, 2003). The purpose of the meeting is for the SAB C–VPESS to discuss a draft advisory report calling for expanded and integrated approach for valuing the protection of ecological systems and services.

These activities are related to the Committee's overall charge: to assess Agency needs and the state of the art and science of valuing protection of ecological systems and services and to identify key areas for improving knowledge, methodologies, practice, and research.

Availability of Meeting Materials: Agendas and materials in support of the May 1–2 meeting will be placed on the SAB Web Site at: *http://www.epa.gov/sab/* in advance of the meeting.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the SAB to consider during the advisory process.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes per speaker, with no more than a total of one hour for all speakers. Interested parties should contact Dr. Nugent, DFO, at the contact information noted above by April 23, 2007 to be placed on the public speaker list for the May 1–2, 2007 meeting.

Written Statements: Written statements should be received in the SAB Staff Office by April 23, 2007, so that the information may be made available to the SAB for their consideration prior to this meeting. Written statements should be supplied to the DFO in the following formats: one hard copy with original signature, and one electronic copy via e-mail to *nugent.angela@epa,.gov* (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format).

Meeting Access: For information on access or services for individuals with disabilities, please contact Dr. Angela Nugent at (202) 343–9981 or *nugent.angela@epa.gov.* To request accommodation of a disability, please contact Dr. Nugent, preferably at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: April 4, 2007.

Anthony Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E7–6713 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8295–9]

Draft Operator Training Grant Guidelines for States; Solid Waste Disposal Act, Subtitle I, as Amended by Title XV, Subtitle B of the Energy Policy Act of 2005

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: By this notice, the Environmental Protection Agency (EPA), Office of Underground Storage Tanks (OUST) is advising the public that EPA is issuing for public comment draft operator training grant guidelines for states. In this notice, EPA is publishing the draft operator training grant guidelines in their entirety. In addition, EPA will subsequently post the draft on EPA's Web site. EPA will accept public comments on the draft guidelines submitted by May 10, 2007.

Because EPA does not consider this a notice and comment rulemaking under the Administrative Procedure Act based on the exemption for grant documents (5 U.S.C. 553(a)(2)), EPA will consider but not respond to comments and will not establish a rulemaking docket. EPA developed the draft operator training grant guidelines as required by Section 9010 of Subtitle I of the Solid Waste Disposal Act, as amended by Section 1524 of the Energy Policy Act of 2005.

DATES: EPA is notifying the public via this notice that the draft operator training grant guidelines are available for public comments as of April 10, 2007 and EPA will accept comments submitted by May 10, 2007.

ADDRESSES: Submit your comments by one of the following methods:

1. *E-mail: OUST_Operator_Training@epa.gov*.
2. *Facsimile:* 703–603–0175.
3. *Overnight, hand delivery, or courier:* OUST Operator Training, c/o Tim R. Smith, U.S. Environmental Protection Agency, 2733 South Crystal Drive, Two Potomac Yard (North Building), Room N–4354, Arlington, VA 22202 (phone 703–603–7158).
4. *U.S. Postal Service mail:* OUST Operator Training, c/o Tim R. Smith, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Mail Code 5401P, Washington, DC 20460.

In addition to publishing the draft operator training grant guidelines here, EPA will post the draft guidelines on EPA's Web site at: *http://www.epa.gov/oust/fedlaws/epact_05.htm#Draft*. You may also obtain paper copies from the National Service Center for Environmental Publications (NSCEP), EPA's publications distribution warehouse, by calling 1–800–490–9198; writing to U.S. EPA/NSCEP, Box 42419, Cincinnati, OH 45242–0419; or faxing your request to NSCEP at 301–604–3408. *Ask for:* Grant Guidelines To States For Implementing The Operator Training Provision Of The Energy Policy Act Of 2005 (EPA–510–D–07–002).

FOR FURTHER INFORMATION CONTACT: Tim R. Smith, EPA's Office of Underground Storage Tanks, at *smith.timr@epa.gov* or (703) 603–7158.

SUPPLEMENTARY INFORMATION: On August 8, 2005, President Bush signed the Energy Policy Act of 2005. Title XV, Subtitle B of this act, entitled the Underground Storage Tank Compliance Act of 2005, contains amendments to Subtitle I of the Solid Waste Disposal Act. This is the first federal legislative change for the underground storage tank (UST) program since its inception over 20 years ago. The UST provisions of the law significantly affect federal and state UST programs, require major changes to the programs, and are aimed at further reducing UST releases to our environment. Among other things, the UST provisions of the Energy Policy Act require that states receiving funding under Subtitle I comply with certain requirements contained in the law. OUST worked, and is continuing to work, with its partners to develop grant guidelines that EPA regional tank programs will incorporate into states' grant agreements. The guidelines will provide states that receive UST funds with specific requirements, based on the UST provisions of the Energy Policy Act, for their state UST programs.

Sections 9010(a) and (b) of Subtitle I of the Solid Waste Disposal Act, as amended by Section 1524 of the Energy Policy Act, require EPA to publish guidelines that establish training requirements for three distinct classes of UST system operators and require states to develop state-specific training requirements consistent with the guidelines. As a result of that requirement, EPA worked with states and other UST stakeholders to develop the draft operator training grant guidelines. EPA is seeking public comments on the draft guidelines and will accept comments submitted by May 10, 2007. After considering the comments, EPA anticipates issuing final operator training grant guidelines in summer 2007, which EPA will then incorporate into grant agreements between EPA and states. States receiving funds from EPA for their UST programs must comply with the UST provisions of the Energy Policy Act and will be subject to action by EPA under 40 CFR 31.43 if they fail to comply with the guidelines.

Statutory and Executive Order Reviews: Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to OMB review. Because this grant action is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) or Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. Although this action does create new binding legal requirements, such requirements do not substantially and directly affect tribes under Executive Order 13175 (63 FR 67249, November 9, 2000). Although this grant action does not have significant federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999), EPA consulted with states in the development of these grant guidelines. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866. This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Draft for Public Comment Only—April 10, 2007 Grant Guidelines to States for Implementing the Operator Training Provision of the Energy Policy Act of 2005

U.S. Environmental Protection Agency; Office of Underground Storage Tanks

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Overview of Operator Training Grant Guidelines

Why is EPA Issuing These Guidelines?

The U.S. Environmental Protection Agency (EPA), in consultation with states, developed these grant guidelines to implement the operator training provision in Section 9010(a)(1) of the Solid Waste Disposal Act (SWDA), enacted by the Underground Storage

Tank Compliance Act, part of the Energy Policy Act of 2005 signed by President Bush on August 8, 2005.

Section 1524 of the Energy Policy Act amends Subtitle I of the Solid Waste Disposal Act by adding section 9010. Section 9010 requires EPA to publish guidelines that specify training requirements for three classes of operators:

- Persons having primary responsibility for on-site operation and maintenance of underground storage tank systems.
- Persons having daily on-site responsibility for the operation and maintenance of underground storage tank systems.
- Daily, on-site employees having primary responsibility for addressing emergencies presented by a spill or release from an underground storage tank system.

Section 9010(a)(2) requires EPA to consider:

- State training programs in existence when the guidelines are published.
- Training programs that are being used by tank owners and operators as of August 8, 2005.
- The high turnover rate of tank operators and other personnel.
- The frequency of improvement in underground storage tank equipment technology.
- The business in which tank operators are engaged.
- The substantial differences in the scope and length of training needed for the three classes of operators.
- Such other factors as EPA finds necessary to carry out section 9010.

Section 9010(b)(2) also requires each state receiving Subtitle I funding (hereafter referred to as ''state''), to develop state-specific training requirements that:

- Are consistent with EPA's guidelines.
- Are developed in cooperation with tank owners and operators.
- Consider training programs implemented by tank owners and operators as of the date of enactment of state-specific operator training guidelines.
- Are appropriately communicated to tank owners and operators.

In addition, section 9010(c) requires that all persons who are subject to the operator training requirements specified in these guidelines must:

- Meet the state-specific training requirements.
- Repeat the state-specific training requirements if the tank for which they have primary daily on-site management responsibilities is determined to be out of compliance with a requirement or standard of 40 CFR part 280 or a requirement or standard of a state program approved under section 9004.

EPA's Office of Underground Storage Tanks (OUST) is issuing these grant guidelines to establish the minimum requirements a state receiving Subtitle I funding must meet in order to comply with the operator training provisions of the Energy Policy Act.

What is in These Guidelines?

These guidelines describe the minimum requirements a state's underground storage tank (UST) program must contain in order for a state to comply with the section 9010 requirements for Subtitle I funding. These guidelines include: a description of the classes of operators; required training for each class of operator; deadlines when operator training is required; and examples of acceptable state approaches to operator training.

When do These Guidelines Take Effect?

These guidelines are effective August 8, 2007.

Operator Training Requirements

What Is Operator Training?

Underground storage tank operator training means any program that meets the requirements of these guidelines. Such a program is designed to ensure knowledge regarding operating and maintaining underground storage tank systems.

What Underground Storage Tank Systems do These Guidelines Apply to?

These guidelines apply to underground storage tank systems regulated under Subtitle I, except those excluded by regulation at 40 CFR 280.10(b) and those deferred by regulation at 40 CFR 280.10(c).

How Does a State Implement These Guidelines?

A state implements these guidelines by:

- Exercising the authority to require operator training for all operators in each class;
- Developing state-specific operator training requirements consistent with EPA's guidelines within two years of EPA publishing these guidelines in the **Federal Register**. State-specific operator training requirements must:
  - Be developed in cooperation with tank owners and operators;
  - Take into consideration training programs implemented by tank owners and tank operators as of August 8, 2005; and
  - Be appropriately communicated to tank owners and operators.
- Establishing a procedure to identify persons who are required to be trained under the operator training requirements specified in these guidelines; and
- Ensuring all operators are trained in accordance with these guidelines.

States may choose to be more stringent than these minimum requirements.

Who is Subject to Operator Training Requirements and What Are the Requirements?

Three classes of operators (i.e., individuals) must be trained. These individuals are:

- Class A operator—Individuals having primary responsibility for on-site operation and maintenance of underground storage tank systems.
- Class B operator—Individuals having daily on-site responsibility for the operation and maintenance of underground storage tank systems.
- Class C operator—Daily on-site employees having primary responsibility for addressing emergencies presented by a spill or release from an underground storage tank system.

States must establish a procedure to identify individuals who are required to meet the operator training requirements specified in these guidelines. For example, a state may accomplish this by requiring that underground storage tank system owners or operators identify, for each underground storage tank system, at least one name for each class of operator outlined in these guidelines.

In accordance with the state's procedure to identify persons who are required to be trained, each underground storage tank system must have a Class A, Class B, and Class C operator designated. Individuals designated as a Class A, B, or C operator must, at a minimum, be trained according to these guidelines. Separate individuals may be designated for each class of operator described above or an individual may be designated to more than one of the above operator classes. An individual who is designated to more than one operator class must be trained in each operator class for which he or she is designated. Class A, Class B, and Class C operators may or may not be the owner or operator defined by 40 CFR 280.12.

These guidelines in no way relieve the owner or operator, as defined in 40 CFR part 280, from any legal responsibility mandated by the federal underground storage tank regulations or requirements of a state underground storage tank program approved by EPA under SWDA section 9004.

The following sections of these guidelines characterize, in general terms, each class of operator to further identify responsible individuals to be trained pursuant to these guidelines. These sections also identify general training requirements pertaining to operating and maintaining underground storage tank systems. Operators might perform the operation or maintenance task or direct or monitor the required activity performed by support or contract personnel. See Appendix A (The Three Operator Classes At A Glance) which describes who fits in each operator class and the training requirements. States must further specify training for each individual class of operator by developing state-specific training requirements.

Class A Operator

Typically, a Class A operator will have primary responsibility to operate and maintain the underground storage tank system. This individual manages resources and personnel, such as establishing work assignments, to achieve and maintain compliance with regulatory requirements.

In general, this individual focuses on the broader aspects of the statutory and regulatory requirements (i.e., 40 CFR part 280 or requirements of a state underground storage tank program approved by EPA under SWDA section 9004) necessary to operate and maintain the underground storage tank system. For example, this individual typically ensures that appropriate individual(s):

- Properly operate and maintain the underground storage tank system.
- Maintain appropriate records.
- Are trained to: Operate and maintain the UST system, and keep records.
- Properly respond to emergencies caused by releases or spills from underground storage tank systems at the facility.
- Make financial responsibility documents available to the underground storage tank implementing agency as required.

At a minimum, the Class A operator must be trained in the following:

- A general knowledge of both tank and piping requirements so he or she can make informed decisions regarding compliance and ensure appropriate individuals are fulfilling operation, maintenance, and recordkeeping requirements of 40 CFR part 280 or requirements of a state underground storage tank program approved by EPA under SWDA section 9004 regarding:
  - Spill prevention.
  - Overfill prevention.
  - Release detection.
  - Corrosion protection.
  - Emergency response.
  - Product compatibility.
- Financial responsibility documentation requirements.
- Notification requirements.
- Release and suspected release reporting.
- Temporary and permanent closure requirements.
- Operator training requirements.

Class B Operator

Generally, a Class B operator implements applicable underground storage tank regulatory requirements (i.e., 40 CFR part 280 or requirements of a state underground storage tank program approved by EPA under SWDA section 9004) in the field. This individual focuses on day-to-day aspects of operating, maintaining, and recordkeeping at the locations he or she is responsible for. For example, this individual typically monitors, maintains, and ensures:

- Release detection method performance, recordkeeping, and reporting requirements are met.
- Release prevention equipment, recordkeeping, and reporting requirements are met.
- All relevant equipment complies with performance standards.
- Appropriate individuals are trained to properly respond to emergencies caused by releases or spills from underground storage tank systems at the facility.

Compared with training for the Class A operator, training for the Class B operator will provide a more in-depth understanding of operation and maintenance aspects, but may cover a narrower breadth of applicable regulatory requirements.

States may require either site-specific operator training, which is focused only on equipment used at the underground storage tank facility, or training regarding regulatory requirements that, at a minimum, encompass the following:

- Components of underground storage tank systems.
- Materials of underground storage tank system components.
- Methods of release detection and release prevention applied to underground storage tank components.
- Operation and maintenance requirements of 40 CFR part 280 or requirements of a state underground storage tank program approved by EPA under SWDA section 9004 that apply to underground storage tank systems and include:
  - Spill prevention.
  - Overfill prevention.
  - Release detection.
  - Corrosion protection.
  - Emergency response.
  - Product compatibility.
- Financial responsibility documentation requirements.
- Notification requirements.
- Release and suspected release reporting.
- Temporary and permanent closure requirements.
- Reporting and recordkeeping requirements.
- Class C operator training requirements.

Class C Operator

A Class C operator is an employee and is, generally, the first line of response to events indicating emergency conditions. This individual is responsible for responding to alarms or other indications of emergencies caused by spills or releases from underground storage tank systems. This individual notifies the Class B or Class A operator and appropriate emergency responders when necessary. Not all employees of the facility are necessarily Class C operators. This individual typically:

- Controls or monitors the dispensing or sale of regulated substances, or
- Is responsible for initial response to alarms or releases.

At a minimum, the Class C operator must be trained to:

- Take action in response to emergencies (such as, situations posing an immediate danger or threat to the public or to the environment and that require immediate action) or alarms caused by spills or releases from an underground storage tank system.

When Must Operators Be Trained?

States must ensure that Class A, Class B, and Class C operators are trained according to state-specific training requirements by August 8, 2012, which is three years after the date states are required to develop state-specific training requirements.

After August 8, 2012, states must require operators be trained as follows:

- Class A and B operators must be trained within 30 days or another reasonable period specified by the state, after assuming operation and maintenance responsibilities at the underground storage tank system.
- Class C operators must be trained before assuming responsibility for responding to emergencies.

States must require Class A and Class B operators, as appropriate, to repeat relevant state-specific training requirements if their underground storage tank systems are determined by the state to be out of compliance. At a minimum, an underground storage tank system is out of compliance if the system:

- Does not meet EPA's Significant Operational Compliance requirements for release prevention and release detection measures identified at:

http://www.epa.gov/oust/cmplastc/soc.htm; or

• Is not in significant compliance with other requirements, such as financial responsibility, as determined by the state.

Operators must be retrained within a reasonable time frame established by the state. At a minimum, retraining must include training of the areas determined not in significant compliance.

What Training Approaches Would Meet the Operator Training Requirements?

Operator training must evaluate operator knowledge of the minimum training requirements described for each class of operator in these guidelines.

The following is a list of acceptable approaches to meet training requirements stated in these guidelines:

• An operator training program conducted or developed by the state or by a third party that has received prior state [1] approval. The program may also include in-class, online, or hands-on training. Such a program must include an evaluation of operator knowledge. Examples include testing, practical demonstration, or other tools determined as acceptable by the state.

• An appropriately administered and evaluated verification of operator knowledge (i.e., examination). This determination must be accomplished through an operator examination designed to measure all aspects of operator knowledge required in these guidelines. The state or a third party acceptable to the state may administer this examination. The examination process must be acceptable to the state and reasonably determine the person tested has the necessary knowledge and skills to be considered competent to operate underground storage tanks.

• For Class C operator training, the state may accept training conducted by a trained Class A or Class B operator at the facility.

• Any combination of the above listed operator training approaches or equivalent training approaches recognized by the state.

[1] States may formally or informally establish criteria they deem appropriate to determine the suitability of any training provider or curriculum of training courses provided.

What Enforcement Authority Must States Have for Operator Training?

At a minimum, states must have enforcement authorities for their operator training requirements comparable to those for current underground storage tank requirements.

How Will States Demonstrate Compliance With These Guidelines?

After August 8, 2009, and before receiving future grant funding, states must provide one of the following to EPA:

• For a state that has met the requirements for operator training, the state must submit a certification indicating that the state meets the requirements in the guidelines.

• For a state that has not yet met the requirements for operator training, the state must provide a document that describes the state's efforts to meet the requirements. This document must include:

  • A description of the state's activities to date to meet the requirements in the guidelines;
  • A description of the state's planned activities to meet the requirements; and
  • The date by which the state expects to meet the requirements.

EPA may verify state certifications of compliance through site visits, record reviews, or audits as authorized by 40 CFR part 31.

How Will EPA Enforce State's Compliance With the Requirements in These Guidelines?

As a matter of law, each state that receives funding under Subtitle I, which would include a Leaking Underground Storage Tank (LUST) Cooperative Agreement, must comply with certain underground storage tank requirements of Subtitle I. EPA anticipates State and Tribal Assistance Grants (STAG) funds will be available for inspection and other underground storage tank compliance activities. EPA will also condition STAG grants with compliance with these guidelines. Absent a compelling reason to the contrary, EPA expects to address noncompliance with these STAG grant conditions by utilizing EPA's grant enforcement authorities under 40 CFR 31.43, as necessary and appropriate.

For More Information About the Operator Training Grant Guidelines

Visit the EPA Office of Underground Storage Tanks Web site at *http://www.epa.gov/oust* or call 703–603–9900.

Background About the Energy Policy Act of 2005

On August 8, 2005, President Bush signed the Energy Policy Act of 2005. Title XV, Subtitle B of this act (titled the Underground Storage Tank Compliance Act) contains amendments to Subtitle I of the Solid Waste Disposal Act—the original legislation that created the underground storage tank (UST) program. These amendments significantly affect federal and state underground storage tank programs, will require major changes to the programs, and are aimed at reducing underground storage tank releases to our environment.

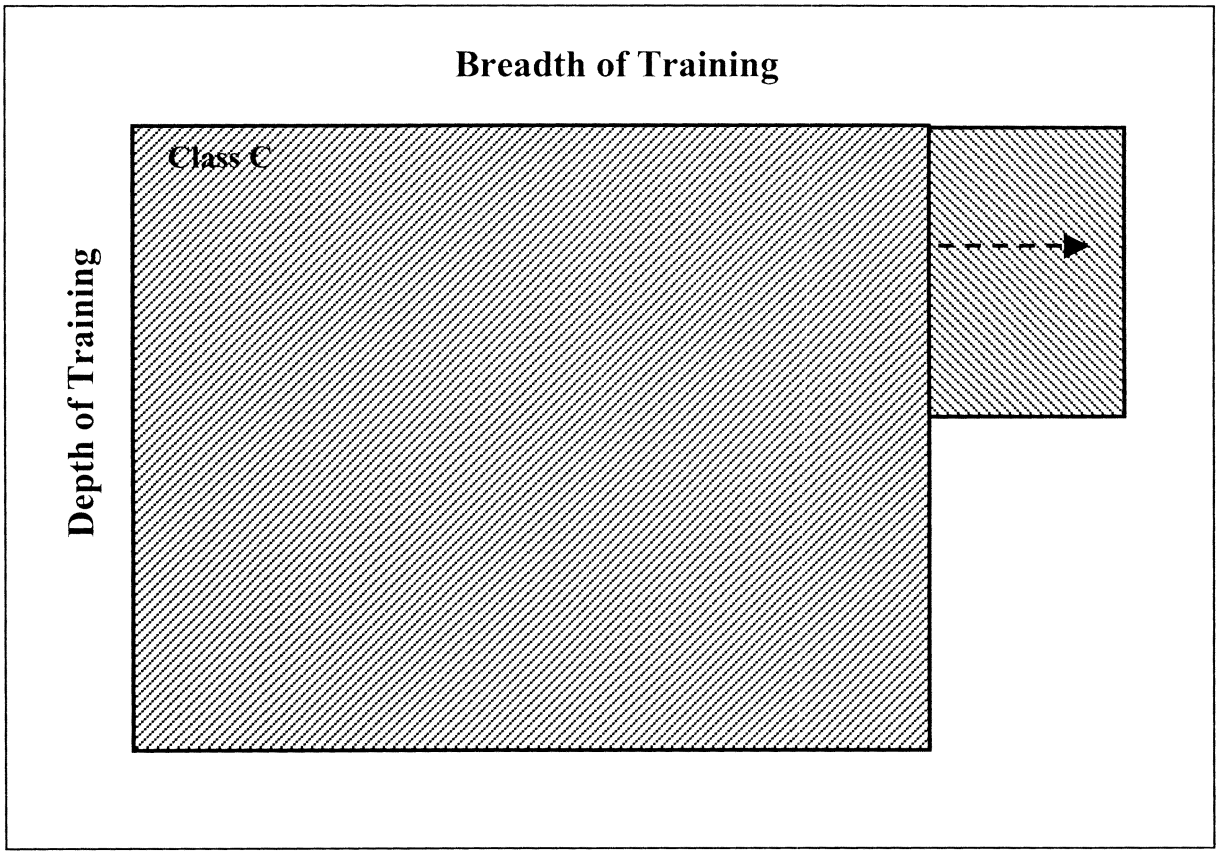
The amendments focus on preventing releases. Among other things, they expand eligible uses of the Leaking Underground Storage Tank (LUST) Trust Fund and include provisions regarding inspections, operator training, delivery prohibition, secondary containment and financial responsibility, and cleanup of releases that contain oxygenated fuel additives.

Some of these provisions require implementation by August 2006; others will require implementation in subsequent years. To implement the new law, EPA and states will work closely with tribes, other federal agencies, tank owners and operators, and other stakeholders to bring about the mandated changes affecting underground storage tank facilities.

To see the full text of this new legislation and for more information about EPA's work to implement the underground storage tank provisions of the law, see: *http://www.epa.gov/oust/fedlaws/nrg05_01.htm*.

Appendix A: The Three Operator Classes at a Glance

	Class A Operator	Class B Operator	Class C Operator
Who fits this class of operator?	The individual who generally focuses on the statutory and regulatory requirements related to operating and maintaining the underground storage tank system	The individual who is generally responsible for field implementation of applicable underground storage tank regulatory requirements and focuses on day-to-day aspects of operating, maintaining, and recordkeeping at each location for which he or she is responsible	The individual who is generally the first line of response to events indicating emergency conditions or responding to alarms
What are the training requirements?	Broad overview of regulatory requirements	In-depth training on implementing regulatory requirements	Actions to take in the event of a leak or other emergency



Dated: April 2, 2007.

Susan Parker Bodine,

Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. E7–6616 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2006–0958; FRL–8297–2]

Expedited Approval of Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: This action announces the Environmental Protection Agency's (EPA's) intent to implement an expedited process for approving alternative testing methods for existing regulations for drinking water contaminants. The Safe Drinking Water Act (SDWA) authorizes EPA to approve the use of alternative testing methods through publication of a notice in the **Federal Register** instead of through rulemaking procedures. EPA plans to use this streamlined authority to make additional methods available for analyzing drinking water compliance and unregulated contaminant monitoring samples. This expedited approach will provide public water systems, laboratories, and primacy agencies with more timely access to new measurement techniques and greater flexibility in the selection of analytical methods, thereby reducing monitoring costs while maintaining public health protection.

This notice requests comments on implementation aspects of the expedited method approval process.

DATES: Comments must be received on or before June 11, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2006–0958, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: OW–Docket@epa.gov.*
- *Fax:* (202) 566–1749.
- *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2006–0958. 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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to Section I.B of the **SUPPLEMENTARY INFORMATION** section of this document.

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, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Patricia Snyder Fair, Technical Support Center, Office of Ground Water and Drinking Water (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268; telephone number: 513–569–7937; e-mail address: *fair.pat@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

This action itself does not impose any requirements on anyone. Instead, it notifies interested parties of EPA's intent to implement an expedited approval process for alternative testing procedures used to measure contaminants in drinking water and seeks comments on options for implementing the process.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit confidential business information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* Your comments will be most helpful if you remember to:

- Identify the action by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a *Code of Federal Regulations* (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.

• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

3. *Timing.* You must submit your comments by the comment period deadline identified above (see **DATES**).

Abbreviations and Acronyms Used in the Notice

ATP: Alternate Test Procedure
CFR: Code of Federal Regulations
EPA: Environmental Protection Agency
MCL: Maximum Contaminant Level
NPDWR: National Primary Drinking Water Regulations
NSDWR: National Secondary Drinking Water Regulations
SDWA: Safe Drinking Water Act
UCMR: Unregulated Contaminant Monitoring Regulations
U.S.C.: United States Code
VCSB: Voluntary Consensus Standard Body

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II. Background

This section provides the purpose of this action, a brief statutory background on approval of testing methods for drinking water contaminants, and a description of how EPA currently approves drinking water testing methods.

A. What Is the Purpose of This Notice?

This action explains the expedited process that EPA plans to implement for the approval of testing methods for drinking water contaminants and seeks comments on specific aspects of the process.

B. Statutory Background

Analytical methods are approved by EPA to support three types of drinking water monitoring. Under the Safe Drinking Water Act (SDWA), EPA promulgates national primary drinking water regulations (NPDWRs) that specify maximum contaminant levels (MCLs) or treatment techniques for drinking water contaminants (SDWA section 1412 (42 U.S.C. 300g–1)). The NPDWRs apply to public water systems pursuant to SDWA section 1401(1)(A) (42 U.S.C. 300f(1)(A)). The NPDWRs include analytical testing methods that are used to measure compliance. Per SDWA section 1401(1)(D), NPDWRs include ''* * * criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including accepted methods for quality control and testing procedures * * *'' (42 U.S.C. 300f(1)(D)). In addition, SDWA section 1445(a)(1) authorizes the Administrator to establish regulations for monitoring to help determine whether persons are acting in compliance with the requirements of SDWA (42 U.S.C. 300j–4). EPA's promulgation of analytical methods for NPDWRs is authorized under these sections of SDWA as well as the general rulemaking authority in SDWA section 1450(a) (42 U.S.C. 300j–9(a)).

SDWA also authorizes EPA to promulgate national secondary drinking water regulations (NSDWRs) for contaminants in drinking water that primarily affect the aesthetic qualities relating to the public acceptance of drinking water (SDWA section 1412 (42 U.S.C. 300g–1)). These regulations are not Federally enforceable but are guidelines for the States (40 CFR 143.1). The NSDWRs also include analytical techniques for determining compliance with the regulations (40 CFR 143.4). EPA's promulgation of analytical methods for NSDWRs is authorized under general rulemaking authority in SDWA section 1450(a) (42 U.S.C. 300j–9(a)).

Section 1445(a)(2) of the Act gives EPA discretion in setting the process for approving analytical methods for unregulated contaminant monitoring. For consistency with the procedures for NPDWRs, EPA includes analytical methods in the unregulated contaminant monitoring regulations (UCMRs).

In the 1996 Amendments to SDWA, Section 1401(1) states the following: ''At any time after promulgation of a regulation referred to in this paragraph, the Administrator may add equally effective quality control and testing procedures by guidance published in the **Federal Register**. Such procedures shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation.'' By this action, EPA is stating that it plans to use this authority to develop an expedited process for establishing alternative testing methods for previously promulgated methods. Under this approach, EPA will publish a notice in the **Federal Register** rather than using a notice-and-comment rulemaking process to approve the use of alternative testing methods for existing regulations.

C. How Does EPA Currently Approve Testing Methods for Drinking Water Contaminants?

When EPA establishes a monitoring requirement for a drinking water contaminant, the Agency also specifies at least one reference analytical method that can be used to determine the contaminant's concentration in drinking water. Public water systems must currently use a testing method listed in the regulation when performing analyses of samples to demonstrate compliance or for use in unregulated contaminant monitoring.

Methods that are incorporated into the regulation are approved through a rulemaking process. In general, this means that EPA publishes a proposed rule, citing the method along with a discussion of how the method can be used to analyze samples. The method is proposed for approval in conjunction with monitoring requirements for one or more specific contaminants. EPA solicits public comment. After consideration of the comments, EPA decides whether to approve the method. If the method is deemed suitable, it is included in a final rule. The method is not approved for analysis of compliance or UCMR samples until it is referenced in a final rule.

EPA examines the performance characteristics of methods prior to proposing them in a regulation. In order for a method to be considered for approval, EPA generally requires that it meet a number of criteria, including the following:

• It must be applicable to routine analyses of samples.

• The method must be suitable for measuring the drinking water contaminant in the concentration range of interest.

• The accuracy and precision of the method must be such that data can be used to demonstrate compliance with the MCL or meet UCMR monitoring objectives in a wide variety of drinking water matrices.

• The method should include instructions for all aspects of the analysis from sample collection to data reporting.

• Appropriate quality control criteria should be incorporated so that acceptable method performance is demonstrated during the analysis of samples.

EPA attempts to approve multiple analytical methods for each contaminant in order to provide public water systems with flexibility in meeting their compliance or unregulated contaminant monitoring requirements. EPA also incorporates as much flexibility as is practical into reference methods that EPA develops itself. Subsequent to the establishment of monitoring requirements, EPA continues to evaluate additional analytical methods as they become available. New methods may be submitted to EPA through the Alternate Test Procedure (ATP) program or from Voluntary Consensus Standard Bodies (VCSBs) such as Standard Methods or ASTM International. Additional methods may also be developed by EPA or EPA may revise existing methods to incorporate improvements in technology, minimize use of hazardous solvents, or reduce the cost of the analysis. To date, when new or revised testing methods were deemed suitable for analyzing compliance or UCMR samples, EPA approved them through the rulemaking process (i.e., by soliciting public comments through a rule proposal and issuing a final rule after taking those comments into consideration). EPA periodically issues method update rules in order to approve additional testing methods.

III. Expedited Method Approval

A. What Is Expedited Method Approval?

Section 1401(1)(D) of SDWA, as amended in 1996, authorizes EPA to approve alternative testing methods outside the normal notice-and-comment rulemaking process. To use this expedited process, EPA must already have promulgated at least one analytical testing method for the contaminant in question through the normal rulemaking process. Once EPA has approved one testing method through the rulemaking process, section 1401(1)(D) allows EPA to approve additional (alternative) testing methods for the same contaminant through an expedited process that simply involves publishing the alternative method in the **Federal Register**. To use this expedited process, EPA must first find that the alternative testing method is ''equally effective'' as the method that was approved through rulemaking.

EPA will examine the performance characteristics of each new method being considered for approval using the expedited process in the same manner as is currently used when promulgating a method by regulation. The method will be evaluated on the basis of its selectivity, bias, precision, quantitation range and detection characteristics. In general, quality control procedures and criteria must be available to provide an on-going demonstration of method performance during the analysis of samples.

After a method is demonstrated to be suitable for analyzing compliance or unregulated contaminant monitoring samples for a specific contaminant, and EPA deems it to be ''equally effective'' as the originally promulgated method, EPA will publish a notice in the **Federal Register** to announce that determination. Because the rulemaking process will not be used, the alternative method will not be cited in the drinking water regulations (which are contained at 40 CFR Part 141). Only the originally promulgated method will continue to be cited in that manner. However, alternative methods approved using the expedited process will be fully available to public water systems for compliance or unregulated contaminant monitoring and reporting to the same extent as the methods that were approved through the normal rulemaking process.

B. Why Is EPA Implementing the Expedited Method Approval Process?

EPA encourages the development of new measurement technologies and the improvement of traditional analytical techniques. These advances often result in benefits such as shorter analysis times, minimized use of solvents, greater specificity in the analytical results, or more robust analytical procedures that are less prone to quality control failures. The benefits can lead to more cost effective monitoring.

The expedited method approval process will improve EPA's ability to make new technologies and improved analytical techniques available in a timely manner. Under the current process, after a method is shown to be suitable for analyzing drinking water compliance or unregulated contaminant monitoring samples, it cannot be used for that purpose until the rulemaking process is completed. The traditional rulemaking process in some cases can take two to three or more years to complete. This means the method is not available for monitoring for several years. Under the expedited process described in this notice, the method will be available as soon as EPA publishes a **Federal Register** notice announcing that the method can be used for analyzing drinking water compliance or UCMR samples. EPA anticipates most alternative methods will be approved in this manner within six to eight months after they are determined to be applicable to the analysis of compliance or UCMR samples.

C. Will EPA Use This Process To Approve All New Methods?

As stated above, EPA will use the expedited methods approval process only to approve additional testing methods for contaminants for which EPA has already promulgated regulations, including at least one analytical method.

EPA anticipates that the expedited process will be the primary mechanism used to approve additional testing methods. EPA expects to use this process to approve new or revised methods from sources such as:

• VCSBs, such as Standard Methods or ASTM International;

• Vendors who have submitted new technologies or methods to the ATP program; and

• EPA or other governmental organizations.

There may be instances in which EPA will seek public comment prior to approving a new or revised method because additional information is needed. In those cases, EPA will consider whether to still approve the new or revised method through the expedited process described in this notice or use the normal rulemaking process.

D. Will EPA Also Use the New Expedited Process To Approve Alternative Methods for National Secondary Drinking Water Regulations and Unregulated Contaminants?

Yes. In addition to using the expedited process with respect to NPDWRs, EPA plans to use the expedited process to approve additional test methods for national secondary drinking water regulations and unregulated contaminants as well. In both cases, there will need to be at least one test method that EPA has already

specified and promulgated by regulation, and EPA will approve the alternative methods only upon finding that they are equally as effective as the specified method.

National secondary drinking water regulations, which are contained in 40 CFR Part 143, are not enforceable but are intended as guidelines for States. Analytical methods are specified in these guidelines at 40 CFR 143.4. EPA will use the expedited process to add any alternative methods that are equally as effective as the methods set forth in the guidelines.

For unregulated contaminants, under the authority of Section 1445(a)(2) of SDWA, EPA promulgates regulations that specify monitoring requirements, including analytical methods. See 40 CFR 141.40. Section 1445(a) gives EPA discretion in setting the process for approving analytical methods for the unregulated contaminants. For consistency with the procedures for NPDWRs, and given Congress's clear intent to expedite the process for adding analytical methods as new methods become available, EPA intends to use these expedited procedures to add methods for the unregulated contaminants as well.

E. Will EPA Use This Process To Withdraw Approval for Methods?

Under certain conditions, it may be necessary for EPA to withdraw approval of a testing method. For example, if an MCL is lowered to better protect public health, a method that was suitable for demonstrating compliance with the higher MCL may no longer have the necessary sensitivity. There may also be instances in which an approved method becomes obsolete because it uses hazardous reagents or fails to meet the performance characteristics of other approved methods.

EPA will not use the expedited process described in this notice to withdraw approval of any method that EPA originally approved through the rulemaking process. In that case, EPA will again use the rulemaking process to withdraw approval for such testing methods when necessary.

However, the new process will be used to withdraw approval of any method that was initially approved using the expedited process. EPA will withdraw approval of such a method by publishing a **Federal Register** notice describing EPA's rationale for the withdrawal and stipulating an effective date for the action.

F. How Often Will Methods Be Approved Using the Expedited Process?

EPA intends to use the expedited approval process in such a manner that methods are approved as soon as possible after they are determined to be suitable for analyzing drinking water compliance or UCMR samples. The frequency will depend on the number of methods that are awaiting approval and the urgency for that approval. For example, EPA may approve a single method using this process if exercising the expedited method could significantly benefit the public by reducing monitoring costs while maintaining data quality. Currently, EPA expects that the process will be implemented at least annually and that it will normally involve approval of multiple methods.

G. How Will I Know When a Method Is Approved Using the Expedited Process?

EPA will publish a notice in the **Federal Register** to announce the expedited method approvals. At a minimum, the notice will list the new method(s) being approved, the contaminant(s) for which each method approval is granted, a reference to the regulation that cites the reference method(s) for each contaminant, and information concerning where a copy of each method can be obtained.

EPA is also considering whether additional information should be included in the **Federal Register** notice. When EPA proposes approval of new methods using the regulatory process, the preamble to the proposed rule usually contains a brief description of the method, a summary of the method performance characteristics, and a discussion of the basis for the approval(s). The information is presented to better inform the reader so that public comment can be obtained. Under the expedited process, EPA does not anticipate publishing this particular information. However, EPA is using this **Federal Register** notice to solicit comment on the type of information that would be useful to the public and regulated entities when new methods are approved using the expedited process.

H. Will There Be a Comprehensive List of All Methods Approved Using the Expedited Process?

EPA plans to maintain a comprehensive list of methods approved through the expedited process. The public availability of the list is one of the subjects EPA is soliciting comment on in this notice. EPA anticipates that State agencies, public water systems, and laboratories will want access to a comprehensive list to simplify the tracking of method approvals listed in multiple **Federal Register** notices.

EPA is requesting input on whether a comprehensive list should be provided and if so, the mechanism for making it available. One option would be to list the methods in the *Code of Federal Regulations* (CFR) as an appendix to the drinking water regulations. A revised hard copy edition of the CFR is printed once per year, but it is continually updated electronically throughout the year and is available to the public through the Internet at *http://ecfr.gpoaccess.gov.* So, while the CFR hard copy would generally contain an up-to-date list of methods, it would not show methods that have been added since the previous published update.

A second option would be to list the methods on an EPA Web site. EPA would update the Web page each time a new method is approved. Under this option, the **Federal Register** notice would list the new method approvals and refer the public to the Web site for a complete listing of methods approved under the expedited process. The Web site could either show the list or provide a link for downloading a fact sheet with the list in an electronic format.

A third option would be to make the list available through the Safe Drinking Water Hotline or through an Agency designated contact for those who do not have Internet access.

A fourth option would combine some or all of the above approaches by listing the methods in an appendix to the CFR, on the Internet, and/or in a fact sheet available from the Agency.

I. Will a Regulation Tell Me Where To Find the Comprehensive List of Methods Approved Using the Expedited Process?

The current regulations at 40 CFR Parts 141 and 143 do not contain any information about where methods approved using the expedited process would be listed. EPA does not plan to immediately change the regulatory text when the expedited method approval process is implemented. If it would be helpful to add a cross-referencing statement in the NPDWRs, NSDWRs, and/or UCMRs, referring to a list of the methods approved using the expedited process so that regulated entities and the public could more easily find the information, EPA may consider such a change to the regulations in future actions.

One option would be to add a paragraph at 40 CFR 141.27, since this section deals with approval of alternate analytical techniques. The paragraph

might state, ''The methods listed in (location of list, per Section III.H, inserted here) may be used as alternatives to the methods listed in the NPDWRs, NSDWRs, and UCMR.''

A second option would be to add a footnote to each table of approved methods in the NPDWRs, NSDWRs and/or UCMR (i.e., 40 CFR 141.21(f)(3), 141.23(k)(1), 141.24(e), 141.25(a), 141.40, 141.74(a)(1), 141.131(b), (c), and (d) and 143.3(b)).

EPA is requesting comment on whether adding the location of the comprehensive list to future regulatory text is warranted, and if so, where that information should be added.

J. Will Regulatory Authorities Accept the Data Generated Using Methods Approved by the Expedited Approach?

In States, territories, and tribes in which EPA has primacy (which includes Wyoming, the District of Columbia, and all Indian lands except the Navajo), when EPA approves an alternative analytical method through the expedited process, a facility will generally be able to use either that new method or the originally promulgated method to meet its regulatory requirements for compliance or unregulated contaminant monitoring and reporting (although there may be State or local restrictions). Note that if a laboratory chooses to use a method approved under the expedited process, it must adhere to the written procedures described in the method and meet all the quality control criteria that are specified, just as it would for a method approved via regulation.

Where the State, territory or tribe has primacy (which, for States and territories, is in most cases), it is up to the State, territory, or tribe to decide whether to allow the use of alternative analytical methods that have been approved by EPA and, if allowed, the process for adopting those new methods within its own program. Since these decisions will vary from State to State, facilities will need to be aware of their Primacy Agency's own requirements prior to using an alternative method that EPA has approved under the expedited method approval process. Primacy Agencies are invited to provide comment on how methods approved under this new procedure will be implemented in their programs and if there are concerns that EPA can address when implementing this new approval process (in order to simplify or expedite Primacy Agency acceptance of the alternative methods).

K. Where Can I Find Copies of the Methods Approved by This Process?

The **Federal Register** notice announcing the approval of methods under the expedited process will include information concerning where the complete methods can be obtained. This information will also be included with the comprehensive list of methods approved under the expedited process.

A docket will be created each time EPA announces approval of methods under the expedited process and a copy of each method will be placed in the docket. All documents in the docket will be listed in the *www.regulations.gov* index. Publicly available docket materials, excluding copyrighted materials, will be available electronically in *www.regulations.gov* and in hard copy at the Water Docket. Copyrighted materials will only be available in hard copy at the Water Docket.

L. Must My Laboratory Be Certified to Use These Methods?

If the originally promulgated regulation requires that the laboratory be certified to perform analyses of compliance samples for a specific contaminant, then EPA plans to extend this requirement to use of methods approved through the expedited process. Similarly, if a ''party approved by the State'' is specified in the regulation, then EPA plans to extend this requirement to use of the alternative method.

M. Are Any Particular Methods Currently Under Consideration for Approval Using the Expedited Process?

In an effort to assist the public in understanding the expedited approval process, EPA is providing two examples of methods that are being considered for approval using this process. Approval is not being granted in this notice, but EPA anticipates approving them when the process is ultimately implemented. They are included herein so that the public can comment on the format of the listing and the type of information presented on each method.

1. EPA Method 200.5, Revision 4.2. Determination of Trace Elements in Drinking Water by Axially Viewed Inductively Coupled Plasma-Atomic Emission Spectrometry (USEPA, 2003)

Axially viewed inductively coupled plasma-atomic emission spectrometry can be used to determine concentrations of several trace elements and water matrix elements in drinking water. The performance characteristics of EPA Method 200.5, Revision 4.2 were compared to the characteristics of the methods listed at 40 CFR 141.23(k)(1) for the same contaminants. Based on this evaluation, EPA expects that it will be able to deem this method to be equally effective as the promulgated methods for determining antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, and selenium concentrations. Therefore, EPA anticipates approving this method when the Expedited Approval Process is implemented in a future **Federal Register** notice (but again, EPA is not approving this method today).

EPA Method 200.5, Revision 4.2, can be accessed and downloaded directly on-line at *http://www.epa.gov/nerlcwww/ordmeth.htm.*

2. Standard Method 6610–04. High-Performance Liquid Chromatographic Method for Carbamate Pesticides (APHA, 2004)

High-performance liquid chromatography with post-column derivatization and fluorescence detection can be used to determine the concentrations of carbamate pesticides in drinking water. Standard Method 6610–04 is based on EPA Method 531.2 (USEPA, 2001), which is approved for analyzing compliance samples for carbofuran and oxamyl (40 CFR 141.24(e)(1)). Therefore, EPA expects that it will be able to deem Standard Method 6610–04 to be equally effective as the promulgated method for determining carbofuran and oxamyl concentrations in compliance samples. Thus, EPA anticipates approving this method when the Expedited Approval Process is implemented in a future **Federal Register** notice (but again, EPA is not approving this method today).

Standard Method 6610 B–04 is available at *http://www.standardmethods.org.*

ALTERNATIVE ANALYTICAL METHODS UNDER CONSIDERATION FOR APPROVAL USING THE EXPEDITED APPROVAL PROCESS

Alternate method (being considered for approval)	Alternate methodology	Contaminant	Citation for methods approved by regulation
EPA Method 200.5, Revision 4.2 [1]	AVICP-AES [2]	Antimony	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Arsenic	40 CFR 141.23(k)(1)

ALTERNATIVE ANALYTICAL METHODS UNDER CONSIDERATION FOR APPROVAL USING THE EXPEDITED APPROVAL PROCESS—Continued

Alternate method (being considered for approval)	Alternate methodology	Contaminant	Citation for methods approved by regulation
EPA Method 200.5, Revision 4.2	AVICP-AES	Barium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Beryllium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Cadmium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Calcium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Chromium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Copper	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Lead	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Magnesium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Selenium	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Silica	40 CFR 141.23(k)(1)
EPA Method 200.5, Revision 4.2	AVICP-AES	Sodium	40 CFR 141.23(k)(1)
Standard Method 6610–04 [3]	HPLC[4]	Carbofuran	40 CFR 141.23(k)(1)
Standard Method 6610–04	HPLC	Oxamyl	40 CFR 141.23(k)(1)

[1] EPA Method 200.5, Revision 4.2, ''Determination of Trace Elements in Drinking Water by Axially Viewed Inductively Coupled Plasma-Atomic Emission Spectrometry,'' USEPA, October 2003, EPA/600/R–06/115 can be accessed and downloaded directly on-line at *http://www.epa.gov/nerlcwww/ordmeth.htm.*

[2] Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).

[3] Carbamate Pesticides—High-Performance Liquid Chromatographic Method. The Standard Method Online version that is approved is indicated by the last two digits in the method number which is the year of approval by the Standard Methods Committee. Standard Methods Online is available at *http://www.standardmethods.org.*

[4] High-performance liquid chromatography (HPLC) in conjunction with a post-column derivatization system and a fluorescence detector.

IV. Request for Comment

EPA seeks comments on several aspects in the implementation of the expedited methods approval process. The information and comments submitted in response to this notice will be considered in determining the final details of the implementation process.

Specifically, EPA seeks comments on the following:

1. EPA requests comment on whether a comprehensive list of methods approved under the expedited process should be publicly maintained. If such a list is desirable, then how should EPA make it available?

- As an appendix in the CFR;
- On an EPA Web page;
- As a table or fact sheet available from an EPA designated contact;
- Using a combination of these approaches or other suggestions.

2. EPA requests comment on the type of information that should be included in the **Federal Register** notice when new method approvals are published using the expedited process. Is a list of the methods being approved sufficient or should the notice include additional information? If additional information is suggested, please indicate the types of information that are desirable and why.

3. EPA requests comment concerning the usefulness of amending future regulatory text to describe where a list of methods approved using the expedited process can be obtained. If such a change is desired, should a reference to the list be included:

- With each methods table;
- In 40 CFR 141.27 under Alternate Test Methods.
- Is there a better suggestion?

4. EPA requests comment on the format of the table that lists methods approved using the expedited approval process. Does the example provided in this notice provide enough information in a usable format or are there better suggestions for listing the information?

5. EPA invites Primacy Agencies to comment on how methods approved under this new procedure will be implemented in their programs and if there are concerns that EPA can address when implementing this new approval process (in order to simplify or expedite Primacy Agency acceptance of the alternative methods).

V. References

American Public Health Association (APHA). 2004. Standard Method 6610–04. Carbamate Pesticides—High-Performance Liquid Chromatographic Method. Standard Methods Online. (Available at *http://www.standardmethods.org.*)

USEPA. 2001. EPA Method 531.2. Measurement of N-methylcarbamoyloximes and N-methylcarbamates in Water by Direct Aqueous Injection HPLC with Postcolumn Derivatization. Revision 1.0. EPA 815–B–01–002. (Available at *http://www.epa.gov/safewater/methods/sourcalt.html.*)

USEPA. 2003. EPA Method 200.5. Determination of Trace Elements in Drinking Water by Axially Viewed Inductively Coupled Plasma-Atomic Emission Spectrometry. Revision 4.2. EPA/600/R–06/115. (Available at *http://www.epa.gov/nerlcwww/ordmeth.htm.*)

Dated: March 30, 2007.

Benjamin H. Grumbles,

Assistant Administrator, Office of Water.

[FR Doc. E7–6726 Filed 4–9–07; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: Equal Employment Opportunity Commission.

DATE AND TIME: Tuesday, April 17, 2007, 9:30 a.m. Eastern Time.

PLACE: Clarence M. Mitchell, Jr. Conference Room on the Ninth Floor of the EEOC Office Building, 1801 ''L'' Street, NW., Washington, DC 20507.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED:

OPEN SESSION:

1. Announcement of Notation Votes,
2. Perspectives on Work/Family Balance and the Federal Equal Employment Opportunity Laws, and
3. Headquarters Project Management and Relocation Services Contract.

Note: In accordance with the Sunshine Act, the meeting will be open to public observation of the Commission's deliberations and voting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.)

Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTY) at any

time for information on these meetings. The EEOC provides sign language interpretation at Commission meetings for the hearing impaired. Requests for other reasonable accommodations may be made by using the voice and TTY numbers listed above.

CONTACT PERSON FOR MORE INFORMATION: Stephen Llewellyn, Acting Executive Officer on (202) 663–4070.

This Notice Issued April 6, 2007.

Stephen Llewellyn,

Acting Executive Officer, Executive Secretariat.

[FR Doc. 07–1799 Filed 4–6–07; 1:03 pm]

BILLING CODE 6570–06–M

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Meeting of the President's Council of Advisors on Science and Technology

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a meeting of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (FACA).

Dates and Place: April 24, 2007, Washington, DC. The meeting will be held in Room 100 at the Keck Center of the National Academies at 500 5th St., NW., Washington, DC.

Type of Meeting: Open. Further details on the meeting agenda will be posted on the PCAST Web site at: *http://www.ostp.gov/PCAST/pcast.html.*

Proposed Schedule and Agenda: The President's Council of Advisors on Science and Technology (PCAST) is scheduled to meet in open session on Tuesday April 24, 2007, at approximately 9 a.m. The co-chairs of the PCAST subcommittee on networking and information technology are tentatively scheduled to lead a discussion on the findings of the PCAST review of the Federal Networking and Information Technology Research and Development (NITRD) Program. The PCAST will hear presentations on modes of interaction between the private sector and traditionally Federally funded research communities. The PCAST also is tentatively scheduled to hear presentations on personalized medicine as part of the Council's study of policy issues associated with realizing the benefits of scientific and technological advances in this area. This session will end at approximately 5 p.m. Additional information and the final agenda will be posted at the PCAST Web site at: *http://www.ostp.gov/PCAST/pcast.html.*

Public Comments: There will be time allocated for the public to speak on the above agenda items. This public comment time is designed for substantive commentary on PCAST's work topics, not for business marketing purposes. Please submit a request for the opportunity to make a public comment five (5) days in advance of the meeting. The time for public comments will be limited to no more than 5 minutes per person. Written comments are also welcome at any time following the meeting. Please notify Celia Merzbacher, PCAST Executive Director, at (202) 456–7116, or fax your request/comments to (202) 456–6021.

FOR FURTHER INFORMATION CONTACT: For information regarding time, place and agenda, please call Celia Merzbacher at (202) 456–7116, prior to 3 p.m. on Friday, January 5, 2007. Information will also be available at the PCAST Web site at: *http://www.ostp.gov/PCAST/pcast.html.* Please note that public seating for this meeting is limited and is available on a first-come, first-served basis.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology was established by Executive Order 13226, on September 30, 2001. The purpose of PCAST is to advise the President on matters of science and technology policy, and to assist the President's National Science and Technology Council in securing private sector participation in its activities. The Council members are distinguished individuals appointed by the President from non-Federal sectors. The PCAST is co-chaired by Dr. John H. Marburger, III, the Director of the Office of Science and Technology Policy, and by E. Floyd Kvamme, a Partner at Kleiner Perkins Caufield & Byers.

Celia Merzbacher,

PCAST Executive Director, Office of Science and Technology Policy.

[FR Doc. E7–6844 Filed 4–9–07; 8:45 am]

BILLING CODE 3170–W4–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Regular Sunshine Act Meeting

AGENCY: Farm Credit Administration.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the regular meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on April 12, 2007, from 9 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Roland E. Smith, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

Open Session

A. Approval of Minutes

- March 8, 2007 (Open).

B. New Business—Reports

- Auditors' Report on FCS Building Association FY 2006 Financial Statements.

Closed Session*

- FCS Building Association Audit Report.
- OSMO Quarterly Report.

* Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

Dated: April 5, 2007.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

[FR Doc. 07–1797 Filed 4–6–07; 12:24 pm]

BILLING CODE 6705–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate

inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 4, 2007.

A. Federal Reserve Bank of New York (Anne MacEwen, Bank Applications Officer) 33 Liberty Street, New York, New York 10045-0001:

1. Banco Bilbao Vizcaya Argentaria, S.A. (BBVA), Bilbao, Spain; to acquire 100 percent of the voting shares of Compass Bancshares, Inc., Birmingham, Alabama, and thereby indirectly acquire voting shares of Compass Bank, Birmingham, Alabama, and Central Bank of the South, Anniston, Alabama.

In addition, Circle Merger Corp., Birmingham, Alabama, a wholly–owned subsidiary of Compass Bancshares, Inc., proposes to become a bank holding company by acquiring 100 percent of the voting shares of Compass Bancshares Inc., for a moment in time, to facilitate the acquisition of Compass Bancshares, Inc., by BBVA.

B. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Capitol Bancorp, Ltd., Lansing, Michigan, and its wholly owned subsidiary, Capitol Development Bancorp Limited VI, Lansing, Michigan, to acquire 51 percent of the voting shares of USNY Bank (in organization), Geneva, New York.

Board of Governors of the Federal Reserve System, April 5, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–6705 Filed 4–9–07; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Applications for the Prevention and Support Services for Women Incarcerated or Newly Released Living With or at Risk for HIV/AIDS/STDs Program

AGENCY: Office on Women's Health, Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Announcement Type: Competitive Cooperative Agreement FY 2007 Initial announcement.

Funding Opportunity Number: Not Applicable.

OMB Catalog of Federal Domestic Assistance: The OMB Catalog of Federal Domestic Assistance number is 93.015.

DATES: No later than 5 p.m. Eastern Time on June 11, 2007.

ADDRESSES: To receive consideration, applications must be received by the Office of Grants Management, Office of Public Health and Science (OPHS), Department of Health and Human Services (DHHS) c/o WilDon Solutions, Office of Grants Management Operations Center, 1515 Wilson Blvd., Third Floor Suite 310, Arlington, VA 22209, Attention Office of Women's Health, HIV.

SUMMARY: This program is authorized by 42 U.S.C. 300u–2(a).

The mission of the Office on Women's Health (OWH) is to promote the health of women and girls through gender-specific approaches. To that end, OWH has established activities to address critical women's health issues nationwide. These include: Developing and implementing model public/private partnerships that address the health issues of incarcerated and newly released women, largely women of color, living with HIV/AIDS/STDs or at increased risk for sexually transmitted infections. These may include piloting a comprehensive system of health related support services, such as ensuring access to health care and most current therapies, pre-release discharge planning, case managing transition processes, and establishing linkages to various community-based support and prevention services.

Funding will be directed at activities designed to improve the delivery of services to women disproportionately impacted by HIV/AIDS.

I. Funding Opportunity Description

The primary purpose of this OWH HIV/AIDS program is to increase health related support services available for HIV infected incarcerated and newly released women. The goals for the Incarcerated/Newly Released Program are to:

- Develop and sustain comprehensive HIV/AIDS/STD prevention and support services to incarcerated and newly released women living with HIV/AIDS in collaboration with health entities, care providers, social services, correctional facilities, and criminal justice offices;
- Establish community linkages and networks for ensuring quality continuum of care, transitional support, discharge planning and preparation, and HIV/STD prevention services for incarcerated and newly released women living with or at high risk for HIV/AIDS; and
- Improve the physical and mental health circumstances as well as the quality of life of incarcerated and newly released women living with HIV/AIDS or at high risk for HIV infection.

The OWH hopes to fulfill this purpose by providing funding to targeted community-based organizations to enhance their prevention and support activities to incarcerated and newly released women living with or at high risk for HIV infection.

The proposed program must address HIV prevention and support services for incarcerated and newly released women through a gender-specific approach. Information and services provided must be culturally and linguistically appropriate for the individuals for whom the information and services are intended. Women's health issues are defined in the context of women's lives, including their multiple social roles and the importance of relationships with other people to their lives. This definition of women's health encompasses mental, dental, and physical health and spans the life course.

The objectives of the OWH program are to:

1. Increase the number of incarcerated women receiving pre-release discharge planning, particularly those who are living with HIV/AIDS or at high risk for HIV infection.

2. Increase the number of HIV infected incarcerated women who are connected to drug assistance programs, medical care, and case management services prior to release or at time of release.

3. Increase the number of community linkages and networks for ensuring continuum of care for incarcerated and newly released women living with or at high risk for HIV/AIDS in locations with high rates of HIV infections and incarcerated populations.

4. Increase the number of newly released women receiving support services and HIV care six months post release.

The grantee must: (1) Develop and implement a model program to provide comprehensive HIV/AIDS/STD prevention and support services to incarcerated and newly released women living with HIV/AIDS in order to establish a continuum of care (*e.g.*, treatment, therapies, case management, reproductive health, HIV/STD testing, etc.) and secondary prevention activities to improve disease management and health outcomes; risk reduction counseling and prevention education components must be developed and integrated in both pre-release and post-release program plans; (2) propose a pilot program to address gaps in services to incarcerated and newly released women living with HIV/AIDS that will be implemented locally in partnership with local entities after reviewing city/county/State data on incarcerated populations, exploring challenges and trends confronting incarcerated and newly released women living with HIV/AIDS, assessing existing local HIV/AIDS network of prevention and care service providers that target incarcerated and newly released women, and identifying available criminal justice programs that service women; (3) establish Memoranda of Understanding with local health care entities, social services, HIV/AIDS prevention/service providers, and criminal justice offices in support of program implementation, collaboration around services, and re-entry support of the women participants; and (4) visit area criminal justice offices/facilities and affiliated programs as well as conduct outreach to communities and women living with HIV/AIDS and are at risk of infection of HIV/AIDS/STDs to identify and enroll participation of target population and to establish program partnerships. In addition, the grantee shall submit reports outlining program activities (*e.g.*, recruitment, participant retention), which reflect how its implementation process reflected an understanding of the realities of women's lives and addressed the issues of the participants to motivate continued participation. Finally, the grantee shall develop a plan to continue the program activities and community linkages beyond OWH funding and shall illustrate how program performance addressed community needs and the needs of incarcerated/newly released women.

The grantee is encouraged to attend at least one national or regional HIV/AIDS Conference (*e.g.*, U.S. Conference on AIDS, the Centers for Disease Control and Prevention (CDC) National HIV Prevention Conference, etc.), and to seek updates in HIV prevention strategies, therapies and priority activities as advised by the CDC, Health Resources and Services Administration, and other public health experts.

Award Information

The OWH program will be supported through the cooperative agreement mechanism. Using this mechanism, the OWH anticipates making five awards in FY 2007. The anticipated start date for new awards is September 01, 2007, and the anticipated period of performance is September 01, 2007, through August 31, 2010. Approximately $625,000 is available to make awards of up to $125,000 total cost (direct and indirect) for a 12-month period. However, the actual number of awards made will depend upon the quality of the applications received and the amount of funds available for the program.

The program is a collaborative effort between the OWH and the Office of HIV/AIDS Policy, OPHS. These offices will provide the technical assistance and oversight necessary for the implementation, conduct, and assessment of program activities.

The applicant shall:

1. Develop and implement the model described in the application.

2. Assess local services and gaps.

3. Establish community partnerships through Memoranda of Understanding/Agreement.

4. Perform outreach to criminal justice offices/facilities and to communities and women living with HIV/AIDS.

5. Participate in special meetings and projects/funding opportunities identified by the OWH.

6. Adhere to all program requirements specified in this announcement and the Notice of Grant Award.

7. Submit required progress, annual, and financial reports by the due dates stated in this announcement and the Notice of Grant Award.

8. Comply with the DHHS Protection of Human Subjects regulations (which require obtaining Institutional Review Board approval), set out at 45 CFR Part 46, if applicable. General information about Human Subjects regulations can be obtained through the Office for Human Research Protections (OHRP) at *http://www.hhs.gov/ohrp, ohrp@osophs.dhhs.gov*, or toll free at (866) 447–4777.

The Federal Government will:

1. Conduct an orientation meeting for the grantees within the first month of funding.

2. Conduct at least one site visit which includes some observation of program progress.

3. Review all quarterly, annual, and final progress reports.

4. Review and concur with requested project modifications.

5. Review implementation plan for approval.

6. Participate in telephone conferences and other activities supporting project performance improvements and evaluation.

The DHHS is committed to achieving the health promotion and disease prevention Objectives of Healthy People 2010 and the HealthierUS Initiative. Emphasis will be placed on aligning OWH activities and programs with the DHHS Secretary's four priority areas: heart disease, cancer, diabetes, and HIV/AIDS and with the Healthy People 2010: Goal 2—eliminating health disparities due to age, gender, race/ethnicity, education, income, disability, or living in rural localities. Applicants are encouraged to indicate the Healthy People 2010 objective this activity will address. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: *http://www.health.gov/healthypeople.*

III. Eligibility Information

1. Eligible Applicants

Eligible Applicants must meet all of the following criteria.

1. Organizations located in locations with high HIV prevalence among women;

2. Locations near incarcerated populations of women; and

3. Organizations indicating history of serving African American women, Hispanic women, substance abusing women, formerly incarcerated women, and women living with HIV/AIDS or whose lifestyles place them at high risk for HIV/STD infection.

Eligible entities may include: Nonprofit community-based organizations, faith-based organizations, national organizations, colleges and universities, clinics and hospitals, research institutions, State and local government agencies, tribal government agencies and tribal/urban Indian organizations.

2. Cost Share or Matching

Cost Sharing or Matching funds are not required for this program.

IV. Application and Submission Information

1. Address To Request Application Kit

Application kits may be obtained by accessing Grants.gov at *http://www.grants.gov* or the eGrants system at *http://www.grantsolutions.gov*. To obtain a hard copy of the application kit, contact WilDon Solutions at 1–888–203–6161. Applicants may fax a written request to WilDon Solutions at 703–351–1135 or e-mail the request to *OPHSgrantsinfor@teamwildon.com*. Applicants must be prepared using Form OPHS–1, which can be obtained at the Web sites noted above.

2. Content and Format of Application and Submission

All completed applications must be submitted to the OPHS Office of Grants Management at the above mailing address. In preparing the application, it is important to follow ALL instructions provided in the application kit. Applications must be submitted on the forms supplied (OPHS–1, Revised 3/2006) and in the manner prescribed in the application kits provided by the OPHS. Applicants are required to submit an application signed by an individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award. The program narrative should not be longer than 25 double-spaced pages, not including appendices and required forms, using an easily readable, 12 point font. All pages, figures and tables should be numbered.

A Dun and Bradstreet Universal Numbering System (DUNS) number is required for all applications for Federal assistance. Organizations should verify that they have a DUNS number or take the steps necessary to obtain one. Instructions for obtaining a DUNS number are included in the application package, and may be downloaded from the Web site: *http://www.dnb.com/US/duns_update/index.html*.

At a minimum, each application for a cooperative agreement grant funded under this OWH announcement must:

- Present a plan to develop and implement a model program in partnership with an array of local service providers, including health care providers, support services, case management, etc. Specify the screening, development and selection process of intervention models and the role of advisory committees and/or board of directors.
- Provide signed Memoranda of Agreement(s) (MOA) with prospective partners to build a consortium of providers for the targeted population based upon prevention, care and re-entry transitioning needs. Detail/specify the roles and resources/services that each partner organization brings to the program, the duration and terms of agreement as confirmed by a signed memorandum of agreement between the applicant organization and each partner. The partnership agreement(s) must name the individual who will work with the program, describe their function, and state their qualifications. The documents, specific to each organization (form letters are not acceptable), must be signed by individuals with the authority to represent and bind the organization (*e.g.*, president, chief executive officer, executive director) and submitted as part of the grant application.
- Be a sustainable organization with an established network of partners capable of providing coordinated and integrated women's health services in the targeted community. The partners and their roles and responsibilities to the program must be clearly identified in the application. OWH prefers that applicants have a minimum of three years' prior demonstrated experience.
- Demonstrate that any prevention intervention (including prevention for positives) contains the core elements of interventions with evidence of effectiveness. (See Compendium of HIV Prevention Interventions with Evidence of Effectiveness, from CDC's HIV/AIDS Prevention Research Synthesis Project, Nov. 1999; see CDC's HIV Prevention Strategic Plan Through 2005.
- Provide a time line and plans for Program Implementation for the funding year, presented in correlation to goals, objectives, and expected outcomes or targets, demonstrating an understanding of the relationship between programmatic activities and HIV prevention outcomes.
- Demonstrate the ways in which the organization and the services that are coordinated through its partners are gender and age appropriate, women-focused, women-friendly, women-relevant as well as culturally and linguistically appropriate to the target population.
- Describe in detail plans for the local evaluation of the program and when and how the evaluation will be used to enhance the program; and describe the approval process of local and state review boards for local evaluation surveys, focus groups, and other client inquiries.
- Describe the organization's skill levels in word processing and data management (Word, Word Perfect, Excel); and specify the filing, storage, and location of client files.

Format and Limitations of Application: Applicants are required to submit an original ink-signed and dated application and 2 photocopies. All pages must be numbered clearly and sequentially beginning with the Project Summary. The application must be typed *double-spaced* on one side of plain 8½″ x 11″ white paper, using at least a 12 point font, and contain 1″ margins all around.

The Project Summary and Project Narrative must not exceed a total of *25 double-spaced* pages, excluding the appendices. The original and each copy must be stapled; the application should be organized in accordance with the format presented in the RFA. An outline for the minimum information to be included in the Project Narrative section is presented below. The content requirements for the Project Narrative portion of the application are divided into five sections and described below within each Factor. Applicants must pay particular attention to structuring the narrative to respond clearly and fully to each review Factor and associated criteria. Applications not adhering to these guidelines may not be reviewed.

Background (Understanding of the Problem)

A. Organization's goals and purpose(s).
B. Local needs assessment and gaps in services for targeted population.
C. Strategy for linking public health, corrections, and community services.
D. Local program objectives:
   1. Tied to program goal(s);
   2. Measurable with time frame.
E. Organizational charts that include partners and a discussion of the proposed resource to be contributed by the partners, personnel and their expertise, and how their involvement will help achieve the program goals.

Implementation Plan (Approach)

A. Describe linkages with multiple systems which impact incarcerated and newly released women living with HIV infection transitioning back into society.
B. Describe pre-release and post release activities relative to secondary prevention and risk reduction counseling.
C. Discuss gender specific program elements
D. Provide systems chart outlining the connection of program components.
E. Show time line of program activities and performance of targets/goals.
F. Partnerships and referral system/follow up.

Management Plan

A. Key project staff, their resumes, and a staffing chart for budgeted staff.
B. To-be-hired staff and their qualifications.
C. Staff responsibilities.
D. Management experience of the lead agency

and partners as related to their role in the program.
E. Management oversight of staff roles and job performance.
F. Address maintenance of confidentiality, ethics in performance, and on-going staff training.
G. Explain decision making hierarchy.

Local Evaluation Plan

A. Purpose.
B. Describe tools and procedures for measuring strengths and weaknesses.
C. Use of results to enhance programs.
D. Indicators that reflect goals/objectives are being met.

Organizational Agency Qualifications

A. Agency history of services for HIV infected individuals, HIV infected women, and women formerly incarcerated.
B. Agency relationships, past and current, with criminal justice systems and local service providers.
C. Community acceptance: staff recognition, media, requests for agency involvement.

Appendices

A. Memorandums of Agreement/ Understanding/Partnership Letters
B. Required Forms (Assurance of Compliance Form, etc.)
C. Key Staff Resumes
D. Charts/Tables (partners, services, population demographics, program components, etc.)
E. Other attachments

Use of Funds: A majority of the funds from the award must be used to support staff and efforts aimed at implementing the program. The Program Coordinator, or the person responsible for the day-to-day management of the program, must devote at least a 75 percent level of effort to the program. Funds may also be used to transfer the lessons learned/ successful strategies/gender specific approaches from the program (technical assistance) through activities such as showcasing the program at conferences, meetings and workshops; providing direct technical assistance to other communities; and providing technical assistance to allied health and health professionals, directly or through their professional organizations, interested in working with incarcerated and newly released women living with HIV/AIDS or who are at high risk for HIV/STD infection. These may include either process-based lessons (*i.e.*, How to bring multiple sectors of community partners together) or outcomes-based lessons (*i.e.*, How to increase the number of incarcerated and newly released women who remain in care and treatment over a period of time). Funds may be used for personnel, consultants, supplies (including screening, education, and outreach supplies), and grant related travel. Funds may *not* be used for construction, building alterations, equipment, medical treatment, or renovations. All budget requests must be justified fully in terms of the proposed goals and objectives and include an itemized computational explanation/breakout of how costs were determined.

Meetings: The OWH will convene grantees once a year for orientation. The meeting will be held in the Washington metropolitan area or in one of the ten (10) DHHS regional office cities. The budget should include a request for funds to pay for the travel, lodging, and meals. The meeting is usually held within the first six weeks post award.

3. Submission Date and Time

To be considered for review, applications must be received by the Office of Public Health and Science, Office of Grants Management, c/o WilDon Solutions, by 5 p.m. Eastern on June 11, 2007. Applications will be considered as meeting the deadline if they are received on or before the deadline date. The application due date requirement in this announcement supercedes the instructions in the OPHS–1 form.

Submission Mechanisms

The Office of Public Health and Science (OPHS) provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of applications submitted using any of these mechanisms. Applications submitted to the OPHS Office of Grants Management after the deadlines described below will not be accepted for review. Applications which do not conform to the requirements of the grant announcement will not be accepted for review and will be returned to the applicant.

While applications are accepted in hard copy, the use of the electronic application submission capabilities provided by the Grants.gov and GrantSolutions.gov systems is encouraged. Applications may only be submitted electronically via the electronic submission mechanisms specified below. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, will not be accepted for review.

In order to apply for new funding opportunities which are open to the public for competition, you may access the Grants.gov website portal. All OPHS funding opportunities and application kits are made available on Grants.gov. If your organization has/had a grantee business relationship with a grant program serviced by the OPHS Office of Grants Management, and you are applying as part of ongoing grantee related activities, please access GrantSolutions.gov.

Electronic grant application submissions must be submitted no later than 5 p.m. Eastern Time on the deadline date specified in the **DATES** section of the announcement using one of the electronic submission mechanisms specified below. All required hardcopy original signatures and mail-in items must be received by the OPHS Office of Grants Management, c/o WilDon Solutions (1515 Wilson Blvd., Suite 310, Arlington, VA 22209) no later than 5 p.m. Eastern Time on the next business day after the deadline date specified in the **DATES** section of the announcement.

Applications will not be considered valid until all electronic application components, hardcopy original signatures, and mail-in items are received by the OPHS Office of Grants Management according to the deadlines specified above. Application submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process, and to submit early on the due date or before. This will aid in addressing any problems with submissions prior to the application deadline.

Electronic Submissions via the Grants.gov Web site Portal

The Grants.gov Web site Portal provides organizations with the ability to submit applications for OPHS grant opportunities. Organizations must successfully complete the necessary registration processes in order to submit an application. Information about this system is available on the Grants.gov Web site, *http://www.grants.gov.*

In addition to electronically submitted materials, applicants may be required to submit hard copy signatures for certain Program related forms, or original materials as required by the announcement. It is imperative that the applicant review both the grant announcement, as well as the application guidance provided within the Grants.gov application package, to determine such requirements. Any required hard copy materials, or documents that require a signature, must be submitted separately via mail to the OPHS Office of Grants Management, c/o WilDon Solutions, and if required,

must contain the original signature of an individual authorized to act for the applicant agency and the obligations imposed by the terms and conditions of the grant award. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Electronic applications submitted via the Grants.gov Web site Portal must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. All required mail-in items must be received by the due date requirements specified above. Mail-In items may only include publications, resumes, or organizational documentation. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Upon completion of a successful electronic application submission via the Grants.gov Web site Portal, the applicant will be provided with a confirmation page from Grants.gov indicating the date and time (Eastern Time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is critical that the applicant print and retain this confirmation for their records, as well as a copy of the entire application package.

All applications submitted via the Grants.gov Web site Portal will be validated by Grants.gov. Any applications deemed ''Invalid'' by the Grants.gov Web site Portal will not be transferred to the GrantSolutions system, and OPHS has no responsibility for any application that is not validated and transferred to OPHS from the Grants.gov Web site Portal. Grants.gov will notify the applicant regarding the application validation status. Once the application is successfully validated by the Grants.gov Web site Portal, applicants should immediately mail all required hard copy materials to the OPHS Office of Grants Management, c/o WilDon Solutions, to be received by the deadlines specified above. It is critical that the applicant clearly identify the Organization name and Grants.gov Application Receipt Number on all hard copy materials.

Once the application is validated by Grants.gov, it will be electronically transferred to the GrantSolutions system for processing. Upon receipt of both the electronic application from the Grants.gov Web site Portal, and the required hardcopy mail-in items, applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of the application submitted using the Grants.gov Web site Portal.

Applicants should contact Grants.gov regarding any questions or concerns regarding the electronic application process conducted through the Grants.gov Web site Portal.

Electronic Submissions via the GrantSolutions System

OPHS is a managing partner of the GrantSolutions.gov system. GrantSolutions is a full life-cycle grants management system managed by the Administration for Children and Families, Department of Health and Human Services (HHS), and is designated by the Office of Management and Budget (OMB) as one of the three Government-wide grants management systems under the Grants Management Line of Business initiative (GMLoB). OPHS uses GrantSolutions for the electronic processing of all grant applications, as well as the electronic management of its entire Grant portfolio.

When submitting applications via the GrantSolutions system, applicants are required to submit a hard copy of the application face page (Standard Form 424) with the original signature of an individual authorized to act for the applicant agency and assume the obligations imposed by the terms and conditions of the grant award. If required, applicants will also need to submit a hard copy of the Standard Form LLL and/or certain Program related forms (*e.g.*, Program Certifications) with the original signature of an individual authorized to act for the applicant agency. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Electronic applications submitted via the GrantSolutions system must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. The applicant may identify specific mail-in items to be sent to the Office of Grants Management separate from the electronic submission; however these mail-in items must be entered on the GrantSolutions Application Checklist at the time of electronic submission, and must be received by the due date requirements specified above. Mail-In items may only include publications, resumes, or organizational documentation. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Upon completion of a successful electronic application submission, the GrantSolutions system will provide the applicant with a confirmation page indicating the date and time (Eastern Time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission including all electronic application components, required hardcopy original signatures, and mail-in items, as well as the mailing address of the OPHS Office of Grants Management where all required hard copy materials must be submitted.

As items are received by the OPHS Office of Grants Management, the electronic application status will be updated to reflect the receipt of mail-in items. It is recommended that the applicant monitor the status of their application in the GrantSolutions system to ensure that all signatures and mail-in items are received.

Mailed or Hand-Delivered Hard Copy Applications

Applicants who submit applications in hard copy (via mail or hand-delivered) are required to submit an original and two copies of the application. The original application must be signed by an individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award.

Mailed or hand-delivered applications will be considered as meeting the deadline if they are received by the OPHS Office of Grant Management, c/o WilDon Solutions, on or before 5 p.m. Eastern Time on the deadline date specified in the **DATES** section of the announcement. The application deadline date requirement specified in this announcement supersedes the instructions in the OPHS–1. Applications that do not meet the deadline will be returned to the applicant unread.

Applications will be screened upon receipt. Those that are judged to be incomplete or arrive after the deadline will not be reviewed. Applications that exceed the specified amount for a twelve-month budget period may also not be reviewed. Applications that are judged to be in compliance will be reviewed for technical merit in accordance with DHHS policies. Applications will be evaluated by a technical review panel composed of experts with experience with sex and

gender programs, program management, service delivery, outreach, health education, Healthy People 2000 and/or Healthy People 2010, leadership development and program assessment. Consideration for award will be given to applicants that best demonstrate progress and/or plausible strategies for eliminating health disparities through sex and gender targeted HP 2010 objectives. Applicants are also advised to pay close attention to the specific program guidelines and general instructions in the application kit.

4. Intergovernmental Review

This program is subject to the Public Health Systems Reporting Requirements. Under these requirements, a community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). Applicants shall submit a copy of the application face page (SF–424) and a one page summary of the project, called the Public Health System Impact Statement. The PHSIS is intended to provide information to State and local health officials to keep them apprised on proposed health services grant applications submitted by community-based, non-governmental organizations within their jurisdictions.

Community-based, non-governmental applicants are required to submit, no later than the Federal due date for receipt of the application, the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted: (a) A copy of the face page of the application (SF 424), (b) a summary of the project (PHSIS), not to exceed one page, which provides: (1) A description of the population to be served, (2) a summary of the services to be provided, and (3) a description of the coordination planned with the appropriate State or local health agencies. Copies of the letters forwarding the PHSIS to these authorities must be contained in the application materials submitted to the OWH.

This program is also subject to the requirements of Executive Order 12372 that allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application kit to be made available under this notice will contain a listing of States that have chosen to set up a review system and will include a State Single Point of Contact (SPOC) in the State for review. Applicants (other than federally recognized Indian tribes) should contact their SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC in each affected State. A complete list of SPOCs may be found at the following Web site: *http://www.whitehouse.gov/omb/grants/spoc.html* The due date for State process recommendations is 60 days after the application deadline. The OWH does not guarantee that it will accommodate or explain its responses to State process recommendations received after that date. (See Intergovernmental Review of Federal Programs, Executive Order 12372, and 45 CFR Part 100 for a description of the review process and requirements.)

5. Funding Restrictions

Funds may not be used for construction, building alterations, equipment purchase, medical treatment, renovations, or to purchase food. Pre-award costs are not an allowable cost for this award.

6. Other Submission Requirements

Beginning October 1, 2003, all applicants are required to obtain a Data Universal Numbering System (DUNS) number as preparation for doing business electronically with the Federal Government. The DUNS number must be obtained prior to applying for OWH funds. The DUNS number is a nine-character identification code provided by the commercial company Dun & Bradstreet, and serves as a unique identifier of business entities. There is no charge for requesting a DUNS number, and you may register and obtain a DUNS number by either of the following methods:

Telephone: 1–866–705–5711.

Web site: *http://www.dnb.com/product/eupdate/requestOptions.html.*

Be sure to click on the link that reads, *DUNS Number Only* at the right hand, bottom corner of the screen to access the free registration page. Please note that registration via the web site may take up to 30 business days to complete.

V. Application Review Information

1. Criteria: The objective technical review of applications will consider the following factors:

Factor 1: Implementation /Approach 30%

This section must discuss:

1. Appropriateness of the existing community resources and linkages established to deliver coordinated, comprehensive women's services to meet the requirements of the program. Describe other community providers that will be affiliated with the program and their role in service delivery.

2. Pre-release and post release program phases; explain the integration of program components to include prevention and risk reduction interventions.

3. Appropriateness of proposed approach, linkages of multiple systems, and specific activities described to address program objectives.

4. Soundness of evaluation objectives for measuring program effectiveness, impact of continuity of care, and improvement in disease management by individual clients.

5. Appropriate MOAs and/or Letters of Intent to support assertions made in this section.

Factor 2: Management Plan—20%

This section must discuss:

1. Applicant organization's capability to manage the project as determined by the qualifications of the proposed staff or requirements for to be hired staff;

2. Proposed staff level of effort; management experience of the lead agency;

3. The experience, resources, and role of each partner organization as it relates to the needs and programs/activities of the program;

4. Staff experience as it relates to meeting the needs of the community and populations served;

5. Detailed position descriptions, resumes of key staff, and a staffing chart should be included in the appendix

Factor 3: Organizational Agency Qualifications—20%

This section should include demonstrated knowledge of local need and existing systems, agency relationships with corrections and incarcerated populations, and agency history of services to HIV infected individuals, HIV infected women, and women formerly incarcerated.

Factor 4: Background / Understanding of the Problem—15%

This section must discuss:

1. The current state of affairs locally for incarcerated and newly released women living with HIV/AIDS or at high risk for HIV/STD infection.

2. Relevance of organizational goals and purpose(s) to community and local needs.

3. Challenges to linking public health, corrections and community services to provide services to an underserved population disproportionately impacted by criminal justice problems and HIV infection.

4. Coordination of independent systems to meet the needs of the target population.

5. Prevention interventions for those living with HIV/AIDS and risk reduction counseling for positive persons and those at risk for HIV/AIDS/STDs.

Factor 5: Evaluation Plan—15%

Provide a clear Statement of program goal(s), feasibility and appropriateness of the local evaluation plan, analysis of results, and procedures to determine if the program goals are met. Provide a clear Statement of willingness to participate actively in the national OWH evaluation.

Review and Selection Process: Funding decisions will be made by the OWH, and will take into consideration the recommendations and ratings of the review panel, program needs, geographic location, Stated preferences, and the recommendations of DHHS Regional Women's Health Coordinators (RWHC).

VI. Award Administration Information

1. Award Notices

Successful applicants will receive a notification letter from the Deputy Assistant Secretary for Health (Women's Health) and a Notice of Grant Award (NGA), signed by the OPHS Grants Management Officer. The NGA shall be the only binding, authorizing document between the recipient and the OWH. Notification will be mailed to the Program Director identified in the application. Unsuccessful applicants will receive a notification letter with the results of the review of their application from the Deputy Assistant Secretary for Health (Women's Health).

2. Administrative and National Policy Requirements

The regulations set out at 45 CFR parts 74 and 92 are the Department of Health and Human Services (DHHS) rules and requirements that govern the administration of grants. Part 74 is applicable to all recipients except those covered by part 92, which governs awards to State and local governments. Applicants funded under this announcement must be aware of and comply with these regulations. The CFR volume that includes parts 74 and 92 may be downloaded from *http://www.access.gpo.gov/nara/cfr/waisidx_03/45cfrv1_03.html.*

The DHHS Appropriations Act requires that, when issuing Statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees shall clearly State the percentage and dollar amount of the total costs of the program or project which will be financed with Federal money and the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

3. Reporting

In addition to those listed above, a successful applicant will submit quarterly reports that include a summary of the local evaluation and a discussion of steps taken to implement each component of the program and the impact of the program on the targeted community/population, an annual Financial Status Report, a final Progress Report, a final Financial Status Report in the format established by the OWH, in accordance with provisions of the general regulations which apply under ''Monitoring and Reporting Program Performance,''(45 CFR Parts 74 and 92). The purpose of the progress reports is to provide accurate and timely program information to program managers and to respond to Congressional, Departmental, and public requests for information about the program. An original and two copies of the progress report(s) must be submitted by December 10, March 10, June 10 and final report by August 25. If these dates fall on a Saturday or Sunday, the report will be due on Monday.

A Financial Status Report (FSR) SF–269 is due 90 days after the close of each 12-month budget period.

VII. Agency Contact(s)

For application kits, information on budget and business aspects, and programmatic questions of the application, please contact: WilDon Solutions, Office of Grants Management Operations Center 1515 Wilson Blvd., Third Floor Suite 310, Arlington, VA 22209 at 1–888–203–6161, e-mail: *OPHSgrantinfo@teamwildon.com,* or fax 703–351–1135.

VIII. Other Information

Three (3) OWH Incarcerated/Newly Released Women Living with HIV/AIDS or at High Risk for HIV/STD Infection programs are currently funded by the OWH. Information about these programs may be found at the following Web site: *http://www.womenshealth.gov/owh/fund/index.htm.*

Definitions

For the purposes of this cooperative agreement program, the following definitions are provided:

AIDS: Acquired immunodeficiency syndrome is a disease in which the body's immune system breaks down and is unable to fight off certain infections and other illnesses that take advantage of a weakened immune system.

Age-appropriate: Provision of prevention education that adapts the assessment and overall counseling education to the developmental level of the individual(s).

Case Management: A collaborative process of assessment, planning, facilitation and advocacy for options and services to meet an individual's health needs through communication and available resources to promote quality cost-effective outcomes.

Community-based: The locus of control and decision-making powers is located at the community level, representing the service area of the community or a significant segment of the community.

Community-based organization: Public and private, nonprofit organizations that are representative of communities or significant segments of communities.

Community health center: A community-based organization that provides comprehensive primary care and preventive services to medically underserved populations. This includes but is not limited to programs reimbursed through the Federally Qualified Health Centers mechanism, Migrant Health Centers, Primary Care Public Housing Health Centers, Healthcare for the Homeless Centers, and other community-based health centers.

Comprehensive women's health services: Services including, but going beyond traditional reproductive health services to address the health needs of underserved women in the context of their lives, including a recognition of the importance of family relationships and responsibilities. Services include basic primary care services; acute, chronic, and preventive services including gender and age-appropriate preventive services; mental and dental health services; patient education and counseling; promotion of healthy behaviors (like nutrition, smoking cessation, substance abuse services, and physical activity); and enabling services. Ancillary services are also provided such as laboratory tests, X-ray, environmental, social referral, and pharmacy services.

Correctional Settings: Secure detention facilities that house individuals convicted of crimes carrying sentences of one year or greater length. These can also be secure detention facilities holding pre-trial and post

conviction inmates serving less than one year sentences or awaiting transfer to other settings.

Culturally competent: Information and services provided at the educational level and in the language and cultural context that are most appropriate for the individuals for whom the information and services are intended. Additional information on cultural competency is available at the following Web site: *http://www.aoa.dhhs.gov/May2001/factsheets/Cultural-Competency.html*

Cultural perspective: Recognizes that culture, language, and country of origin have an important and significant impact on the health perceptions and health behaviors that produce a variety of health outcomes.

Discharge Planning: The process of developing a re-entry support program for an incarcerated individual scheduled for upcoming release to reduce obstacles to care, medication, eligibility for public benefits, housing, employment, substance abuse treatment, mental health, and other support services needed.

Enabling services: Services that help women access health care, such as transportation, parking vouchers, translation, child care, and case management.

Gender-Specific: An approach which considers the social and environmental context in which women live and therefore structures information, activities, program priorities and service delivery systems to compliment those factors.

Healthy People 2010: A set of national health objectives that outlines the prevention agenda for the Nation. *Healthy People 2010* identify the most significant preventable threats to health and establishes national goals for the next ten years. Individuals, groups, and organizations are encouraged to integrate *Healthy People 2010* into current programs, special events, publications, and meetings. Businesses can use the framework, for example, to guide worksite health promotion activities as well as community-based initiatives. Schools, colleges, and civic and faith-based organizations can undertake activities to further the health of all members of their community. Health care providers can encourage their patients to pursue healthier lifestyles and to participate in community-based programs. By selecting from among the national objectives, individuals and organizations can build an agenda for community health improvement and can monitor results over time. More information on the *Healthy People 2010* objectives may be found on the *Healthy People 2010* Web site: *http://www.health.gov/healthypeople.*

HIV: The human immunodeficiency virus that causes AIDS.

Holistic: Looking at women's health from the perspective of the whole person and not as a group of different body parts. It includes dental, mental, as well as physical health.

Incarcerated Person: Refers to an individual involuntarily confined in the secure custody of law enforcement, judicial, or penal authorities.

Integrated: The bringing together of the numerous spheres of activity that touch women's health, including clinical services, research, health training, public health outreach and education, leadership development for women, and technical assistance. The goal of this approach is to unite the strengths of each of these areas, and create a more informed, less fragmented, and efficient system of care for underserved women that can be replicated in other populations and communities.

Lifespan: Recognizes that women have different health and psychosocial needs as they encounter transitions across their lives and that the positive and negative effects of health and health behaviors are cumulative across a woman's life.

Multi-disciplinary: An approach that is based on the recognition that women's health crosses many disciplines, and that women's health issues need to be addressed across multiple disciplines, such as adolescent health, geriatrics, cardiology, mental health, reproductive health, nutrition, dermatology, endocrinology, immunology, rheumatology, dental health, etc.

Newly Released: The status of an individual returning to society and the community after incarceration.

Re-entry: The process of returning to society and the community after incarceration.

Rural Community: All territory, population, and housing units located outside of urban areas and urban cluster.

Social Role: Recognizes that women routinely perform multiple, overlapping social roles that require continuous multi-tasking.

Sustainability: An organization's or program's staying power: The capacity to maintain both the financial resources and the partnerships/linkages needed to provide adequate and effective services in the target area and to the target population. It also involves the ability to survive change, incorporate needed changes, and seize opportunities provided by a changing environment.

Underserved Women: Women who encounter barriers to health care that result from any combination of the following characteristics: Poverty, ethnicity and culture, mental or physical State, housing status, geographic location, language, age, and lack of health insurance/under-insured.

Women-centered/women-focused: Addressing the needs and concerns of women (women-relevant) in an environment that is welcoming to women, fosters a commitment to women, treats women with dignity, and empowers women through respect and education. The emphasis is on working *with* women, not *for* women. Women clients are considered active partners in their own health and wellness.

Dated:April 3, 2007.

Wanda K. Jones,

Deputy Assistant Secretary for Health (Women's Health).

[FR Doc. E7–6719 Filed 4–9–07; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 13th meeting of the American Health Information Community in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.). The American Health Information Community will advise the Secretary and recommend specific actions to achieve a common interoperability framework for health information technology (IT).

DATES: April 24, 2007, from 8:30 a.m. to 1:30 p.m. (EDT)

ADDRESSES: Hubert H. Humphrey building (200 Independence Avenue, SW., Washington, DC 20201), Conference Room 800.

FOR FURTHER INFORMATION CONTACT: Visit *http://www.hhs.gov/healthit/ahic.html.*

SUPPLEMENTARY INFORMATION: The meeting will include presentations by the Electronic Health Records and Chronic Care Workgroups on Recommendations and an update, as well as reports from the National Governors Association's State Alliance Task Force and a report on the First Year of the Nationwide Health Information Network (NHIN) initiative.

A Web cast of the Community meeting will be available on the NIH

Web site at: *http://www.videocast.nih.gov/*.

If you have special needs for the meeting, please contact (202) 690–7151.

Dated: April 2, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–1762 Filed 4–9–07; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services ((HHS) gives notice concerning the final effect of the HHS decision to designate a class of employees at the General Atomics facility, La Jolla, California, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On February 16, 2007, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

Atomic Weapons Employer (AWE) employees who were monitored or should have been monitored for exposure to ionizing radiation while working at the General Atomics facility in La Jolla, California, at the following locations: Science Laboratories A, B, and C (Building 2); Experimental Building (Building 9); Maintenance (Building 10); Service Building (Building 11); Buildings 21 and 22; Hot Cell Facility (Building 23); Waste Yard (Buildings 25 and 26); Experimental Area (Buildings 27 and 27–1); LINAC Complex (Building 30); HTGR–TCF (Building 31); Fusion Building (Building 33); Fusion Doublet III (Building 34); SV–A (Building 37); SV–B (Building 39); and SV–D (no building number) for a number of work days aggregating at least 250 work days from January 1, 1960, through December 31, 1969, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on March 18, 2007, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on March 18, 2007, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

Dated: April 5, 2007.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 07–1761 Filed 4–9–07; 8:45 am]

BILLING CODE 4163–19–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice concerning the final effect of the HHS decision to designate a class of employees at the Monsanto Chemical Company, Dayton, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On February 16, 2007, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

Atomic Weapons Employer (AWE) employees who were monitored or should have been monitored for exposure to ionizing radiation while working at Monsanto Chemical Company Units I, III, or IV in Dayton, Ohio, for a number of work days aggregating at least 250 work days during the period from January 1, 1943, through December 31, 1949, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on March 18, 2007, as provided for under 42 U.S.C. 7384*1*(14)(C). Hence, beginning on March 18, 2007, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

Dated: April 5, 2007.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 07–1763 Filed 4–9–07; 8:45 am]

BILLING CODE 4163–19–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–07–05BW]

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) 639–4794 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

Survey of Primary Care Physicians' Practices regarding Prostate Cancer Screening—New—National Center for Chronic Disease and Public Health Promotion (NCDDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Prostate cancer is the most common cancer in men and is the second leading cause of cancer deaths, behind lung cancer. The American Cancer Society estimated that there would be about 234,460 new cases of prostate cancer and about 27,350 deaths in 2006. Although prostate cancer deaths have declined over the past several years, it ranks fifth among deaths from all causes. The digital rectal examination (DRE) and prostate specific antigen

(PSA) test are used to screen for prostate cancer. Screening is controversial and many are not in agreement as to whether the potential benefits of screening outweigh the risks, that is, if prostate specific antigen (PSA) based screening, early detection, and later treatment increases longevity. Although major medical organizations are divided on whether men should be routinely screened for this disease, it appears that all of the major organizations recommend discussion with patients about the benefits and risks of screening.

The purpose of this project is to develop and administer a national survey to a sample of American primary care physicians to examine whether or not they: Screen for prostate cancer using (PSA and/or DRE), recommend testing and under what conditions, discuss the tests and the risks and benefits of screening with patients, and if their screening practices vary by factors such as age, ethnicity, and family history. This study will examine demographic, social, and behavioral characteristics of physicians as they relate to screening and related issues, including knowledge and awareness, beliefs regarding efficacy of screening and treatment, frequency of screening, awareness of the screening controversy, influence of guidelines from medical, practice and other organizations, and participation and/or willingness to participate in shared decision-making.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 1,032.5.

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)
Primary Care Physicians (eligible) ...	Survey of Physicians' Practices	2,000	1	30/60	1,000
Primary Care Physicians (ineligible)	Survey of Physicians' Practices	390	1	5/60	32.5

Dated: April 4, 2007.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–6745 Filed 4–9–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS), Center for Medicare & Medicaid Services (CMS).

ACTION: Notice of a New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system titled, ''Master Demonstration, Evaluation, and Research Studies (DERS) for the Office of Research, Development and Information (ORDI),'' System No. 09–70–0591. This notice serves as the Master system for all demonstration, evaluation, and research studies administered by ORDI. Sixteen existing ORDI demonstration, evaluation, and research studies will be included under this notice and the separate, existing systems of records notices for those studies will be deleted upon the effective date of this notice. DERS will become effective 30 days from the publication of the notice in the **Federal Register**, or 40 days from the date submitted to OMB and the Congress, whichever is later.

With the publication of this master system, ORDI will only be deleting the systems of records listed below as separate stand alone notices to the public. Retention and destruction of the data contained in these systems will follow the schedules listed in this DERS system notice. The existing ORDI systems of records to be included under DERS and which will be deleted by this notice are as follows:

- ''Municipal Health Services Program System No. 09–70–0022,'' 65 **Federal Register** (FR) 37792 (June 16, 2000);
- ''Monitoring of the Home Health Agency Prospective Payment Demonstration,'' System No. 09–70–0048, 65 FR 37792 (June 16, 2000);
- ''Person-Level Medicaid Data System, System No. 09–70–0507'' last published at 71 FR 60726 (October 16, 2006);
- ''Medicare Cancer Registry Record System,'' System No. 09–70–0509, last published at 71 FR 67133 (November 20, 2006);
- ''End Stage Renal Disease Program Management and Medical Information System,'' System No. 09–70–0520, last published at 67 FR 41244 (June 17, 2002);
- ''Evaluations of the Medicaid Reform Demonstrations,'' System No. 09–70–0523, last published at 71 FR 60540 (October 13, 2006);
- ''MMA Section 641 Prescription Drug Benefit Demonstration,'' System No. 09–70–0545, last published at 69 FR 32587 (June 10, 2004);
- ''Medicare Physician Group Practice Demonstration,'' System No. 09–70–0559, last published at 70 FR 58432 (October 6, 2005);
- ''Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities,'' System No. 09–70–0560, last published at 70 FR 57602 (October 3, 2005);
- ''Medicare Care Management Performance Demonstration,'' System No. 09–70–0562, last published at 70 FR 58442 (October 6, 2005);
- ''Rural Hospice Demonstration,'' System No. 09–70–0563, last published at 71 FR 57968 (October 2, 2006);
- ''Medicare Chiropractic Coverage Demonstration and Evaluation,'' System No. 09–70–0577, last published at 71 FR 41450 (July 21, 2006);
- ''Low Vision Rehabilitation Demonstration,'' System No. 09–70–0582, last published at 71 FR 58621 (October 4, 2006);
- ''Medicare Lifestyle Modification Program Demonstration,'' System No. 09–70–0585, last published at 71 FR 41807 (July 24, 2006);
- ''Competitive Bidding for Clinical Laboratory Services,'' System No. 09–70–0589, last published at 71 FR 60713 (October 16, 2006); and
- ''Senior Risk Reduction Demonstration and Evaluation,'' System No. 09–70–0592, last published at 71 FR 60718 (October 16, 2006).

The purpose of this system is to document, track, monitor, evaluate, and conduct ORDI-administered demonstration, evaluation, and research studies. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy

functions performed within the agency or by a contractor, consultant or CMS grantee; (2) assist another Federal or state agency with information to contribute to the accuracy of CMS's payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support litigation involving the agency; and (5) combat fraud, waste and abuse in certain Federally-funded health benefits programs. We have provided background information about the new system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See *Effective Dates* section for comment period.

DATES: *Effective Dates:* CMS filed a new SOR report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on April 3, 2007. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and the Congress, whichever is later. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should send comments to: CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

FOR FURTHER INFORMATION CONTACT: James Beyer, Division of Research and Information Dissemination, Information and Methods Group, Office of Research Development and Information, Mail Stop C3–24–01, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1849. He can be reached by telephone at 410–786–6693, or via e-mail at *James.Beyer@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: The DERS system of records will serve as the constructive notice to the Medicare beneficiary population and health care communities on activities related to all demonstrations, evaluations, and research studies administered by ORDI. The consolidation of the existing multiple notices into one master notice will serve the public interest by providing a single clear and concise format, a plain language notification easily understood, a central point of contact for access and correction of record information, and a new web based service to provide detailed information on each separate ORDI project. ORDI currently has 43 active projects and an additional 8 future projects anticipated to be included under DERS. An electronic web based list of current and each new demonstration, evaluation, and research studies administered by ORDI will be made accessible via the CMS public Web site. In addition to the Web based information and notification, other methods of direct notification, CMS will publish timely modification and updates to DERS as required keeping our Medicare community as informed as possible.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for maintenance of this system is given under the provisions of § 1110 of the Social Security Act (the Act), which authorizes research and demonstration projects under Social Security Act programs; § 1115 of the Act, which authorizes Medicaid demonstrations; and § 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1), which authorizes waivers of Medicaid and Medicare provisions under certain demonstrations. Many of the individual studies and demonstrations are specifically mandated in other legislation (§§ 235, 302(b) [amends section 1847(e) (42 United States Code (U.S.C.) §§ 1395w–3)], 303(d), 409, 410(a), 434, 623(e), 641, 646, 648, 649, 651, 702, and 703 of the Medicare Modernization Act, §§ 121 and 122 of the Benefits Improvement and Protection Act of 2000, the Deficit Reduction Act of 1984, § 5007 of the Deficit Reduction Act of 2005, the Balanced Budget Act of 1997, § 222 of the Consolidated Appropriations Act of 2001, and Conference Report No. 106–1033 for the Consolidated Appropriations Act of 2001. This system also covers all demonstrations, evaluation, and research studies administered by ORDI that may be authorized or mandated by future legislation.

B. Collection and Maintenance of Data in the System

The system will collect and maintain records related to Medicare beneficiaries, Medicaid recipients, and physician and providers of services who voluntarily participate in demonstrations, evaluations, and research studies administered by ORDI. In addition, Medicare enrollment data, claims data or provider enrollment information currently maintained in existing systems of records will be used in demonstrations, evaluation, and research studies administered by ORDI. Examples include, but are not limited to: provider name, unique provider identification number, unique demonstration practice identification number, beneficiary name, health insurance claim number, beneficiary demographic and diagnostic information relevant to the project, types and costs of health services used, and measures of the quality of health care received.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The Government will only release DERS information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use. We will only collect the minimum personal data necessary to achieve the purpose of DERS.

CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; *e.g.*, to document, track, monitor, evaluate, and conduct ORDI-administered research, demonstration, and evaluation activities.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy, at the earliest time, all patient-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees, who have been engaged by the agency to assist in the performance of a service related to this collection and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS functions relating to purposes for this system.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, consultant or grantee whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant or grantee from using or disclosing the information for any purpose other than that described in the contract and requires the contractor, consultant or grantee to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits;

b. Enable such agency to administer a Federal health benefits program, or, as necessary, to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; and/or

c. Assist Federal/state Medicaid programs within the State.

Other Federal or State agencies, in their administration of a Federal health program, may require DERS information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The DERS data will provide for research or support of evaluation projects and a broader, longitudinal, national perspective of the status of Medicare beneficiaries. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policies that govern their care.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

5. To a CMS contractor (including, but not necessarily limited to, fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual, grantee, cooperative agreement or consultant relationship with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste and abuse. CMS occasionally contracts out certain of its functions or makes grants or cooperative agreements when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, grantee, consultant or other legal agent whatever information is necessary for the agent to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the agent from using or disclosing the information for any purpose other than that described in the contract and requiring the agent to return or destroy all information.

6. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

Other agencies may require DERS information for the purpose of combating fraud, waste and abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, Subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that an individual could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system 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.

CMS 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 patients whose data are maintained in this system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Dated: March 28, 2007.

Charlene Frizzera,

Acting Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09–70–0591

SYSTEM NAME:

''Master Demonstration, Evaluation, and Research Studies for the Officer of Research, Development and Information (DERS),'' HHS/CMS/ORDI.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various co-locations of CMS agents.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system will collect and maintain records related to Medicare beneficiaries, Medicaid recipients, and physician and providers of services who voluntarily participate in demonstrations, evaluations, and research studies administered by ORDI. In addition, Medicare enrollment data, claims data or provider enrollment information currently maintained in existing systems of records will be used in demonstrations, evaluation, and research studies administered by ORDI.

CATEGORIES OF RECORDS IN THE SYSTEM:

The collected information will include, but is not limited to: provider name, unique provider identification number, unique demonstration practice identification number, beneficiary name, health insurance claim number (HICN), beneficiary demographic and diagnostic information relevant to the project, types and costs of health services used, and measures of the quality of health care received.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for maintenance of this system is given under the provisions of § 1110 of the Social Security Act (the Act), which authorizes research and demonstration projects under Social Security Act programs; § 1115 of the Act, which authorizes Medicaid demonstrations; and § 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1), which authorizes waivers of Medicaid and Medicare provisions under certain demonstrations. Many of the individual studies and demonstrations are specifically mandated in other legislation (§§ 235, 302 (b) [amends section 1847(e) (42 United States Code (U.S.C.) §§ 1395w–3)], 303(d), 409, 410(a), 434, 623(e), 641, 646, 648, 649, 651, 702, and 703 of the Medicare Modernization Act, §§ 121 and 122 of the Benefits Improvement and Protection Act of 2000, the Deficit Reduction Act of 1984, § 5007 of the Deficit Reduction Act of 2005, the Balanced Budget Act of 1997, § 222 of the Consolidated Appropriations Act of 2001, and Conference Report No. 106–1033 for the Consolidated Appropriations Act of 2001. This system also covers all demonstrations, evaluation, and research studies administered by ORDI that may be authorized or mandated by future legislation.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to document, track, monitor, evaluate, and conduct ORDI-administered demonstration, evaluation, and research studies. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant or CMS grantee; (2) assist another Federal or state agency with information to contribute to the accuracy of CMS's payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or to enable

such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support litigation involving the agency; and (5) combat fraud, waste and abuse in certain federally-funded health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees, who have been engaged by the agency to assist in the performance of a service related to this collection and who need to have access to the records in order to perform the activity.

2. To another Federal or State agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits;

b. Enable such agency to administer a Federal health benefits program, or, as necessary, to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; and/or

c. Assist Federal/state Medicaid programs within the State.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

5. To a CMS contractor (including, but not necessarily limited to, fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

6. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a) (1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that an individual could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on electronic media.

RETRIEVABILITY:

The collected data are retrieved by the name or other identifying information of the participating provider or beneficiary, and may also be retrieved by a distinct identifier such as the HICN, at the individual beneficiary level.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain identifiable information maintained in the DERS system of records for a period of 5 years after the end of the research, demonstration, or evaluation project. Data residing with the designated claims payment contractor shall be returned to

CMS at the end of the project, with all data then being the responsibility of CMS for adequate storage and security. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Deputy Director, Office of Research Development and Information, Mail Stop C3–18–07, CMS, 7500 Security Boulevard, Baltimore, MD 21244–1849.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, employee identification number, tax identification number, national provider number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), HICN, and/or SSN (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

Data will be collected from Medicare administrative and claims records, patient medical charts, and physician records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

APPENDIX A. Current ORDI run Demonstration, Evaluation and Research Activities

The following is a listing of the current ORDI run demonstration, evaluation and research activities at CMS, with the appropriate contact person. A perpetual list of current demonstrations and evaluations will be made accessible through the CMS public Web site (*http://www.cms.hhs.gov*). The list will be amended for each new project that is implemented.

1. ORDI Run Demonstration, Evaluation and Research Activities

- Bundled Case-Mix Adjusted Payment System for End Stage Renal Disease Services Demonstration. Contact: Henry Bachofer, 410–786–0340.
- Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities. Contact: Diane Merriman, 410–786–7237.
- Consumer Directed Chronic Outpatient Services. Contact: Pauline Lapin, 410–786–6883.
- Cost-effectiveness of Daily versus Conventional Hemodialysis for the Medicare Population. Contact: Penny Mohr, 410–786–6502.
- Data Collection and Administering the Medicare Health Improvement Survey. Contact: David Bott, 410–786–0249.
- Design and Implementation of a Beneficiary Survey on Access to Selected Prescriptions and Biologicals. Contact: Penny Mohr, 410–786–6502.
- Disease Management for Severely Chronically Ill Medicare Beneficiaries. Contact: J. Sherwood, 410–786–6651.
- End Stage Renal Disease (ESRD) Disease Management Demonstration. Contact: Sid Mazumdar, 410–786–6673.
- Evaluation of Care Management for High Cost Beneficiaries Demonstration. Contact: David Bott, 410–786–0249.
- Evaluation of Second Phase of Oncology Demonstration Program. Contact: James Menas, 410–786–4507.
- Evaluation of the Medicare Preferred Provider Organization Demonstration. Contact: Victor McVicker, 410–786–6681.
- Evaluation of the State Medicaid Reform Demonstrations. Contact: Paul Boben, 410–786–6629.
- Expansion of Coverage of Chiropractic Services Demonstration. Contact: Carol Magee, 410–786–6611.
- Frontier Extended Stay Clinic Demonstration Project. Contact: Sid Mazumdar, 410–786–6673.
- Home Health Agency Prospective Payment Demonstration. Contact: J. Sherwood, 410–786–6651.
- Impact of Payment Reform for Part B Covered Outpatient Drugs and Biologicals. Contact: Usree Bandyopadhyay, 410–786–6650.
- Informatics for Diabetes Education and Telemedicine Demonstration (IDEATel). Contact: Diana Ayres, 410–786–7203.
- Inhalation Drug Therapy Demonstration. Contact: Debbie Vanhoven, 410–786–6625.
- Life Masters. Contact: Linda Colantino, 410–786–3343.
- Low Vision Rehabilitation Demonstration. Contact: James Coan, 410–786–9168.
- Massachusetts Senior Care Options. Contact: William Clark, 410–786–1484.
- Medical Adult Day Care Services Demonstration. Contact: Armen Thoumaian, Ph.D., 410–786–6672.
- Medicare + Choice Phase II—PPO Demonstration. Contact: Debbie Vanhoven, 410–786–6625.
- Medicare Advantage CCRC (Erickson) Demonstration. Contact: Henry Bachofer, 410–786–0340.
- Medicare Cancer Registry Record System. Contact: Gerald Riley, 410–786–6699.
- Medicare Care Management Performance Demonstration. Contact: Jody Blatt, 410–786–6921.
- Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project. Contact: Linda Lebovic, 410–786–3402.
- Medicare Coordinated Care Demonstration. Contact: Cynthia Mason, 410–786–6680.
- Medicare Drug Replacement Demonstration. Contact: Jody Blatt, 410–786–6921.
- Medicare Health Care Quality Demonstration Programs. Contact: Cynthia Mason, 410–786–6680.
- Medicare Home Health Independence Demonstration. Contact: Armen Thoumaian, Ph.D., 410–786–6672.
- Medicare Hospital Gainsharing Demonstration. Contact: Lisa Waters, 410–786–6615.
- Medicare Preventive Services—Medicare Lifestyle Modification Program Demonstration. Contact: Armen Thoumaian, Ph.D., 410–786–6672.
- Mercy Medicare Skilled Nursing Facility Payment Demonstration. Contact: J. Sherwood, 410–786–6651.
- Minnesota Senior Health Options. Contact: Susan Radke, 410–786–4450.
- Municipal Health Services Program Demonstration. Contact: Michael Henesch, 410–786–6685.
- New York Graduate Medical Education Demonstration. Contact: Sid Mazumdar, 410–786–6673.
- Nursing Home Value-Based Purchasing. Contact: Ronald Lambert, 410–786–6624.
- PACE-for-Profit Demonstration. Contact: Michael Henesch, 410–786–6685.
- Payment Development, Implementation and Monitoring for the BIPA Disease Management Demonstration. Contact: J. Sherwood, 410–786–6651.
- Person-Level Medicaid Data System. Contact: Dave Baugh, 410–786–7716.
- Physician Group Practice Demonstration. Contact: John Pilotte, 410–786–6658.
- Premier Hospital Quality Incentive Demonstration. Contact: Katharine Pirotte, 410–786–6774.
- Rural Community Hospital Demonstration. Contact: Sid Mazumdar, 410–786–6673.
- Rural Hospice Demonstration: Quality Assurance Metrics Implementation Support. Contact: Cindy Massuda, 410–786–0652.
- Senior Risk Reduction Demonstration. Contact: Pauline Lapin, 410–786–6883.
- Social Health Maintenance Organization for Long-Term Care Demonstration. Contact: Thomas Theis, 410–786–6654.
- State-Based Home Health Agency TPL Payments. Contact: J. Sherwood, 410–786–6651.
- United Mine Workers of America Demonstration. Contact: Jason Petroski, 410–786–4681.
- Utah Graduate Medical Education. Contact: Sid Mazumdar, 410–786–6673.

• Wisconsin Partnership Program. Contact: James Hawthorne, 410–786–6689.

[FR Doc. E7–6693 Filed 4–9–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel, Roadmap Interdisciplinary Center.

Date: May 2–3, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel & Executive Meeting Center, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, National Center for Research Resources, or, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1076, MSC 4874, Bethesda, MD 20892–4874, 301–435–0814, *lambert@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, 2007 CTSA Meeting #1.

Date: May 8–9, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Mohan Viswanathan, PhD, Deputy Director, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892–4874, 301–435–0829, *mv10f@nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, Residency II.

Date: May 8, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville (Remodeled to Hilton), 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: John R. Glowa, PhD, Scientific Review Administrator, National Center for Research Resources, or, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1078—Msc 4874, Bethesda, MD 20892–4874, 301–435–0807, *glowaj@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, 2007 CTSA Meeting #2.

Date: May 15–16, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Mohan Viswanathan, PhD, Deputy Director, Office of Review, NCRR, National Instiutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892–4874, 301–435–0829, *mv10f@nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, 2007 BT Review Mtg#1.

Date: May 23, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Steven Birken, PhD, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Office of Review, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1078, Bethesda, MD 20892, (301) 435–0815, *birkens@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, 2007 BT Review Mtg.#2.

Date: June 12–13, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Steven Birken, PhD, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Office of Review, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1078, Bethesda, MD 20892, (301) 435–0815, *birkens@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: April 4, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1767 Filed 4–9–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 National Advisory Research Resources Council.

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 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 Advisory Research Resources Council.

Date: May 22, 2007.

Time: 8 a.m. to 12 p.m

Agenda: NCRR's Director's Report and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, Floor 6C, Room 10, Bethesda, MD 20892.

Closed: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

National Institutes of Health, Building 31, 31 Center Drive, Floor 6C, Room 10, Bethesda, MD 20892.

Contact Person: Louise E. Ramm, PhD, Deputy Director, National Center for Research Resources, National Institutes of Health, Building 31, Room 3B11, Bethesda, MD 20892, 301–496–6023, *Louiser@ncrr.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the

committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page *http://www.ncrr.nih.gov/newspub/minutes.htm.* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: April 4, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1768 Filed 4–9–07; 8:45 am]

BILLING CODE 4140–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Loan Repayment Program—Meeting 1.

Date: May 1–2, 2007.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Ellen S. Buczko, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2676, *ebuczko1@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 4, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1766 Filed 4–9–07; 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, A Phase III Trial of Lorenzo's Oil in Adrenomyeloneuropathy.

Date: April 25, 2007.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 6100 Executive Boulevard, 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 496–1485, *changn@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, 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 4, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1769 Filed 4–9–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, NEURO AIDS.

Date: April 26–27, 2007.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Stanford Court Renaissance Hotel, 905 California Street-Nob Hill, San Francisco, CA 94108.

Contact Person: Phillip F Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard; MSC 9529, Neuroscience Center; Room 3203, Bethesda, MD 20892–9529, (301) 496–5388, *wiethorp@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Neurofibromatosis Center Without Walls.

Date: April 27, 2007.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific

Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–4056.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 3, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1770 Filed 4–9–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following 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 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 constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Immunology Member Conflict—Antigen Processing.

Date: April 20, 2007.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Samuel C. Edwards, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, MSC 7812, Bethesda, MD 20892, (301) 435–1152. *edwardss@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Cellular and Molecular Biology of Neurodegeneration Study Section.

Date: May 30–31, 2007.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Carole L. Jelsema, PhD., Chief and Scientific Review Administrator, MDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435–1248. *jelsemac@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Medical Imaging BRP.

Date: May 30, 2007.

Time: 3 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.

Contact Person: Antonio Sastre, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 52150, MSC 7412, Bethesda, MD 20892, (301) 435–2592. *sastrea@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Cellular and Molecular Biology of Glia Study Section.

Date: June 1, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Toby Behar, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics C Study Section.

Date: June 7–8, 2007.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, (301) 435–4511, *whitmarshb@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.893, National Institutes of Health, HHS)

Dated: April 4, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1765 Filed 4–9–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revised information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the e-Grants application used to determine whether mitigation activities proposed for funding meets eligibility criteria. To better reflect all of the mitigation grant programs using the mitigation e-Grants application, the Flood Mitigation Assistance (FMA) e-Grant Program, the Pre-Disaster Mitigation (PDM) e-Grant Program and the Repetitive Flood Claims (RFC) e-Grant Program have been combined and renamed to be called the Mitigation Grant Program/e-Grants.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: Mitigation Grant Program/e-Grants (previously named Flood Mitigation Assistance (e-Grants)).

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0072.

Form Numbers: None.

Abstract: The States will utilize the Mitigation Grant Program/e-Grants, automated application to report to FEMA on a quarterly basis, certify how funding is being used and to report on the progress of mitigation activities funded under grant awards, made to Grantees by FEMA. FEMA will use this system to review the Grantees quarterly reports to ensure that mitigation grant activities are progressing on schedule and to track the expenditure of funds.

Affected Public: State, Local or Tribal Government, and Federal Government.

ESTIMATED TOTAL ANNUAL BURDEN HOURS:

Data collection activities/instrument	Number of respondents (A)	Frequency of responses (B)	Hours burden per response (C)	Annual responses (D+A*B)	Annual burden hours (E=C*D)
FMA					
Benefit-Cost Determination	56	2	5 hours	112	560
Environmental Review	56	2	7.5 hours	112	840
Project Narrative—Sub-grant Application	56	4	12 hours	224	2,688
Subtotal for FMA e-Grants Supplemental Information.	56		24.5	448	4,088
PDM					
Benefit-Cost Determination	56	20	5 hours	1,120	5,600
Environmental Review	56	20	7.5 hours	1,120	8,400
Project Narrative—Sub-grant application (including PDM Evaluation Information Questions [5]).	56	20	12 hours	1,120	13,440
Subtotal for PDM e-Grants Supplemental Information.	56		24.5	3,360	27,440
RFC					
Benefit-Cost Determination	56	1	5 hours	56	280
Environmental Review	56	1	7.5 hours	56	420
Project Narrative—Sub-grant application	56	2	12 hours	112	1,344
Subtotal for RFC e-Grants Supplemental Information.	56		24.5	224	2,084
Totals	56		24.5	4,032	33,612

Estimated Cost: The total annual estimated costs to States and tribal governments for information collection associated with the mitigation grant programs is $891,726.36. This calculation is based on the number of annual burden hours for wage rates for Urban and Regional Planners, responsible for collecting the information or completing the e-Grants information at the State level. The cost for developing e-Grants system is approximately $4.4 million. System enhancements will continue into future years, at an average cost to FEMA of $750,000 annually in contract costs.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Comments must be submitted on or before June 11, 2007.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management and Privacy, Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, 500 C Street, SW., Room 609, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Cecelia Rosenberg, Section Chief, Mitigation Division, (202) 646–3321 for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA-Information-Collections@dhs.gov.*

Dated: April 2, 2007.

John A. Sharetts-Sullivan,

Chief, Records Management and Privacy Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E7–6757 Filed 4–9–07; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1690–DR]

New Mexico; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New Mexico (FEMA–1690–DR), dated April 2, 2007, and related determinations.

DATES: *Effective Date:* April 2, 2007.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Disaster Assistance Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 2, 2007, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of New Mexico resulting from severe storms and tornadoes during the period of March 23–24, 2007, is of sufficient severity and magnitude to warrant a major disaster declaration under

the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of New Mexico.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation, and Other Needs Assistance will be limited to 75 percent of the total eligible costs. If Public Assistance is later warranted, Federal funds provided under that program will also be limited to 75 percent of the total eligible costs. Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Justin A. Dombrowski, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of New Mexico to have been affected adversely by this declared major disaster:

Curry and Quay Counties for Individual Assistance.

All counties within the State of New Mexico are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–6758 Filed 4–9–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request.

ACTION: 30-Day Notice of Information Collection under Review: Form G–1054, Request for Fee Waiver Denial Letter; OMB Control No. 1615–0089.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on February 1, 2007, at 72 FR 4722, allowing for a 60-day public comment period. USCIS did not receive any comments on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until May 10, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. *Comments may be submitted to:* USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor 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*, and to the OMB USCIS Desk Officer via facsimile at 202–395–6974 or via e-mail at *kastrich@omb.eop.gov.*

When submitting comments by e-mail please make sure to add OMB Control Number 1615–0089. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Request for Fee Waiver Denial Letter.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form G–1054; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or Households. The regulations at 8 CFR 103.7(c) allows U.S. Citizenship and Immigration Services (USCIS) to waive fees for benefits under the Immigration and Nationality Act (Act). This form is used to maintain consistency in the adjudication of fee waiver requests, to collect accurate data on amounts of fee waivers, and to facilitate the public-use process.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 16,000 responses at 1.25 hours (75 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 20,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact the Chief, USCIS, Regulatory Management Division, 111 Massachusetts Avenue, Suite 3008, Washington, DC 20529, (202) 272–8377.

Dated: April 5, 2007.

Stephen Tarragon,

Deputy Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 07–1756 Filed 4–9–07; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4964–N–03]

Annual Indexing of Basic Statutory Mortgage Limits for Multifamily Housing Programs

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In accordance with section 206A of the National Housing Act, HUD has adjusted the basic statutory mortgage limits for multifamily housing programs for calendar year 2007.

DATES: *Effective Date:* January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Joseph E. Malloy, Acting Director, Office of Multifamily Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–8000, telephone (202) 708–1142 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The FHA Downpayment Simplification Act of 2002 (Pub. L. 107–326, approved December 4, 2002) amended the National Housing Act by adding a new section 206A (12 U.S.C. 1712a). Under section 206A, the following are affected:

(1) Section 207(c)(3)(A) (12 U.S.C. 1713(c)(3)(A));

(2) Section 213(b)(2)(A) (12 U.S.C. 1715e(b)(2)(A));

(3) Section 220(d)(3)(B)(iii)(I) (12 U.S.C. 1715k(d)(3)(B)(iii)(I));

(4) Section 221(d)(3)(ii)(I) (12 U.S.C. 1715l(d)(3)(ii)(I));

(5) Section 221(d)(4)(ii)(I) (12 U.S.C. 1715l(d)(4)(ii)(I));

(6) Section 231(c)(2)(A) (12 U.S.C. 1715v(c)(2)(A)); and

(7) Section 234(e)(3)(A) (12 U.S.C. 1715y(e)(3)(A)).

The dollar amounts in these sections, which are collectively referred to as the ''Dollar Amounts,'' shall be adjusted annually (commencing in 2004) on the effective date of the Federal Reserve Board's adjustment of the $400 figure in the Home Ownership and Equity Protection Act of 1994 (HOEPA) (Pub. L. 103–325, approved September 23, 1994). The adjustment of the Dollar Amounts shall be calculated using the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) as applied by the Federal Reserve Board for purposes of the above-described HOEPA adjustment.

HUD has been notified of the percentage change in the CPI–U used for the HOEPA adjustment and the effective date of the HOEPA adjustment. The percentage change in the CPI–U is 3.55 percent and the effective date of the HOEPA adjustment is January 1, 2007. The Dollar Amounts have been adjusted correspondingly and have an effective date of January 1, 2007.

The adjusted Dollar Amounts for calendar year 2007 are shown below:

Basic Statutory Mortgage Limits for Calendar Year 2007

Multifamily Loan Program

- Section 207—Multifamily Housing.
- Section 207 pursuant to section 223(f)—Purchase or refinance housing.
- Section 220—Housing in urban renewal areas.

Bedrooms	Non-elevator	Elevator
0	$42,614	49,171
1	47,203	55,071
2	56,381	67,528
3	69,494	84,574
4+	78,674	95,627

- Section 213—Cooperatives.

Bedrooms	Non-elevator	Elevator
0	$46,180	49,171
1	53,245	55,709
2	64,216	67,741
3	82,195	87,635
4+	91,570	96,197

- Section 221(d)(3)—Moderate income housing.
- Section 234—Condominium housing.

Bedrooms	Non-elevator	Elevator
0	$47,122	49,590
1	54,332	56,845
2	65,525	69,124
3	83,873	89,423
4+	93,438	98,160

- Section 221(d)(4)—Moderate income housing.

Bedrooms	Non-elevator	Elevator
0	$42,408	45,809
1	48,138	52,514
2	58,186	63,856
3	73,034	82,608
4+	82,760	90,679

- Section 231—Housing for the Elderly.

Bedrooms	Non-elevator	Elevator
0	$40,320	45,809
1	45,074	52,514
2	53,825	63,856
3	64,773	82,608
4+	76,151	90,679

- Section 207—Manufactured Home Parks.

Per Space—$19,565

Dated: April 2, 2007.

Brian D. Montgomery,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. E7–6654 Filed 4–9–07; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

DATES: Written data, comments or requests must be received by May 10, 2007.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: John K. Maher, Corpus Christi, TX, PRT–133297.

The applicant requests an interstate commerce permit to transport a pair of captive-born San Esteban Island chuckwalls (*Sauromalus varius*) for the purpose of enhancement of the species through captive propagation.

Applicant: Archie Carr Center for Sea Turtle Research, University of Florida, Gainesville, FL, PRT–724540.

The applicant requests re-issuance of a permit to import biological samples collected from wild, captive held, and/or captive hatched leatherback sea turle (*Dermochelys coriacea*), hawksbill sea turtle (*Eretmochelys imbricata*), green sea turtle (*Chelonia mydas*), Kemp's ridley sea turtle (*Lepidochelys kempii*), and olive ridley sea turtle (*Lepidochelys olivacea*) for the purpose of scientific research. Samples are to be collected from live or salvaged specimens. This notification covers activities conducted by the applicant over a five year period.

Applicant: National Marine Fisheries Service, La Jolla, CA, PRT–844694.

The applicant requests an amendment and re-issuance of their permit to import and/or introduce from the sea, biological samples collected from the wild on the high seas, both from opportunistically salvaged and incidentally captured specimens of Kemp's ridley sea turtle (*Lepidochelys kempii*), hawksbill sea turtle (*Eretmochelys imbricata*), and leatherback sea turtle (*Dermochelys coriacea*) for the purpose of scientific research. The amendment request is for the import of biological samples collected on land, opportunistically from wild, captive-held and/or captive hatched specimens of Kemp's ridley sea turtle (*Lepidochelys kempii*), hawksbill sea turtle (*Eretmochelys imbricata*), leatherback sea turtle (*Dermochelys coriacea*), green sea turtle (*Chelonia mydas*), and olive ridley sea turtle (*Lepidochelys olivacea*). Samples are to be collected from live or salvaged specimens. This notification covers activities conducted by the applicant over a period of 5 years.

Applicant: Lemur Conservation Foundation, Myakka City, FL, PRT–137431.

The Fish and Wildlife Service is reopening the comment period for the applicant to import three live captive born ring-tailed lemurs (*Lemur catta*) for the purpose of enhancement of the survival of the species through captive propagation and scientific research. The application was submitted to satisfy the requirements of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). A notice of receipt of this application for a permit was published in the **Federal Register** on February 23, 2007, Vol. 72 and page #8194. The comment period will close on March 26, 2007. On February 26, 2007, the applicant requested that another ring-tailed lemur and two mongoose lemurs (*Eulemur mongoz*) be added to the application. We are reopening the comment period to allow all interested parties to review the new information and provided us with any additional comments regarding the application.

Applicant: Michelle P. Williamson Austine, Huntington Beach, CA, PRT–148365.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: George D. Cummans, Gadsden, AL, PRT–148763.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Ralph G. Merrill, Bountiful, UT, PRT–148895.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: John R. Hopkins, Littleton, CO, PRT–148787.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Marine Mammals

The public is invited to comment on the following applications for a permit to conduct certain activities with marine mammals. The applications were submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing marine mammals (50 CFR Part 18). Written data, comments, or requests for copies of the complete applications or requests for a public hearing on these applications should be submitted to the Director (address above). Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Applicant: Leo F. Neuls, Trenton NJ, PRT–147859.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Northern Beaufort Sea polar bear population in Canada for personal, noncommercial use.

Applicant: Rick J. Zitzloff, Minnetrista, MN, PRT–148408.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Northern Beaufort Sea polar bear population in Canada for personal, noncommercial use.

Applicant: Daniel A. Hoffler, Virginia Beach, VA, PRT–148820.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Viscount Melville Sound polar bear population in Canada for personal, noncommercial use.

Dated: March 16, 2007.

Michael L. Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E7–6695 Filed 4–9–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits for endangered species and/or marine mammals.

SUMMARY: The following permits were issued.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on the dates below, as authorized by the provisions of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service issued the

requested permits subject to certain conditions set forth therein.

Marine Mammals

Permit No.	Applicant	Receipt of application FEDERAL REGISTER notice	Permit issuance date
141735	Jeffrey K. Chaulk	72 FR 2538; January 19, 2007	March 6, 2007.
133557	Larry R. McNeill	71 FR 62291; October 24, 2006	February 12, 2007.

Dated: March 16, 2007.

Michael L. Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E7–6696 Filed 4–9–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[F–14892–A, F–14892–A2; AK–964–1410–HY–P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: As required by 43 CFR 2650.7(d), notice is hereby given that an appealable decision approving lands for conveyance pursuant to the Alaska Native Claims Settlement Act will be issued to Maserculiq, Incorporated. The lands are in the vicinity of the Native village of Marshall, Alaska, and are located in:

Tract C, U.S. Survey No. 4415, Alaska.

Containing approximately 10 acres.

Seward Meridian, Alaska

T. 21 N., R. 68 W.,
Secs. 20 to 29, inclusive;
Secs. 31 to 36, inclusive.

Containing 10,234.58 acres.

T. 19 N., R. 69 W.,
Secs. 21 and 22;
Secs. 27 to 34, inclusive.

Containing 5,176.42 acres.

T. 21 N., R. 69 W.,
Secs. 1, 2, and 3;
Secs. 10, 12, and 15.

Containing 3,840.00 acres.

T. 22 N., R. 69 W.,
Sec. 21.

Containing approximately 80 acres.

T. 19 N., R. 70 W.,
Secs. 25 and 36.

Containing 1,061.53 acres.

T. 20 N., R. 70 W.,
Secs. 22 and 23.

Containing 1,096.49 acres.

T. 21 N., R. 70 W.,
Secs. 4 and 8;
Secs. 15, 16, and 32.

Containing approximately 187 acres.

T. 20 N., R. 71 W.,
Secs. 10, 16, and 25.

Containing approximately 74 acres.

Aggregating approximately 21,760 acres.

The subsurface estate in these lands will be conveyed to Calista Corporation when the surface estate is conveyed to Maserculiq, Incorporated. Notice of the decision will also be published four times in the Tundra Drums.

DATES: The time limits for filing an appeal are:

1. Any party claiming a property interest which is adversely affected by the decision shall have until 30 days after publication in the **Federal Register** to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E, shall be deemed to have waived their rights.

ADDRESSES: A copy of the decision may be obtained from: Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: The Bureau of Land Management by phone at 907–271–5960, or by e-mail at *ak.blm.conveyance@ak.blm.gov.* Persons who use a telecommunication device (TTD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8330, 24 hours a day, seven days a week, to contact the Bureau of Land Management.

Kara Marciniec,

Land Law Examiner, Branch of Adjudication II.

[FR Doc. E7–6739 Filed 4–9–07; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–957–1420–BJ]

Idaho: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Surveys.

SUMMARY: The Bureau of Land Management (BLM) has officially filed the plats of survey of the lands described below in the BLM Idaho State Office, Boise, Idaho, effective 9 a.m., on the dates specified.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709–1657.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management to meet their administrative needs. The lands surveyed are:

This supplemental plat was prepared to amend old lot 22 to lots 24 and 25, in section 15, T. 48 N., R. 3 E., Boise Meridian, Idaho, was accepted February 14, 2007.

This supplemental plat was prepared to add certain aliquot part acreages in section 6, T. 9 S., R. 41 E., Boise Meridian, Idaho, was accepted March 14, 2007.

The field notes representing the remonumentation of certain corners in T. 11 S., R. 16 E., Boise Meridian, Idaho, were approved March 21, 2007.

This survey was executed at the request of the Bureau of Indian Affairs to meet certain administrative and management purposes. The lands surveyed are:

The plat representing the dependent resurvey of a portion of the east boundary, a portion of the subdivisional lines, the subdivision of sections 24 and 25, and the metes-and-bounds surveys of certain lots and the rights-of-way boundaries of U.S. Highway No. 95 and the Union Pacific Railroad in section 24, T. 47 N., R. 5 W., Boise Meridian, Idaho, was accepted February 28, 2007.

Dated: April 4, 2007.

Stanley G. French,

Chief Cadastral Surveyor for Idaho.

[FR Doc. E7–6741 Filed 4–9–07; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–350–07–1910–BJ–5WY4]

Notice of Filing of Plats of Survey, Nebraska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey, Nebraska.

SUMMARY: The Bureau of Land Management (BLM) is scheduled to file the plats of survey of the lands described below thirty (30) calendar days from the date of this publication in the BLM Wyoming State Office, Cheyenne, Wyoming.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Bureau of Indian Affairs and is necessary for the management of these lands. The lands surveyed are:

The plat and field notes representing the dependent resurvey of a portion of the subdivisional lines, the survey of the subdivision of sections 25 and 26, and the metes-and-bounds survey of Parcels A of sections 25 and 26, Township 32 North, Range 7 West, of the Sixth Principal Meridian, Nebraska.

Copies of the preceding described plat and field notes are available to the public at a cost of $1.10 per page.

Dated: April 2, 2007.

John P. Lee,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. E7–6636 Filed 4–9–07; 8:45 am]

BILLING CODE 4467–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

South Coast Conduit Secondary Pipeline, Santa Barbara County, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of Intent to prepare an environmental impact statement/ environmental impact report (EIS/EIR).

SUMMARY: The Bureau of Reclamation (Reclamation) and the Cachuma Operation and Maintenance Board (COMB) are planning to prepare a combined EIS/EIR for the proposed construction of a second pipeline adjacent to the South Coast Conduit (SCC) between the South Portal of the Tecolote Tunnel (SPTT) and the Corona Del Mar Water Treatment Plant (CDMWTP) for the purposes of increasing the operational flexibility, reliability, and the conveyance capacity of the SCC, accommodating peak demand levels, and allowing maintenance of the pipeline.

The project site is located in Glen Annie Canyon, north of the City of Goleta, in Santa Barbara County, California. The project site encompasses the area surrounding the existing SCC between the SPTT and the CDMWTP.

DATES: Reclamation and COMB will hold a scoping meeting to seek public input on topics, issues, and alternatives to be considered in the EIS/EIR. The scoping meeting will be held on May 17, 2007 from 7 p.m. to 9 p.m. in Santa Barbara, California.

Send written comments on the scope of alternatives and impacts to be considered to Mrs. Laura Myers at the below address by close of business Friday, June 15, 2007

ADDRESSES: The scoping meeting will be held at the COMB office, 3301 Laurel Canyon Road, Santa Barbara, California.

Send written comments on the scope of the EIS/EIR to Mrs. Laura Myers, Bureau of Reclamation, 1243 N Street, Fresno, California 93721.

FOR FURTHER INFORMATION CONTACT: Mrs. Laura Myers, Reclamation, at the above address, (559) 487–5179 or Mr. Brett Gray, Cachuma Operations and Maintenance Board, 3301 Laurel Canyon Road, Santa Barbara, CA 93105–2017; *telephone:* (805) 687–4011, *fax:* (805) 569–5825.

SUPPLEMENTARY INFORMATION: The increase in operational flexibility, reliability, and capacity are intended to accommodate peak demand levels and to allow maintenance of the pipeline. The limitations and age of the original equipment, significant system modifications, and increased demands constrain the ability of the SCC to function at the system's original design capacity. Because of these limitations, COMB is forced to rely on water stored in Lauro, Ortega, and Carpinteria reservoirs to meet regional water needs. In addition, no redundant supply or pipeline exists to convey Cachuma Project water or State Water Project (SWP) water to the South Coast if the Tecolote Tunnel or the Upper Reach of the SCC is out of service due to scheduled and/or unexpected repairs.

As the Upper Reach of the SCC has the largest demand deficit and is located upstream from the sources of demand, the proposed action would allow more water flow farther along the pipeline to improve the level of service and reliability. The proposed action would also provide COMB the ability to perform regularly scheduled inspections and maintenance to one pipeline while the second is operational. Operational flexibility would increase due to the ability to provide higher flow rates to CDMWTP and increased flow rates to facilities downstream of the CDMWTP during times of peak demands. The total amount of water delivered per year, however, would not increase.

Potential alternatives include different alignments of the pipeline which would still meet the purpose and need, as well as pumping structures and or disinfection facilities. A no action alternative would include construction of site improvements and operational activities that could occur without issuance of Federal permits.

The EIS/EIR will evaluate the potential impacts of the project on Indian Trust Assets (ITAs), which are held in trust by the U.S. Government for Indian Tribes or individual Tribal members. Potential ITAs include water rights, lands, minerals (i.e., oil, gas, sand), and hunting and fishing rights.

If special assistance is required for these meetings, please contact Mrs. Laura Myers at (559) 487–5179. Please notify Mrs. Myers as far in advance of the meeting as possible to allow Reclamation to secure the needed services. If a request cannot be honored, the requester will be notified. A telephone device for the hearing impaired (TDD) is available at 916–978–5608.

Comments received in response to this notice will become part of the administrative record and are subject to public inspection. Our practice is to make comments, including names, home addresses, home phone numbers, and e-mail addresses of respondents, available for public review. Individual respondents may request that we withhold their names and/or home addresses, etc., but if you wish us to consider withholding this information, you must state this prominently at the beginning of your comments. In addition, you must present a rationale for withholding this information. This rationale must demonstrate that disclosure would constitute a clearly unwarranted invasion of privacy. Unsupported assertions will not meet this burden. In the absence of exceptional, documentable circumstances, this information will be released. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of

organizations or businesses, available for public inspection in their entirety.

Dated: April 4, 2007.

Robert Eckart,

Acting Regional Environmental Officer, Mid-Pacific Region.

[FR Doc. E7–6747 Filed 4–9–07; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0006]

Civil Rights Division, Disability Rights Section; Agency Information Collection Activities Under Review

ACTION: 30-day notice of information collection under review: Nondiscrimination on the basis of disability in State and local government services (self-evaluation)

The Department of Justice, Civil Rights Division, Disability Rights Section, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The information collection extension is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on January 31, 2007, Volume 72, Number 20, Pages 4529–4530, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment. Comments are encouraged and will be accepted until May 10, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions are requested from the public and affected agencies concerning the extension of a currently approved collection of information. Your comments 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 function 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;

(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).

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget (OMB), Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the U.S. Department of Justice (DOJ), Justice Management Division, Policy and Planning Staff, Attention: Department Clearance Officer, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1534.

The information collection is listed below:

(1) *Type of information collection:* Extension of Currently Approved Collection.

(2) *The title of the form/collection:* Nondiscrimination on the Basis of Disability in State and Local Government Services (Self-Evaluation).

(3) *The agency form number and applicable component of the Department sponsoring the collection:* No form number. Disability Rights Section, Civil Rights Division, U.S. Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:* Primary: State, Local or Tribal Government. Under title II of the Americans with Disabilities Act, State and local governments are required to evaluate their current services, policies, and practices for compliance with the ADA. Under certain circumstances, such entities must also maintain the results of such self-evaluation on file for public review.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 8,000 respondents at 6 hours per self-evaluation.

(6) An estimate of the total public burden (in hours) associated with the collection: 48,000 hours annual burden.

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: April 5, 2007.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E7–6732 Filed 4–9–07; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0009]

Civil Rights Division, Disability Rights Section; Agency Information Collection Activities Under Review

ACTION: 30-day notice of information collection under review: Title II of the Americans with Disabilities Act of 1990/Section 504 of the Rehabilitation Act of 1973 Discrimination Complaint Form.

The Department of Justice, Civil Rights Division, Disability Rights Section, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The information collection extension is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on January 31, 2007, Volume 72, Number 20, Pages 4531–4532, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment. Comments are encouraged and will be accepted until May 10, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions are requested from the public and affected agencies concerning the proposed collection of information. Your comments 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 function 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;

(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).

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget (OMB), Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the U.S. Department of Justice (DOJ), Justice Management Division, Policy and Planning Staff, Attention: Department Clearance Officer, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1534.

The information collection is listed below:

(1) *Type of information collection:* Extension of Currently Approved Collection.

(2) *The title of the form/collection:* Title II of the Americans with Disabilities Act/Section 504 of the Rehabilitation Act of 1973 Discrimination Complaint Form.

(3) *The agency form number and applicable component of the Department sponsoring the collection:* No form number. Disability Rights Section, Civil Rights Division, U.S. Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:* Primary: Individuals alleging discrimination by public entities based on disability. Under title II of the Americans with Disabilities Act, an individual who believes that he or she has been subjected to discrimination on the basis of disability by a public entity may, by himself or herself or by an authorized representative, file a complaint. Any Federal agency that receives a complaint of discrimination by a public entity is required to review the complaint to determine whether it has jurisdiction under section 504. If the agency does not have jurisdiction, it must determine whether it is the designated agency responsible for complaints filed against that public entity. If the agency does not have jurisdiction under section 504 and is not the designated agency, it must refer the complaint to the Department of Justice. The Department of Justice then must refer the complaint to the appropriate agency.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 5,000 respondents per year at 0.75 hours per complaint form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,750 hours annual burden.

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: April 5, 2007.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E7–6733 Filed 4–9–07; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0005]

Civil Rights Division, Disability Rights Section; Agency Information Collection Activities Under Review

ACTION: 30-day notice of information collection under review: Title III of the Americans with Disabilities Act, certification of State and local government accessibility requirements.

The Department of Justice, Civil Rights Division, Disability Rights Section, has submitted the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The information collection extension is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on January 31, 2007, Volume 72, Number 20, Pages 4530–4531 allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment. Comments are encouraged and will be accepted until May 10, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions are requested from the public and affected agencies concerning the extension of a currently approved collection of information. Your comments 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 function 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;

(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).

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the U.S. Department of Justice (DOJ), Justice Management Division, Policy and Planning Staff, Attention: Department Clearance Officer, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1534.

The information collection is listed below:

(1) *Type of information collection:* Extension of Currently Approved Collection.

(2) *The title of the form/collection:* Title III of the Americans with Disabilities Act, Certification of State and Local Government Accessibility Requirements.

(3) *The agency form number and applicable component of the Department sponsoring the collection:* No form number. Disability Rights Section, Civil Rights Division, U.S. Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:* Primary: State, Local or Tribal Government. Under title III of the Americans with Disabilities Act, on the application of a State or local government, the Assistant Attorney General for Civil Rights (or his or her designee) may certify that a State or local building code or similar ordinance that establishes accessibility requirements (Code) meets or exceeds the minimum requirements of the ADA for accessibility and usability of ''places of public accommodation'' and ''commercial facilities.''

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 10 respondents per year at 32 hours per certification.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 320 hours annual burden.

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: April 5, 2007.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E7–6734 Filed 4–9–07; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0004]

Civil Rights Division, Disability Rights Section; Agency Information Collection Activities Under Review

ACTION: 30-day notice of information collection under review: nondiscrimination on the basis of disability in state and local government services (Transition Plan).

The Department of Justice, Civil Rights Division, Disability Rights Section, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The information collection extension is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on January 31, 2007, Volume 72, Number 20, Page 4531, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment. Comments are encouraged and will be accepted until May 10, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions are requested from the public and affected agencies concerning the extension of a currently approved collection of information. Your comments 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 function 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;

(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).

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget (OMB), Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the U.S. Department of Justice (DOJ), Justice Management Division, Policy and Planning Staff, Attention: Department Clearance Officer, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to (202) 514–1534.

The information collection is listed below:

(1) *Type of information collection:* Extension of Currently Approved Collection.

(2) *The title of the form/collection:* Nondiscrimination on the Basis of Disability in State and Local Government Services (Transition Plan).

(3) *The agency form number and applicable component of the Department sponsoring the collection:* No form number. Disability Rights Section, Civil Rights Division, U.S. Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:* Primary: State, Local or Tribal Government. Under title II of the Americans with Disabilities Act, State and local governments are required to operate each service, program, or activity so that the service, program, or activity, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities (''program accessibility''). If structural changes to existing facilities are necessary to accomplish program accessibility, a public entity that employs 50 or more persons must develop a ''transition plan'' setting forth the steps necessary to complete the structural changes. A copy of the transition plan must be made available for public inspection.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 3,000 respondents at 8 hours per transition plan.

(6) An estimate of the total public burden (in hours) associated with the collection: 24,000 hours annual burden.

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: April 5, 2007.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E7–6736 Filed 4–9–07; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *March 26 through March 30, 2007.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W–61,116; Alsons Corporation, Advance Employment, Hillsdale, MI, March 15, 2006.

TA–W–60,895; General Binding Corporation, Also Known As GBC Velobind, Velobind Plastic Division, Pleasant Prairie, WI: January 30, 2006.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

TA–W–60,990; Andersen Corporation, Menomonie Division, Menomonie, WI, February 15, 2006.

TA–W–61,002; Reddog Industries, Inc., Affiliated With Anson Mold and Manufacturing, Inc., Erie, PA, February 16, 2006.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W–60, 993; Guardian Automotive, A Subsidiary of Guardian Industries Corp., LaGrange, GA: February 14, 2006.

TA–W–61,063; General Motors Corporation, Mansfield Metal Center, Mansfield, OH: March 3, 2006.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–60,876C; Armstrong Wood Products, Inc., Armstrong Hardwood Flooring Co., Solid Strip Flooring Department, Oneida, TN, January 31, 2006.

TA–W–60,917; Kasper, Ltd., Sample and Pattern Makers, New York, NY, February 5, 2006.

TA–W–60,947; Meadows Knitting Corp., Division of Safer Textiles, Newark, NJ, February 7, 2006.

TA–W–60,948; Kuttner Prints, Inc., A Subsidiary of Safer Holding Corp., East Rutherford, NJ: February 7, 2006.

TA–W–60,994; Yoder Brothers, Inc., Pendleton, SC: February 15, 2006.

TA–W–61,056; Klaussener Furniture Industries, Inc., Klaussener of Mississippi, Bruce, MS, February 28, 2006.

TA–W–60,657; Dura Automotive Systems, Inc., Mancelona, MI, December 20, 2005.

TA–W–60,892; Fenton Art Glass Co., Williamstown, WV, September 20, 2006.

TA–W–60,903; Clarion Technologies, Inc., Ames, IA, January 30, 2006.

TA–W–60,961; Vytech Industries, Inc., Anderson, SC: February 9, 2006.

TA–W–60,984; Westby Moulding and Millwork Co. LLC, ABR Services, Westby, WI, February 7, 2006.

TA–W–61,016; Modine Manufacturing Co., Corporate Headquarters, Racine, WI: February 20, 2006.

TA–W–61,024; Menasha Packaging Company, LLC, Pittsburgh Plant, Industrial Employees, Pittsburgh, PA: February 23, 2006.

TA–W–61,058; Vishay Resistive Systems, A Subsidiary of Vishay Intertechnology, Hagerstown, MD, February 19, 2006.

TA–W–61,071; American Camshaft Specialties, Inc., A Subsidiary of Asimco Technologies, Inc., Grand Haven, MI, March 6, 2006.

TA–W–61,121; Azdel, Inc., Joint Venture of Gen Electric & PPG Industries, Shelby, NC: March 15, 2006.

TA–W–60,940; U.S. Global Flag LLC, Inc., Paterson, NJ: January 31, 2006.

TA–W–61,055; Fung Lum Sewing Co., San Francisco, CA: March 1, 2006.

TA–W–61,076; Durham Manufacturing, Fort Payne, AL: March 5, 2006.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–60,979; Bright Wood Corporation, Madras Plant, Madras, OR: February 16, 2006.

TA–W–60,979A; Bright Wood Corporation, Redmond Plant, Redmond, OR: February 16, 2006.

TA–W–61,043; Judco Manufacturing, Inc., Assembly Department and Quality Control Department, Harbor City, CA: February 27, 2006.

TA–W–61,087; Haz-Waste, Inc., Work On-Site at Continental Tire North America, Mayfield, KY: March 8, 2006.

TA–W–61,098; Indera Mills Company, Yadkinville, NC: March 12, 2006.

TA–W–61,151; Autoliv North America, Madisonville, KY: March 19, 2006.

TA–W–61,182; Ferrero U.S.A., Inc., Somerset, NJ, March 23, 2006.

TA–W–61,092; Hillerich and Bradsby Co., A Subsidiary of Louisville Slugger, Loomis, CA: March 8, 2006.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–60,373; Admiral Tool and Manufacturing Co. of Illinois, Chicago, IL: November 4, 2005.

TA–W–60,546; Phillips Diversified Manufacturing, Inc., Annville, KY: November 28, 2005.

TA–W–60,973; Collins and Aikman, Plastic Division, Oklahoma City, OK: February 13, 2006.

TA–W–61,028; Stantex, Inc., Milledgeville, GA: February 26, 2006.

TA–W–61,049; Morton Metalcraft Co., Honea Path, SC: February 28, 2006.

TA–W–61,070; Greenfield Research, Inc., Greenfield, OH: March 2, 2006.

TA–W–61,089; Commercial Vehicle Group, Interior Systems Division, Vancouver, WA: March 9, 2006.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. Workers at the firm are 50 years of age or older.

None.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

TA–W–61,116; Alsons Coproration, Advance Employment, Hillsdale, MI.

TA–W–60,895; General Binding Corporation, Also Known As GBC Velobind, Velobind Plastic Division, Pleasant Prairie, WI.

TA–W–60,990; Andersen Corporation, Menomonie Division, Menomonie, WI.

TA–W–61,002; Reddog Industries, Inc., Affiliated With Anson Mold and Manufacturing, Inc., Erie, PA.

TA–W–60,993; Guardian Automotive, A Subsidiary of Guardian Industries Corp., LaGrange, GA.

TA–W–61,063; General Motors Corporation, Mansfield Metal Center, Mansfield, OH.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–60,876; Armstrong Wood Products, Inc., Armstrong Hardwood Flooring Co., Parquet Flooring Department, Oneida, TN.

TA–W–60,963; American Greetings (Plus Mark), Afton, TN.

TA–W–61,010; Avon Automotive, Inc., Manton Plant, Manton, MI.

TA–W–61,109; Laufen International, Inc., Canton Distribution Center, Canton, OH.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–60,876A; Armstrong Wood Products, Inc., Armstrong Hardwood Flooring Co., Floor Care Products Department, Oneida, TN.

TA–W–60,876B; Armstrong Wood Products, Inc., Armstrong Hardwood Flooring Co., Pattern Plus Flooring Department, Oneida, TN.

TA–W–60,988; Collins and Aikman, Americus Division, Americus, GA.

TA–W–60,989; National Lumber #5, A Division of Silvacor, Inc., Glasgow, KY.

TA–W–60,998; Continental Industries, LLC, Benzonia, MI.

TA–W–61,139; Steward Advanced Materials, Inc., Chattanooga, TN.

TA–W–60,835; Kimberly Clark World Wide, Neenah, WI.

TA–W–60,835A; Kimberly Clark Global Sales, Rosewell, GA.

TA–W–60,835B; Kimberly Clark World Wide, Roswell, TN.

TA–W–60,835C; Kimberly Clark Global Sales, Knoxville, TN.

TA–W–60,835D; Kimberly Clark World Wide, Knoxville, TN.

TA–W–60,835E; Kimberly Clark Global Sales, Irving, TX.

TA–W–60,835F; Kimberly Clark World Wide, Irving, TX.

The investigation revealed that the predominate cause of worker separations is unrelated to criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.C) (shift in production to a foreign country under a free trade agreement or a beneficiary country under a preferential trade agreement, or there has been or is likely to be an increase in imports).

TA–W–60,879; VIA Information Tools, Inc., Troy, MI.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–60,830; GE Engine Services, Inc., A Subsidiary of GEAviation, Ontario Plant #1, Ontario, CA.

TA–W–61,129; Romar Textile Co., Inc, Wampum, PA.

TA–W–60,850; The Alan White Company, Inc., Corporate Office, Stamps, AR.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

I hereby certify that the aforementioned determinations were issued during the period of *March 26 through March 30, 2007.* Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address

Dated: April 3, 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–6658 Filed 4–9–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than April 20, 2007.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than April 20, 2007.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 3rd day of April 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 3/26/07 and 3/30/07]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
61175	Beard Hosiery Co. Inc. (Wkrs)	Lenior, NC	03/26/07	03/12/07
61176	Schoeller Arca Systems (Wkrs)	Detroit, MI	03/26/07	03/23/07
61177	Bartech (Wkrs)	Kokomo, IN	03/26/07	03/23/07
61178	Owens-Illinois (Comp)	Hayward, CA	03/26/07	03/22/07
61179	Rebtex Inc. (State)	Sommerville, NJ	03/26/07	03/23/07
61180	Weley Incorporated (Wkrs)	Blue Bell, PA	03/26/07	03/26/07
61181	Pine River Plastics, Inc. (Wkrs)	Westminister, SC	03/26/07	03/22/07
61182	Ferrero U.S.A., Inc. (Comp)	Somerset, NJ	03/26/07	03/23/07
61183	Duro Textiles LLC (State)	Fall River, MA	03/26/07	03/26/07
61184	Diversified Precision Products (Comp)	Spring Arbor, MI	03/27/07	03/21/07
61185	Loparex Inc. (Union)	Dixon, IL	03/27/07	03/13/07
61186	New London Textile (Comp)	Newark, DE	03/27/07	03/20/07
61187	PointCare Corporation (Wkrs)	San Jose, CA	03/27/07	03/16/07
61188	Merrill Lynch (State)	New York, NY	03/27/07	03/23/07
61189	Analog Devices Incorporated (Wkrs)	Sunnyvale, CA	03/27/07	03/22/07
61190	Entronix (State)	Rogers, MN	03/27/07	03/23/07
61191	Collins & Aikman Products Co (27573)	Roxboro, NC	03/27/07	03/23/07
61192	Arrow Electronics Inc. (State)	Shawnee Mission, KS	03/27/07	03/23/07
61193	Administaff formerly named Star Products (State)	Monroe, LA	03/27/07	03/23/07
61194	Triana Industries, Inc. (Comp)	Madison, AL	03/27/07	03/26/77
61195	Eaton Corporation (Comp)	Laurinburg, NC	03/27/07	03/20/07
61196	Avx Corporation (Comp)	Raleigh, NC	03/27/07	03/26/07
61197	Ferguson Enterprises c/o Freightline (State)	Portland, OR	03/27/07	03/26/07
61198	L.A. Darling Company (Comp)	Sun Prairie, WI	03/27/07	03/26/07
61199	Emerson Network Power (Comp)	Lorain, OH	03/28/07	03/26/07
61200	Neff-Perkins Company (Union)	Perry, OH	03/28/07	03/09/07
61201	Photronics, Inc. (Comp)	Brookfield, CT	03/28/07	03/23/07
61202	Glenoit LLC/Excell Home Fashion, Inc. (Comp)	Goldsboro, NC	03/28/07	03/27/07
61203	Calgon Carbon Corporation (Wkrs)	Columbus, OH	03/28/07	03/27/07
61204	Gildan Activewear Malone, Inc. (Comp)	Bombay, NY	03/28/07	03/27/07
61205	Collins and Aikman (UAW)	Sterling Hghts, MI	03/28/07	03/27/07
61206	The Hershey Company (State)	Hershey, PA	03/28/07	03/27/07
61207	Gorecki Mfg. (State)	Millaca, MN	03/29/07	03/28/07
61208	GKN Sinter Metals, Inc. (Comp)	Worcester, MA	03/29/07	03/27/07
61209	Reum Corporation (Wkrs)	Waukegan, IL	03/29/07	03/28/07
61210	Carlsen Wood Products Inc. (Comp)	Sinclairville, NY	03/29/07	03/22/07
61211	Dundee Manufacturing Co., Inc. (Comp)	Dundee, MI	03/29/07	03/28/07

APPENDIX—Continued

[TAA petitions instituted between 3/26/07 and 3/30/07]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
61212	MPA Motorcar Parts of America (State)	Torrance, CA	03/29/07	03/27/07
61213	Stark Ceramics Inc. (Wkrs)	East Canton, OH	03/30/07	03/21/07
61214	Link Technologies, LLC (Comp)	Brown City, MI	03/30/07	03/27/07
61215	Tool Dex Inc. (Wkrs)	Warren, MI	03/30/07	03/29/07
61216	Broyhill Pacemaker Furniture & Power Plant (Comp)	Lenior, NC	03/30/07	03/29/07
61217	Douglas Quikut (stamping dept) (State)	Walnut Ridge, AR	03/30/07	03/29/07
61218	Hanesbrands, Inc. (Comp)	Winston-Salem, NC	03/30/07	03/29/07
61219	Collins & Aikman-Automotive Technology Center (Other)	Dover, NH	03/30/07	03/28/07
61220	Silberline Mfg. Company Inc. (Comp)	Decatur, IN	03/30/07	03/28/07

[FR Doc. E7–6657 Filed 4–9–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,884]

C.A. Lawton Company, Machinery Division; De Pere, WI; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at C.A. Lawton Company, Machinery Division, De Pere, Wisconsin. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–60,884; C.A. Lawton Company, Machinery Division, De Pere, Wisconsin, (April 2, 2007)

Signed at Washington, DC this 3rd day of April 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–6660 Filed 4–9–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,197]

Ferguson Enterprises; Portland, OR; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on March 27, 2007 in response to a worker petition filed by a state agency on behalf of workers at Ferguson Enterprises, Portland, Oregon.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 3rd day of April, 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–6656 Filed 4–9–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–57,802; TA–W–57,802A; TA–W–57,802B; TA–W–57,802C; TA–W–57,802D]

Sara Lee Branded Apparel; Division Office, Formerly Known as National Textiles, Currently Known as Hanesbrands, Inc., Winston-Salem, NC; Including Employees of Sara Lee Branded Apparel, Division Office, Formerly Known as National Textiles, Currently Known as Hanesbrands, Inc., Winston-Salem, NC Located in Bristol, CT; Norwalk, CT; Madison, CT; New Canaan, CT; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Negative Determination Regarding Eligibility To Apply for Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and a Negative Determination Regarding Eligibility to Apply for Alternative Trade Adjustment Assistance on September 28, 2005, applicable to workers of Sara Lee Branded Apparel, Division Office, Winston-Salem, North Carolina. The notice was published in the **Federal Register** on October 31, 2005 (70 FR 62347).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers at the Division Office, Winston-Salem, North Carolina location were engaged in activities related to the production of underwear (shorts and T-shirts). New information shows that Sara Lee Branded Apparel was formerly known as National Textiles and is currently known as Hanesbrands, Inc.

Workers separated from employment at the subject firm had their wages reported under a separated unemployment (UI) tax account for Sara Lee Branded Apparel, Division Office, formerly known as National Textiles, currently known as Hanesbrands, Inc.

Accordingly, the Department is amending the certification to correctly identify the subject firm name in its entirety.

The intent of the Department's certification is to include all workers of Sara Lee Branded Apparel, Division Office, Winston-Salem, North Carolina who were adversely affected by increased imports.

The amended notice applicable to TA–W–57,802 is hereby issued as follows:

All workers of Sara Lee Branded Apparel, Division Office, formerly known as National Textiles, currently known as Hanesbrands, Inc., Winston-Salem, North Carolina (TA–W–57,802), and including employees of Sara Lee Branded Apparel, Division Office, formerly known as National Textiles, currently known as Hanesbrands, Winston-Salem, North Carolina, located in Bristol, Connecticut (TA–W–57,802A), Norwalk, Connecticut (TA–W–57,802B), Madison, Connecticut (TA–W–57,802C) and New Canaan, Connecticut (TA–W–57,802D), who became totally or partially separated from employment on or after July 29, 2004, through September 28, 2007, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

I further determine that all workers of Sara Lee Branded Apparel, Division of the Sara Lee Corporation, Winston-Salem, North Carolina, are denied eligibility to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 2nd day of April 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–6659 Filed 4–9–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Announcement of Public Briefings on the H–2B Temporary Non-Agricultural Worker Labor Certification Program

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Employment and Training Administration (ETA) of the Department of Labor (Department) is issuing this notice to announce the Department will offer two public briefings to educate the public on filing procedures and standards of review for employer applications for labor certification under the H–2B Temporary Non-Agricultural Worker Labor Certification Program. The two briefings will take place the first week in May 2007—one in Chicago, a second in Atlanta. This notice provides the public with locations, dates, and registration information regarding these briefings.

DATES: The Department will hold a public meeting in Chicago, Illinois, on Tuesday, May 1, 2007, and one in Atlanta, Georgia, on Friday, May 4, 2007.

FOR FURTHER INFORMATION CONTACT: William L. Carlson, Administrator, Office of Foreign Labor Certification, Employment and Training Administration, 200 Constitution Avenue, NW., Room C–4312, Washington, DC 20210; Telephone: (202) 693–3010 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In July 2005, Federal processing activities for the H–2A and H–2B temporary labor certification programs were transferred from ETA Regional Offices to ETA National Processing Centers (NPC) in Atlanta and Chicago. The briefings planned for May 2007 follow a national training session convened for State Workforce Agencies in November 2006, and are part of ETA's ongoing effort to assist program partners and program users in understanding H–2B filing procedures, application requirements, and NPC standards of review. These sessions will reinforce information previously provided as well as new guidance, and respond to questions from stakeholders on issues of general interest. The sessions will not address specialized non-agricultural occupations—including boilermakers, entertainers, logging or other forestry occupations, or professional team sports—all of which require special procedures and will be covered in guidance being issued separately by ETA. The following registration information should be used by any member of the public to attend an H–2B briefing session.

Chicago, Illinois

Date: Tuesday, May 1, 2007.
Time: 9 a.m.–1 p.m.
Location: Chicago Marriott Downtown, 540 North Michigan Avenue, Chicago, IL 60611.

Atlanta, Georgia

Date: Friday, May 4, 2007.
Time: 9 a.m.–1 p.m.
Location: Atlanta Hilton Downtown, 255 Courtland Street NE., Atlanta, GA 30303.

To Register: To register for one of the H–2B briefings listed above, please use the following information. To complete the registration process online, please visit *http://www.dtiassociates.com/H2Bstakeholdersmeeting*. For questions regarding the registration process, please call (703) 299–1618.

Signed in Washington, DC, this 4th day of April, 2007.

Emily Stover DeRocco,

Assistant Secretary, Employment and Training Administration.

[FR Doc. E7–6694 Filed 4–9–07; 8:45 am]

BILLING CODE 4510–FP–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before May 10, 2007 (Note that the new time period for requesting copies has changed from 45 to 30 days after publication). Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These,

too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting the Life Cycle Management Division (NWML) using one of the following means:

Mail: NARA (NWML), 8601 Adelphi Road, College Park, MD 20740–6001.

E-mail: requestschedule@nara.gov.

FAX: 301–837–3698.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Laurence Brewer, Director, Life Cycle Management Division (NWML), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: 301–837–1539. E-mail: *records.mgt@nara.gov.*

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending (Note that the new time period for requesting copies has changed from 45 to 30 days after publication):

1. Department of Agriculture, Rural Development (N1–572–06–1, 3 items, 3 temporary items). Inputs, outputs, and documentation relating to an electronic system that manages and oversees loans, grants, and rental subsidies for a multi-family housing program for the low-income, elderly, or disabled rural population.

2. Department of the Army, Agency-wide (N1–AU–07–11, 1 item, 1 temporary item). Records relating to training media files accumulated at divisions, installations, and lower level echelon activities. Included are training schedules, programs, lesson plans, memorandums, directives, and similar information. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

3. Department of the Army, Agency-wide (N1–AU–07–12, 3 items, 3 temporary items). Records relating to Army storage and supply activity operations. Included are supply item references and warehouse and open storage space planning files to include control sheets, location sheets, layout plans, diagrams, and cross reference aids. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

4. Department of the Army, Agency-wide (N1–AU–07–13, 2 items, 2 temporary items). Records relating to Corps of Engineers Civil Works projects evaluations and reviews. Included are summaries of board actions, statements of decisions, monthly status reports on preliminary examinations, survey reports, and work plans. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

5. Department of Defense, Defense Information Systems Agency (N1–371–02–7, 24 items, 20 temporary items). Records accumulated by the Ada Joint Programming Office related to the development of Ada, DOD's first embedded computer programming language. Included are agency reports, software development files, educational and training materials, and correspondence related to the language's development. Proposed for permanent retention are standardization/language control files, agency publications and reports, and memoranda of agreements and understanding with foreign governments.

6. Department of Defense, Defense Security Service (N1–446–06–1, 6 items, 5 temporary items). Security training and education records relating to program management, registration requirements, and copies of curriculum development master copies. Included are correspondence files; requirement reviews; evaluation reports; financial transaction records; memoranda agreements; and records relating to a participant's profile, including enrollment, training, course, and special access histories. Proposed for permanent retention are master copies of course content, including curriculum requirements, presentations, and examinations.

7. Department of Defense, Joint Staff (N1–218–06–1, 4 items, 4 temporary items). Records tracking and controlling top secret classified documents. Included are such records as receipts, unclassified electronic data, reports and annual snapshots.

8. Department of Homeland Security, U.S. Coast Guard (N1–26–07–1, 1 item, 1 temporary item). Case files accumulated by coordinators within the Family Support Program who counsel Coast Guard members and their families. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

9. Department of Homeland Security, U S. Coast Guard (N1–26–07–2, 4 items, 4 temporary items). Records maintained by Office of Boat Forces relating to equipment maintenance procedures and personal protective clothing issued to and returned by members.

10. Department of Housing and Urban Development, Agency-wide (N1–207–06–5, 15 items, 6 temporary items). Routine still photographs and video recordings and associated finding aids in analog or digital format. Proposed for permanent retention are digital and analog photographs and video

recordings of core mission related activities and principal figures of the Department and associated finding aids.

11. Environmental Protection Agency, (N1–412–07–4, 3 items, 3 temporary items). This schedule authorizes the agency to apply the existing disposition instructions to several record series regardless of recordkeeping medium. The records include National Contingency Plan product files, spill prevention control and countermeasure facility plans, and oil removal contingency plans. Paper recordkeeping copies of these files were previously approved for disposal.

12. Environmental Protection Agency, Agency-wide (N1–412–07–6, 2 items, 1 temporary item). This schedule authorizes the agency to apply the existing disposition instructions to record series regardless of recordkeeping medium. The records include Resource Conservation and Recovery Act permit files for hazardous waste generators, transporters and treatment, storage and disposal facilities, as well as facilities that comply with regulations without following the usual permitting process. Paper recordkeeping copies of these files were previously approved for disposal. Also included are Resource Conservation and Recovery Act hazardous waste land disposal permit files, for which paper recordkeeping copies previously were approved as permanent.

Dated: April 4, 2007.

Michael J. Kurtz,

Assistant Archivist for Records Services—Washington, DC.

[FR Doc. E7–6697 Filed 4–9–07; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Sunshine Act Meeting

TIME AND DATE: 10 a.m., Thursday, April 12, 2007.

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. *Proposed Rule:* Part 708b of NCUA's Rules and Regulations, Disclosure of Merger Related Compensation.
3. *Proposed Rule:* Section 701.3 of NCUA's Rules and Regulations, Member Inspection of Credit Union Books, Records, and Minutes.

RECESS: 11:15 a.m.

TIME AND DATE: 11:30 a.m., Thursday, April 12, 2007.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. One (1) Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to Exemptions (8), (9)(A)(ii), and (B).
2. Part 703 of NCUA's Rules and Regulations, Pilot Program Request. Closed pursuant to Exemptions (4) and (8).
3. One (1) Personnel Matter. Closed pursuant to Exemptions (2) and (6).

FOR FURTHER INFORMATION CONTACT: Mary Rupp, Secretary of the Board, Telephone: 703–518–6304.

Mary Rupp,

Secretary of the Board.

[FR Doc. 07–1774 Filed 4–5–07; 4:07 pm]

BILLING CODE 7535–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–1]

General Electric Company; Morris Operation, Independent Spent Fuel Storage Installation; Notice of Consideration of Approval of Transfer of Special Nuclear Material License and Conforming Amendment and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering the issuance of an order under 10 CFR 72.50 approving the direct transfer of the Special Nuclear Material License No. SNM–2500 for the Morris Operation, Independent Spent Fuel Storage Installation (ISFSI) currently held by General Electric Company, as owner and licensed operator. The facility is located in Grundy County, Illinois, near Morris, Illinois. The transfer would be to GE-Hitachi Nuclear Energy Americas, LLC. The Commission is also considering amending the license for administrative purposes to reflect the proposed transfer.

According to an application for approval filed by General Electric Company, GE-Hitachi Nuclear Energy Americas, LLC, a newly formed entity, would acquire ownership of the facility following approval of the proposed license transfer, and would be responsible for the operation and maintenance of the Morris Operation, ISFSI. This new entity will be wholly owned by GE-Hitachi Nuclear Energy Holdings, LLC, created as a parent company. A U.S. subsidiary or subsidiaries of Hitachi Ltd., a Japanese company will hold a 40% ownership interest. General Electric, through various subsidiaries, will hold a 60% ownership interest.

No physical changes to the Morris Operation, ISFSI facility or operational changes are being proposed in the application.

The proposed amendment would replace references to General Electric Company in the license with references to GE-Hitachi Nuclear Energy Americas, LLC, to reflect the proposed transfer.

Pursuant to 10 CFR 72.50, no license, or any part included in a license issued under this part for an ISFSI, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. The Commission will approve an application for the transfer of a license, if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of an ISFSI which does no more than conform the license to reflect the transfer action involves no genuine issue as to whether the health and safety of the public will be significantly affected. No contrary determination has been made with respect to this specific license amendment application.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person whose interest may be affected by the Commission's action on the application may request a hearing and, if not the applicant, may petition for leave to intervene in a hearing proceeding on the Commission's action. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C ''Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of

Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings,'' of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)–(viii).

Requests for a hearing and petitions for leave to intervene should be served upon Mr. Donald J. Silverman, Morgan Lewis & Bockius, LLP, 1111 Pennsylvania Avenue, NW., Washington, DC 20004 (*tel:* 202–739–5502; *fax:* 202–739–3001; *e-mail: dsilverman@morganlewis.com*); the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 (e-mail address for filings regarding license transfer cases only: *OGCLT@NRC.gov*); and the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *Attention:* Rulemakings and Adjudications Staff, in accordance with 10 CFR 2.302 and 2.305.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

As an alternative to requests for hearing and petitions to intervene, within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this action, see the application dated January 19, 2007, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737 or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland this 20th day of March, 2007.

For the Nuclear Regulatory Commission.

Robert A. Nelson,

Chief, Licensing Branch, Licensing and Inspection Directorate, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E7–6742 Filed 4–9–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Sunshine Act Meeting

DATE: Weeks of April 9, 16, 23, 30, May 7, 14, 2007.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of April 9, 2007

There are no meetings scheduled for the Week of April 9, 2007.

Week of April 16, 2007—Tentative

Monday, April 16, 2007

1:30 p.m. Discussion of Security Issues (Closed-Ex. 1, 2, & 3).

Tuesday, April 17, 2007

9 a.m. Briefing on New Reactor Issues—Environmental Issues (Public Meeting) (Contact: James Lyons, 301 415–3050).

This meeting will be webcast live at the Web address, *http://www.nrc.gov.*

12:55 p.m. Affirmation Session (Public Meeting) (Tentative) a. Entergy Nuclear Vermont Yankee, LLC, and Entergy Nuclear Operations, Inc. (Vermont Yankee Nuclear Power Station) Docket No. 50–271–LR, LBP–06–20, 64 NRC 131, 175–82 (2006) (Tentative).

1 p.m. Briefing on Office of Nuclear Regulatory Research (RES) Programs, Performance, and Plans (Public Meeting) (Contact: Ann Ramey-Smith, 301 415–6877).

This meeting will be webcast live at the Web address, *http://www.nrc.gov.*

Week of April 23, 2007—Tentative

There are no meetings scheduled for the Week of April 23, 2007.

Week of April 30, 2007—Tentative

There are no meetings scheduled for the Week of April 30, 2007.

Week of May 7, 2007—Tentative

Monday, May 7, 2007

1:30 p.m. Briefing on Office of Federal and State Materials and Environmental Management Programs (FSME) Programs, Performance, and Plans (Public Meeting).

This meeting will be webcast live at the Web address, *http://www.nrc.gov.*

Week of May 14, 2007—Tentative

There are no meetings scheduled for the Week of May 14, 2007.

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*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, Deborah Chan, at 301–415–7041, TDD: 301–415–2100, or by e-mail at *DLC@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 5, 2007.

Rochelle C. Bavol,

Office of the Secretary.

[FR Doc. 07–1795 Filed 4–6–07; 11:49 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from March 16, 2007 to March 29, 2007. The last biweekly notice was published on March 27, 2007 (72 FR 14303).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of

which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HearingDocket@nrc.gov*; or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to (301) 415–3725 or by e-mail to *OGCMailCenter@nrc.gov*. A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov*.

AmerGen Energy Company, LLC, Docket No. 50–461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of amendment request: November 13, 2006.

Description of amendment request: The proposed amendment changes the technical specification (TS) testing frequency for the surveillance requirement (SR) in TS 3.1.4, ''Control Rod Scram Times.'' The proposed change revises the test frequency of SR 3.1.4.2, control rod scram time testing, from ''120 days cumulative operation in MODE 1'' to ''200 days cumulative operation in Mode 1.''

AmerGen has reviewed the proposed no significant hazards consideration determination published in the **Federal Register** on August 23, 2004 (69 FR 51864), as part of the consolidated line item improvement process (CLIIP) and has concluded that the proposed determination presented in the notice is applicable to Clinton Power Station, Unit No. 1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below.

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change extends the frequency for testing control rod scram time testing from every 120 days of cumulative Mode 1 operation to 200 days of cumulative Mode 1 operation. The frequency of surveillance testing is not an initiator of any accident previously evaluated. The frequency of surveillance testing does not affect the ability to mitigate any accident previously evaluated, as the tested component is still required to be operable. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change extends the frequency for testing control rod scram time testing from every 120 days of cumulative Mode 1 operation to 200 days of cumulative Mode 1 operation. The proposed change does not result in any new or different modes of plant operation. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change extends the frequency for testing control rod scram time testing from every 120 days of cumulative Mode 1 operation to 200 days of cumulative Mode 1 operation. The proposed change continues to test the control rod scram time to ensure the assumptions in the safety analysis are protected. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, the proposed change presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and accordingly, a finding of ''no significant hazards consideration'' is justified.

Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. Bradley J. Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Russell Gibbs.

Detroit Edison Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: January 26, 2007.

Description of amendment request: The proposed amendment would revise technical specifications (TS) requirements for unavailable barriers by

adding limiting condition for operation (LCO) 3.0.9. This would establish conditions under which TS systems would remain operable when required physical barriers are not capable of providing their related support function. Also, the proposed amendment would make editorial changes to LCO 3.0.8 to be consistent with the terminology in LCO 3.0.9.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration by a reference to a generic analysis published in the **Federal Register** on October 3, 2006 (71 FR 58444), which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

The proposed change allows a delay time for entering a supported system technical specification (TS) when the inoperability is due solely to an unavailable barrier if risk is assessed and managed. The postulated initiating events which may require a functional barrier are limited to those with low frequencies of occurrence, and the overall TS system safety function would still be available for the majority of anticipated challenges. Therefore, the probability of an accident previously evaluated is not significantly increased, if at all. The consequences of an accident while relying on the allowance provided by proposed LCO 3.0.9 are no different than the consequences of an accident while relying on the TS required actions in effect without the allowance provided by proposed LCO 3.0.9. Therefore, the consequences of an accident previously evaluated are not significantly affected by this change. The addition of a requirement to assess and manage the risk introduced by this change will further minimize possible concerns.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed). Allowing delay times for entering supported system TS when inoperability is due solely to an unavailable barrier, if risk is assessed and managed, will not introduce new failure modes or effects and will not, in the absence of other unrelated failures, lead to an accident whose consequences exceed the consequences of accidents previously evaluated. The addition of a requirement to assess and manage the risk introduced by this change will further minimize possible concerns. Thus, this change does not create the possibility of a new or different kind of accident from an accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change allows a delay time for entering a supported system TS when the inoperability is due solely to an unavailable barrier, if risk is assessed and managed. The postulated initiating events which may require a functional barrier are limited to those with low frequencies of occurrence, and the overall TS system safety function would still be available for the majority of anticipated challenges. The risk impact of the proposed TS changes was assessed following the three-tiered approach recommended in RG 1.177. A bounding risk assessment was performed to justify the proposed TS changes. This application of LCO 3.0.9 is predicated upon the licensee's performance of a risk assessment and the management of plant risk. The net change to the margin of safety is insignificant as indicated by the anticipated low levels of associated risk (ICCDP and ICLERP) as shown in Table 1 of Section 3.1.1 in the Safety Evaluation.

Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David G. Pettinari, Legal Department, 688 WCB, Detroit Edison Company, 2000 2nd Avenue, Detroit, Michigan 48226–1279.

NRC Branch Chief: L. Raghavan.

Entergy Nuclear Operations, Inc., Docket No. 50–286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of amendment request: January 18, 2007.

Description of amendment request: The proposed amendment would revise the expiration limit for the reactor coolant system Pressure/Temperature (P/T) limit graphs in Technical Specifications (TS); revise the adjusted reference temperature for the reactor vessel; and revise the Low Temperature Overpressure Protection (LTOP) arming temperature value specified in TSs. It would also make editorial changes in the use of inequality signs in TSs associated with the LTOP arming temperature in order to make them consistent.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No

The proposed change does not affect the accident initiators or mitigation assumptions associated with any of the accidents previously evaluated. Operating restrictions on pressure-temperature conditions for the reactor pressure vessel provide assurance that reactor vessel integrity will be maintained under accident or transient conditions. The proposed change uses approved criteria and analysis methods to update the time period for which the current operating limits remain valid.

The LTOP system performs an automatic function by opening relief valves if reactor coolant system pressure reaches a temperature-dependent limit. The proposed change includes establishing a more restrictive temperature limit for when this system must be in service, to reflect the material condition of the reactor vessel at the new EFPY limit proposed for the pressure-temperature graphs. The mitigation function and capability of the LTOP system is not being changed by this request.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No

There are no new accident initiators being introduced by this proposed change. The proposed change does not involve installation of new plant equipment, modification of existing equipment, or changes in the way that plant equipment is operated. Pressure-temperature operating limits depicted by graphs in the technical specifications will not be changed and will continue to be used by plant operators. A change in the LTOP system arming temperature will assure that the graphs remain valid for the proposed new operating period of 27.2 EFPY [effective full power years].

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No

Operating limits on pressure and temperature conditions for the reactor coolant system (RCS) are important to assure that the RCS pressure boundary stresses are within analyzed limits. Margins of safety are inherent in the analysis methods, assumptions, and limits specified in regulations and guidance documents. The proposed change is based on NRC-accepted methods, assumptions and limits and maintains the required margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this

review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

NRC Acting Branch Chief: Douglas V. Pickett.

Entergy Nuclear Operations, Inc., Docket Nos. 50–247 and 50–286, Indian Point Nuclear Generating Unit Nos. 2 (IP2) and 3 (IP3), Westchester County, New York

Date of amendment request: March 13, 2007.

Description of amendment request: The amendment would revise License Condition 2.K for IP2 and License Condition 2.H for IP3, which require the implementation and maintenance of an approved Fire Protection Program for each unit.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No

The proposed changes are strictly an administrative relocation of the specific fire protection SER [safety evaluation report] references and do not modify any requirements of the fire protection programs.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes are strictly an administrative relocation of the specific fire protection SER references and do not modify any requirements of the fire protection programs.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes are strictly an administrative relocation of the specific fire protection SER references and do not modify any requirements of the fire protection programs.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

NRC Acting Branch Chief: Douglas V. Pickett.

Entergy Nuclear Operations, Inc., Docket No. 50–247, Indian Point Nuclear Generating Unit No. 2, Westchester County, New York

Date of amendment request: March 22, 2007.

Description of amendment request: The proposed amendment will revise the test acceptance criteria specified in Technical Specification Surveillance Requirement (SR) 3.8.1.10 for the diesel generator endurance test.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed change revises the acceptance criteria to be applied to an existing surveillance test of the facility emergency diesel generators (DGs). Performing a surveillance test is not an accident initiator and does not increase the probability of an accident occurring. The proposed new acceptance criteria will assure that the DGs are capable of carrying the peak electrical loading assumed in the various existing safety analyses which take credit for the operation of the DGs. Establishing acceptance criteria that bound existing analyses validates the related assumption used in those analyses regarding the capability of equipment to mitigate accident conditions. Therefore the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed change revises the test acceptance criteria for a specific performance test conducted on the existing DGs. The proposed change does not involve installation of new equipment or modification of existing equipment, so no new equipment failure modes are introduced. The proposed revision to the DG surveillance test acceptance criteria also is not a change to the way that the equipment or facility is operated and no new accident initiators are created. Therefore the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. The conduct of performance tests on safety-related plant equipment is a means of assuring that the equipment is capable of maintaining the margin of safety established in the safety analyses for the facility. The proposed change in the DG technical specification surveillance test acceptance criteria is consistent with values assumed in existing safety analyses and is consistent with the design rating of the DGs. Therefore the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

NRC Acting Branch Chief: Douglas V. Pickett.

Entergy Nuclear Operations, Inc., Docket No. 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of amendment request: February 15, 2007.

Description of amendment request: The proposed changes would revise Technical Specification (TS) 3.10.1 to expand its scope to include provisions for reactor coolant temperature excursions greater than 212 °F as a consequence of inservice leak and hydrostatic testing, and as a consequence of scram time testing initiated in conjunction with an inservice leak or hydrostatic test, while considering operational conditions to be in Mode 4, which is defined to be reactor coolant temperature less than or equal to 212 °F.

This change was proposed by the industry's TS Task Force (TSTF) and is designated TSTF–484. The NRC staff issued a notice of opportunity for comment in the **Federal Register** on August 21, 2006 (71 FR 48561), on possible amendments concerning TSTF–484, including a model safety evaluation and model no significant hazards (NSHC) determination, using the consolidated line item improvement process (CLIIP). The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on October 27,

2006 (71 FR 63050). The licensee affirmed the applicability of the following NSHC determination in its application dated February 15, 2007.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

Criterion 1: The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Technical Specifications currently allow for operation at greater than 212 °F while imposing MODE 4 requirements in addition to the secondary containment requirements required to be met. Extending the activities that can apply this allowance will not adversely impact the probability or consequences of an accident previously evaluated. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2: The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Technical Specifications currently allow for operation at greater than 212 °F while imposing MODE 4 requirements in addition to the secondary containment requirements required to be met. No new operational conditions beyond those currently allowed by LCO 3.10.1 are introduced. The changes do not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not impose any new or different requirements or eliminate any existing requirements. The changes do not alter assumptions made in the safety analysis. The proposed changes are consistent with the safety analysis assumptions and current plant operating practice. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3: The proposed change does not involve a significant reduction in a margin of safety.

Technical Specifications currently allow for operation at greater than 212 °F while imposing MODE 4 requirements in addition to the secondary containment requirements required to be met. Extending the activities that can apply this allowance will not adversely impact any margin of safety. Allowing completion of inspections and testing and supporting completion of scram time testing initiated in conjunction with an inservice leak or hydrostatic test prior to power operation results in enhanced safe operations by eliminating unnecessary maneuvers to control reactor temperature and pressure. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, the NRC staff concludes that the proposed change presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of no significant hazards consideration is justified.

Attorney for licensee: Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

NRC Acting Branch Chief: Douglas V. Pickett.

Exelon Generation Company, LLC (EGC), Docket Nos. 50–373 and 50–374, LaSalle County Station (LSCS), Units 1 and 2, LaSalle County, Illinois

Date of amendment request: November 17, 2006.

Description of amendment request: The proposed amendments would replace references to Section XI of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code) with a reference to the ASME Code of Operation and Maintenance of Nuclear Power Plants (OM Code) in Technical Specification (TS) 5.5.7, ''Inservice Testing Program [IST].'' These proposed changes are consistent with the implementation of the LSCS, Units 1 and 2 third 10-year IST program in accordance with the requirements of Title 10 of the Code of Federal Regulations (10 CFR) Section 50.55a, ''Codes and standards,'' paragraph (f), ''Inservice testing requirements.'' The third 10-year interval for LSCS, Units 1 and 2 is scheduled to start on October 12, 2007.

In addition to the replacement of the references, EGC is also adding provisions in TS 5.5.7, item b, to only apply Surveillance Requirement (SR) 3.0.2 to those inservice testing frequencies of two years or less. These proposed changes are based on TS Task Force (TSTF) Traveler No. 479–A (TSTF–479–A), Revision 0, ''Changes to Reflect Revision of 10 CFR 50.55a,'' as modified by TSTF–497, Revision 0, ''Limit Inservice Testing Program SR 3.0.2 Application to Frequencies of 2 Years or Less'' and approved by the NRC in December 6, 2005, and October 4, 2006.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes revise TS 5.5.7 for LSCS Units 1 and 2 to conform to the requirements of 10 CFR 50.55a, ''Codes and standards,'' paragraph (f) regarding the inservice testing of pumps and calves for the Third 10-year Interval. The current TS reference the [American Society of Mechanical Engineers] ASME Boiler and Pressure Vessel Code, Section XI, requirements for the inservice testing of ASME Code Class 1, 2, and 3 pumps and valves. The proposed changes would reference the ASME OM Code, which is consistent with 10 CFR 50.55a, paragraph (f), ''Inservice testing requirements,'' and approved for use by the NRC. In addition, provisions modifying TS 5.5.7, item b, clarify that SR 3.0.2 is only applied to those inservice testing frequencies of two years or less. The definitions of the frequencies are not changed by this license amendment request.

The proposed changes are administrative in nature, do not affect any accident initiators, do not affect the ability of LSCS to successfully respond to previously evaluated accidents and do not affect radiological assumptions used in the evaluations. Thus, the radiological consequences of any accident previously evaluated are not increased.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes revise TS 5.5.7 for LSCS Units 1 and 2 to conform to the requirements of 10 CFR 50.55a(f) regarding the inservice testing of pumps and valves for the Third 10-year Interval. The current TS reference the ASME Boiler and Pressure Vessel Code, Section XI, requirements for the inservice testing of ASME Code Class 1, 2, and 3 pumps and valves. The proposed changes would reference the ASME OM Code, which is consistent with the 10 CFR 50.55a(f) and approved for use by the NRC. In addition, provisions modifying TS 5.5.7, item b, clarify that SR 3.0.2 is only applied to those inservice testing frequencies of two years or less. The definitions of the frequencies are not changed by this license amendment request.

The proposed changes to TS Section 5.5.7 do not affect the performance of any LSCS structure, system, or component credited with mitigating any accident previously evaluated and do not introduce any new modes of system operation or failure mechanisms.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes revise TS 5.5.7 for LSCS Units 1 and 2 to conform to the requirements of 10 CFR 50.55a(f) regarding the inservice testing of pumps and valves for the Third 10-Year Interval. The current TS reference the ASME Boiler and Pressure Vessel Code, Section XI, requirements for the inservice testing of ASME Code Class 1, 2,

and 3 pumps and valves. The proposed changes would reference the ASME OM Code, which is consistent with the 10 CFR 50.55a(f) and approved for use by the NRC. In addition, provisions modifying TS 5.5.7, item b, clarify that SR 3.0.2 is only applied to those inservice testing frequencies of two years or less. The definitions of the frequencies are not changed by this license amendment request.

The proposed changes do not modify the safety limits setpoints at which protective actions are initiated and do not change the requirements governing operation or availability of safety equipment assumed to operate to preserve the margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Bradley J. Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Russell Gibbs.

Exelon Generation Company, LLC, Docket Nos. 50–352 and 50–353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of amendment request: June 2, 2006.

Description of amendment request: The proposed amendments incorporates revised 10 CFR Part 20 requirements for Limerick Generating Station Units 1 and 2 technical specifications (TSs).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

Updating the Technical Specifications (TS) to be consistent with 10 CFR Part 20 has no impact on plant structures, systems, or components, does not affect any accident initiators, and does not change any safety analysis. Therefore, the proposed changes do not involve an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Updating the TS to be consistent with 10 CFR Part 20 will not change any equipment, require new equipment to be installed, or change the way current equipment operates. No credible new failure mechanisms, malfunctions, or accident initiators are created by the proposed changes.

Therefore, the changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Updating the TS to be consistent with 10 CFR Part 20 does not adversely affect existing plant safety margins or the reliability of equipment assumed to operate in the safety analysis. As such, there are no changes being made to safety analysis assumptions, safety limits or limiting safety system settings that would adversely affect plant safety as a result of the proposed changes. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. Brad Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Harold K. Chernoff.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: February 12, 2007.

Description of amendment request: The proposed license amendment would revise Technical Specification (TS) Limiting Condition for Operation 3.9.4, ''Containment Penetrations'', to allow penetrations included under TS 3.9.4(c) to be opened during core alterations or movement of irradiated fuel, under administrative controls. This change is based on the TS Task Force Traveler No. 312–A, Revision 1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change would allow containment penetrations identified under Technical Specification 3.9.4(c) to remain open during fuel movement and core alterations. These penetrations are normally closed during this time period to prevent the release of radioactive material in the event of a Fuel Handling Accident inside containment. These penetrations are not initiators of any accident. The probability of a Fuel Handling Accident is unaffected by the status of these penetrations.

The Fuel Handling Accident analyses demonstrate that the maximum offsite dose is well [within] the acceptance limits specified in SRP [Standard Review Plan] 15.7.4, and the control room dose is within the acceptance criteria specified in GDC [General Design Criterion] 19. Furthermore, the existing analysis results are independent of the containment release path, and therefore are unaffected by the proposed change.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve the addition or modification of any plant equipment. Also, the proposed change will not alter the design, configuration, or method of operation of the plant beyond the standard functional capabilities of the equipment. The proposed change involves a Technical Specification change that will allow containment penetrations identified under Technical Specification 3.9.4(c) to remain open during fuel movement and core alterations. Open penetrations are not accident initiators, and will not create the possibility of a new kind of accident. Administrative controls will be implemented to ensure the capability to close the affected containment penetrations in the event of a Fuel Handling Accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change has the potential to slightly increase the post-Fuel Handling Accident dose at the site boundary and in the control room. However, the existing analyses take no credit for containment of the release, so that the existing analysis results will remain bounding.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Attorney, FirstEnergy Corporation, Mail Stop A–GO–18, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: Russell Gibbs.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: January 19, 2007.

Description of amendment request: The proposed amendment would modify Technical Specification (TS) 5.5.9, ''Diesel Fuel Oil Testing Program,'' by relocating a reference to a specific American Society for Testing and Materials (ASTM) international standard for fuel oil testing to licensee-controlled documents, and by adding an alternate criteria to the ''clear and bright'' acceptance test for new fuel oil, per the consolidated line item improvement process (CLIIP).

The U.S. Nuclear Regulatory Commission (NRC) staff issued a notice of opportunity for comment in the **Federal Register** on February 22, 2006 (71 FR 9179), on possible amendments concerning the CLIIP, including a model safety evaluation and a model no significant hazards consideration determination. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on April 21, 2006 (71 FR 20735), as part of the CLIIP.

In its application dated January 19, 2007, the licensee affirmed the applicability of the following determination.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

The proposed changes relocate the specific ASTM standard references from the Administrative Controls Section of TS to a licensee-controlled document. Requirements to perform testing in accordance with applicable ASTM standards are retained in the TS as are requirements to perform surveillances of both new and stored diesel fuel oil. Future changes to the licensee-controlled document will be evaluated pursuant to the requirements of 10 CFR 50.59, ''Changes, tests and experiments,'' to ensure that such changes do not result in more than a minimal increase in the probability or consequences of an accident previously evaluated. In addition, the ''clear and bright'' test used to establish the acceptability of new fuel oil for use prior to addition to storage tanks has been expanded to recognize more rigorous testing of water and sediment content. Relocating the specific ASTM standard references from the TS to a licensee-controlled document and allowing a water and sediment content test to be performed to establish the acceptability of new fuel oil will not affect nor degrade the ability of the emergency diesel generators (DGs) to perform their specified safety function. Fuel oil quality will continue to meet ASTM requirements.

The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed changes do not adversely affect the ability of structures, systems, and components (SSCs) to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. Further, the proposed changes do not increase the types and amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposures.

Therefore, the changes do not involve a significant increase in the probability or consequences of any accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes relocate the specific ASTM standard references from the Administrative Controls Section of TS to a licensee-controlled document. In addition, the ''clear and bright'' test used to establish the acceptability of new fuel oil for use prior to addition to storage tanks has been expanded to allow a water and sediment content test to be performed to establish the acceptability of new fuel oil. The changes do not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The requirements retained in the TS continue to require testing of the diesel fuel oil to ensure the proper functioning of the DGs.

Therefore, the changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes relocate the specific ASTM standard references from the Administrative Controls Section of TS to a licensee-controlled document. Instituting the proposed changes will continue to ensure the use of applicable ASTM standards to evaluate the quality of both new and stored fuel oil designated for use in the emergency DGs.

Changes to the licensee-controlled document are performed in accordance with the provisions of 10 CFR 50.59. This approach provides an effective level of regulatory control and ensures that diesel fuel oil testing is conducted such that there is no significant reduction in a margin of safety.

The ''clear and bright'' test used to establish the acceptability of new fuel oil for use prior to addition to storage tanks has been expanded to allow a water and sediment content test to be performed to establish the acceptability of new fuel oil. The margin of safety provided by the DGs is unaffected by the proposed changes since there continue to be TS requirements to ensure fuel oil is of the appropriate quality for emergency DG use. The proposed changes provide the flexibility needed to improve fuel oil sampling and analysis methodologies while maintaining sufficient controls to preserve the current margins of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: Russell A. Gibbs

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant (CR–3), Citrus County, Florida

Date of amendment request: December 14, 2006, as supplemented by letter dated March 14, 2007.

Description of amendment request: The proposed amendment would modify the technical specification (TS) requirements for inoperable snubbers by adding Limiting Condition for Operation (LCO) 3.0.8. The changes are consistent with NRC approved Industry/Technical Specification Task Force (TSTF) standard TS change TSTF–372, Revision 4.

The proposed amendment includes an administrative change to LCO 3.0.1 that will clarify that LCO 3.0.7 allows specified TS requirements to be suspended during physics tests performed in accordance with TSs 3.1.8 and 3.1.9. This administrative change will make the CR–3 TSs more consistent with the standard TSs and with TSTF–372, Revision 4.

The NRC staff issued a notice of availability of a model safety evaluation and model no significant hazards consideration (NSHC) determination for referencing in license amendment applications in the **Federal Register** on May 4, 2005 (70 FR 23252). The licensee affirmed the applicability of the model NSHC determination in its application dated April 26, 2006.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change allows a delay time before declaring supported TS systems inoperable when the associated snubber(s) cannot perform its required safety function. Entrance into Actions or delaying entrance into Actions is not an initiator of any accident previously evaluated. Consequently, the probability of an accident previously evaluated is not significantly increased. The consequences of an accident while relying on the delay time allowed before declaring a TS supported system inoperable and taking its Conditions and Required Actions are no different than the consequences of an accident under the same plant conditions while relying on the existing TS supported system Conditions and Required Actions. Therefore, the consequences of an accident previously evaluated are not significantly increased by this change. Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change allows a delay time before declaring supported TS systems inoperable when the associated snubber(s) cannot perform its required safety function. The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or a change in the methods governing normal plant operations. Thus, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change allows a delay time before declaring supported TS systems inoperable when the associated snubber(s) cannot perform its required safety function. The proposed change restores an allowance in the pre-ISTS [improved Standard Technical Specifications] conversion TS that was unintentionally eliminated by the conversion. The pre-ISTS TSs were considered to provide an adequate margin of safety for plant operation, as does the post-ISTS conversion TS. Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: Thomas H. Boyce.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: March 16, 2007.

Description of amendment request: The proposed amendment would add new Technical Specification (TS) requirements for the response times associated with a steam generator feedwater pump (SGFP) trip and feedwater isolation valve (FIV) closure. The amendment would also revise the TS requirements for the containment fan cooler unit (CFCU) cooling water flow rate. These changes are associated with a revised containment response analysis that credits a SGFP trip and FIV closure (on a feedwater regulator valve failure) to reduce the mass/energy release to the containment during a main steam line break (MSLB). The containment analysis also credits a reduced heat removal capability for the CFCUs, allowing a reduction in the required service water (SW) flow to the CFCUs.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed change establishes response time requirements for feedwater isolation and reduced CFCU flow rates to support containment analyses to accommodate reduced CFCU heat removal capacity. The changes in analysis input assumptions affect plant response to an accident and are not accident initiators; therefore, they have no bearing on the probability of an accident. The Salem FSAR [Final Safety Analysis Report] Chapter 15 accidents which are impacted by a change in the CFCU modeling parameters are LOCA [loss-of-coolant accident] and MSLB mass and energy release Containment analyses. The consequences of these postulated accidents are shown to be acceptable using assumptions consistent with the proposed changes.

For the LOCA transients, the containment cooling systems are considered for three aspects: core response, containment response and dose. The core response is most limiting when the containment conditions minimize back pressure since this increases the blowdown and reduces the effectiveness of the ECCS [emergency core cooling system]. The LOCA core response (10 CFR 50.46 [Section 50.46 of Title 10 of the *Code of Federal Regulations*]—PCT [peak cladding temperature]) is conservatively biased to minimize the containment backpressure such that any safety injection effectiveness is minimized (the core becomes the highest resistance flow path). Thus, any reduction in the accident capability of the CFCUs has no bearing on the LOCA core response.

The bounding containment integrity analyses are the LBLOCA [large-break LOCA] and the MSLB Inside Containment events. The containment integrity analysis relies on two heat removal paths to maintain containment pressure and temperature conditions. The CFCU air-to-water heat exchangers reject containment energy to the SW System and the Containment Spray System removes containment energy by using spray droplet direct contact heat exchange to transfer the energy from the containment ambient to the containment sump, where it is transferred out of containment via the RHR [residual heat removal] heat exchanger and CCW [component cooling water]/SW Systems. Containment integrity analyses for both LOCA and MSLB, using input assumptions consistent with the proposed changes, show that containment integrity is maintained with reduced CFCU heat removal capacity.

The potential dose impacts due to reduced CFCU heat removal capacity are bounded as the design basis assumptions concerning the number of operating CFCUs (three of five), and the thermal-hydraulic transient operation of the Containment Spray System are unchanged. The Salem design basis only credits Containment Spray iodine removal effectiveness during the LOCA injection and recirculation phases based on a single failure of an entire ESF [engineered safety features] train. This assumption results in 3 of 5 CFCUs being available to ensure adequate mixing of the containment ambient air as well as operation of a single Containment Spray Train, which controls containment spray droplet size and pH, as described in UFSAR [updated FSAR] Section 6.2.3. As a further conservatism, the current LOCA Alternate Source Term (AST) analysis (Calculation S–C–ZZ–MDC–1945, an interim revision of which was sent to the NRC [Nuclear Regulatory Commission] staff for review via letter dated September 16, 2004) only credits two CFCUs for mixing. The Containment Building and Auxiliary Building leakage rates are unaffected by the revised containment analysis as the peak containment pressure and temperatures are less than the design basis values described in the Salem UFSAR. Therefore, there is no impact on offsite dose rates due to the reduced CFCU heat removal capacity.

One other high energy line break for consideration is the rupture of a feedwater line break. From a containment response aspect, this event is bounded by the MSLB event, so it is not explicitly analyzed (or even discussed in the Salem UFSAR).

A review of the Salem design basis for AST dose calculations shows that the revised Containment Integrity Analysis, WCAP–16503, does not challenge any of the assumptions that are part of the AST design basis.

Section 6.2 of the UFSAR indicates that the Appendix J Type A containment leak rate test

pressure is based on the containment design pressure of 47.0 psig, not the calculated accident pressure. Since the design pressure value bounds the peak pressure calculated in WCAP–16503 and is not being changed, the Appendix J testing requirements are not impacted.

Thus, in conclusion, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed change modifies response time requirements for feedwater isolation, and reduces CFCU flow rates and heat removal requirements consistent with the new containment analysis.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes support revised containment analysis to accommodate the reduced CFCU heat removal capacity.

The response time-related changes impose new surveillance acceptance criteria to existing plant equipment that actuates to isolate feedwater following a safety injection signal. There is no change in actuation logic associated with the addition of response time criteria; therefore no new accident sequences would result from the imposition of response time test criteria to existing plant equipment.

The reduction in minimum service water system flow to the CFCUs is supported by analyses demonstrating acceptable system performance and containment integrity following a demand for system operation. The post-accident conditions resulting from the proposed reduction in flow do not adversely impact the environmental qualification of equipment, such that no new consequential failures are introduced to any design basis accident scenario. CFCU operation with the proposed reduction in minimum required accident flow would not result in the progression of any design basis event into a previously unanalyzed accident. Therefore, no new accident scenarios are created from the CFCU flowrate reduction.

3. Does the proposed change involve a significant reduction in [a] margin of safety?

Response: No.

The proposed change does not involve a significant reduction in the margin of safety. The revised containment analyses accommodate reduced CFCU heat removal capacity using input assumptions consistent with the proposed changes.

The proposed change involves the addition of feedwater isolation response time surveillance criteria and reduction in minimum service water system flows to CFCUs. These changes affect input to the analyses of mass/energy releases and containment response to a design basis main steam line break or loss of coolant accident. The analyses, consistent with the proposed changes, demonstrate that the acceptance criteria continue to be met, and the post-accident conditions do not adversely affect containment integrity or otherwise challenge any safety limit. The margin of safety with respect to containment pressure is preserved by demonstrating that the calculated pressures do not exceed the design limit of 47 psig.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Branch Chief: Harold K. Chernoff.

TXU Generation Company LP, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Units 1 and 2, Somervell County, Texas

Date of amendment request: December 19, 2006.

Brief description of amendments: The amendments requested would revise Technical Specifications (TS) requirement 3.7.5, ''Auxiliary Feedwater (AFW) System,'' TS 3.8.1, ''AC Sources—Operating,'' TS 3.8.9, ''Distribution Systems—Operating,'' and TS Example 1.3–3.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. D[o] the proposed change[s] involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes eliminate certain Completion Times from the Technical Specifications. Completion Times are not an initiator to any accident previously evaluated. As a result, the probability of an accident previously evaluated is not affected. The consequences of an accident during the revised Completion Time are no different than the consequences of the same accident during the existing Completion Times. As a result, the consequences of an accident previously evaluated are not affected by this change. The proposed changes do not alter or prevent the ability of structures, systems, and components from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of an accident previously evaluated. Further, the proposed changes do not increase the types or amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposures. The proposed changes are consistent with the safety analysis assumptions and resultant consequences.

Therefore, the proposed change[s] d[o] not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. D[o] the proposed change[s] create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The changes do not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The changes do not alter any assumptions made in the safety analysis.

Therefore, the proposed change[s] d[o] not create the possibility of a new or different accident from any accident previously evaluated.

3. D[o] the proposed change[s] involve a significant reduction in a margin of safety?

Response: No.

The proposed change to delete the second Completion Time does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by this change. The proposed changes will not result in plant operation in a configuration outside of the design basis.

Therefore, the proposed change[s] d[o] not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: George L. Edgar, Esq., Morgan, Lewis and Bockius, 1800 M Street, NW., Washington, DC 20036.

NRC Branch Chief: David Terao

TXU Generation Company LP, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Units 1 and 2, Somervell County, Texas

Date of amendment request: January 18, 2007.

Brief description of amendments: The amendments requested would revise Technical Specifications (TS) requirement 3.8.1, ''AC Sources—Operating,'' Extension of Completion Times for Diesel Generators.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed Technical Specification (TS) changes do not significantly increase the probability of occurrence of a previously evaluated accident because the Diesel Generators (DGs) are not initiators of previously evaluated accidents involving a loss of offsite power (LOOP). The proposed changes to the TS Required Actions and Completion Times (CT) do not affect any of the assumptions used in the deterministic or the Probabilistic Safety Assessment (PSA) analysis. Implementation of the proposed changes does not result in a risk significant impact. The onsite AC [alternating current] power sources will remain highly reliable and the proposed changes will not result in a significant increase in the risk of plant operation. This is demonstrated by showing that the impact on plant safety as measured by the increase in core damage frequency (CDF) is less than 1E–06 per year and the increase in large early release frequency (LERF) is less than 1E–07 per year. In addition, for the CT changes, the incremental conditional core damage probabilities (ICCDP) and incremental conditional large early release probabilities (ICLERP) are less than 5E–07 and 5E–08, respectively. These changes meet the acceptance criteria in Regulatory Guides 1.174 and 1.177. Therefore, since the onsite AC power sources will continue to perform their functions with high reliability as originally assumed and the increase in risk as measured by ΔCDF, ΔLERF, ICCDP, and ICLERP risk metrics is within the acceptance criteria of existing regulatory guidance, there will not be a significant increase in the consequences of any accidents.

The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility or the manner in which the plant is operated and maintained.

The proposed changes do not alter or prevent the ability of structures, systems, and components (SSCs) from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of an accident previously evaluated. The proposed changes are consistent with safety analysis assumptions and resultant consequences.

The proposed TS changes will continue to ensure the DGs perform their function when called upon. Extending the TS CT to 14 days, when an AACPS [alternate AC power source] is available, does not affect the design, the operational characteristics, the function, or the reliability of the DGs. Additionally, the CT extension to 14 days does not affect the interfaces between the DGs and other plant systems. Conversely, in the absence of an AACPS, the DG 72-hour CT will be applied. The availability of the onsite AC power system to perform its accident mitigation function is not affected by the proposed activity and thus there is no impact to the radiological consequences of any accident analysis.

To fully evaluate the effect of the changes to the CT, PSA methods were utilized. The results of this analysis show no significant increase in the CDF and LERF.

The Configuration Risk Management Program (CRMP) in TS 5.5.18 is an administrative program that assesses risk based on plant status. The risk-informed CT will be implemented consistent with the CRMP and approved plant procedures. When utilizing the 14-day extension, requirements of the CRMP per TS 5.5.18 call for the consideration of other measures to mitigate the consequences of an accident occurring while a DG is inoperable. Furthermore, administrative controls will be applied when exercising the 14-day CT extension and are adequate to maintain defense-in-depth and sufficient safety margins.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not result in a change in the manner in which the electrical distribution subsystems provide plant protection. The changes to the CT do not change any existing accident scenarios, nor create any new or different accident scenarios.

In addition, the changes do not impose any new or different accident mitigation requirements or eliminate any existing requirements.

The proposed changes are consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No.

The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. Neither the safety analyses nor the safety analysis acceptance criteria are impacted by these changes. The proposed changes will not result in plant operation in a configuration outside the current design basis. The proposed activities only involve changes to certain TS CTs.

Therefore the proposed change does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: George L. Edgar, Esq., Morgan, Lewis and Bockius, 1800 M Street, NW., Washington, DC 20036.

NRC Branch Chief: David Terao.

Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Duke Power Company LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: March 8, 2007.

Brief description of amendment request: The proposed amendments would revise the McGuire Nuclear Station, Units 1 and 2, Technical Specification 3.5.2.8, and the associated Bases and authorizes changes to the Updated Final Safety Analysis Reports concerning modifications to the emergency core cooling system sump.

Date of publication of individual notice in ***Federal Register***: March 19, 2007.

Expiration date of individual notice: Comments April 18, 2007; Hearing May 18, 2007.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination,

and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

Carolina Power & Light Company, et al., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of application for amendment: May 23, 2006, as supplemented by letters dated October 3, 2006, and October 24, 2006.

Brief description of amendment: This amendment revises Technical Specification by modifying the steam generator tube surveillance program at Shearon Harris Nuclear Power Plant, Unit 1.

Date of issuance: March 16, 2007.

Effective date: This amendment is effective as of the date of issuance and shall be implemented within 90 days of issuance.

Amendment No. 124.

Facility Operating License No. NPF–63: Amendment revises the Technical Specifications.

Date of initial notice in ***Federal Register***: December 19, 2006 (71 FR 75991). The supplemental letters provided additional information that was within the scope of the initial notice and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in the Safety Evaluation dated: March 16, 2007.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., Docket No. 50–423, Millstone Power Station, Unit No. 3 New London County, Connecticut

Date of application for amendment: July 19, 2006.

Brief description of amendment: The proposed amendment changed the Millstone Power Station, Unit No. 3 (MPS3) reactor core safety limits Technical Specification (TS) and relocated the reactor core safety limit figure to the Core Operating Limits Report in the MPS3 Technical Requirements Manual.

Date of issuance: March 14, 2007

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 236

Facility Operating License No. NPF–49: The amendment revised the TSs.

Date of initial notice in ***Federal Register***: August 29, 2006 (71 FR 51227). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 14, 2007.

No significant hazards consideration comments received: No.

Duke Power Company LLC, et al., Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of application for amendments: April 11, 2006.

Brief description of amendments: (TSTF–372, Rev. 4) The amendments added Technical Specification (TS) Limiting Condition for Operation (LCO) 3.0.8 to allow a delay time for entering a supported system TS when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed with an approved Bases Control Program that is consistent with the TS Bases Control Program described in Section 5.5 of the applicable vendor's Standard Technical Specifications. The amendment also made an administrative change, renumbering existing LCO 3.0.8 to LCO 3.0.9.

Date of issuance: March 19, 2007

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: 235, 231

Renewed Facility Operating License Nos. NPF–35 and NPF–52: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register:*** December 5, 2006 (71 FR 70555). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 19, 2007.

No significant hazards consideration comments received: No

Duke Power Company LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: April 11, 2006.

Brief description of amendments: (TSTF–372, Rev. 4) The amendments added Technical Specification (TS) Limiting Condition for Operation (LCO) 3.0.8 to allow a delay time for entering a supported system TS when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed with an approved Bases Control Program that is consistent with the TS Bases Control Program described in Section 5.5 of the applicable vendor's Standard Technical Specifications. The amendment also made an administrative change, renumbering existing LCO 3.0.8 to LCO 3.0.9.

Date of issuance: March 29, 2007.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: 238, 220.

Renewed Facility Operating License Nos. NPF–9 and NPF–17: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register***: December 5, 2006 (71 FR 70556). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 29, 2007.

No significant hazards consideration comments received: No.

Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington

Date of application for amendment: May 22, 2006, as supplemented by letter dated February 5, 2007.

Brief description of amendment: The amendment revised Technical Specification Surveillance Requirements 3.8.1.11, 3.8.1.12, 3.8.1.16, and 3.8.1.19 to eliminate the specific test-performance mode

restrictions for the High-Pressure Core Spray Division 3 diesel generator.

Date of issuance: March 23, 2007.

Effective date: As of the date of issuance and shall be implemented within 45 days from the date of issuance.

Amendment No.: 203.

Facility Operating License No. NPF–21: The amendment revised the Technical Specifications and Facility Operating License.

Date of initial notice in ***Federal Register***: July 18, 2006 (71 FR 40745). The supplemental letter dated February 5, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 23, 2007.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts.

Date of application for amendment: December 27, 2006.

Brief description of amendment: The amendment revised the Technical Specification Limiting Condition for Operation 3.14.A to adopt the Technical Specification Task Force 484, Revision 0, ''Use of Technical Specification 3.10.1 for Scram Time Testing Activities.''

Date of issuance: March 26, 2007.

Effective date: As of the date of issuance, and shall be implemented within 60 days.

Amendment No.: 226.

Facility Operating License No. DPR–35: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: February 20, 2007 (72 FR 7776). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 26, 2007.

No significant hazards consideration comments received: No

Entergy Nuclear Operations, Inc., Docket No. 50–293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts.

Date of application for amendment: January 15, 2007.

Brief description of amendment: The amendment revised the Technical Specifications (TS) to extend the use of the current pressure-temperature limits as specified in TS Figures 3.6.1, 3.6.2, and 3.6.3 through the end of operating cycle 18.

Date of issuance: March 26, 2007.

Effective date: As of the date of issuance, and shall be implemented within 60 days.

Amendment No.: 227.

Facility Operating License No. DPR–35: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: February 12, 2007 (72 FR 6609). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 26, 2007.

No significant hazards consideration comments received: No.

Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc., Docket No. 50–271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of application for amendment: April 22, 2006.

Brief description of amendment: The amendment revised Technical Specification (TS) requirements for inoperable snubbers by relocating the current TS requirements Limiting Condition for Operation (LCO) 3.6.I and Surveillance Requirement (SR) 4.6.I to the Technical Requirements Manual and adding LCO 3.0.8 to the TSs. The associated TS Bases section has also been relocated.

Date of Issuance: March 26, 2007.

Effective date: As of the date of issuance, and shall be implemented within 60 days.

Amendment No.: 230.

Facility Operating License No. DPR–28: The amendment revised the License and TSs.

Date of initial notice in ***Federal Register***: June 6, 2006 (71 FR 32604). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated March 26, 2007.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of application for amendment: January 18, 2007.

Brief description of amendment: The amendment revised the description of the control rod assemblies in Grand Gulf Nuclear Station, Unit 1, Technical Specification 4.2.2, ''Control Rod Assemblies,'' to allow the use of hafnium as an additional type of control material.

Date of issuance: March 16, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment No: 174.

Facility Operating License No. NPF–29: The amendment revises the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: February 13, 2007 (72 FR 6782). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 16, 2007.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: September 26, 2006.

Brief description of amendment: The amendment deleted reference to the containment fan cooler condensate flow switch from Technical Specification 3.4.5.1, ''Reactor Coolant System Leakage—Leakage Detection Instrumentation,'' and modified or deleted associated actions. The Nuclear Regulatory Commission staff had determined that the remaining leak detection methods provided adequate means for detecting, and to the extent practical, identifying the location of the source of potential reactor coolant leakage.

Date of issuance: March 19, 2007.

Effective date: As of the date of issuance and shall be implemented 60 days from the date of issuance.

Amendment No.: 212.

Facility Operating License No. NPF–38: The amendment revised the Operating License and the Technical Specifications.

Date of initial notice in ***Federal Register***: February 13, 2007 (72 FR 6782). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 19, 2007.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Units 1 and 2, Berrien County, Michigan

Date of application for amendments: May 26, 2006, as supplemented on December 26, 2006, and March 14, 2007.

Brief description of amendments: The amendments revised the existing steam

generator (SG) tube surveillance program. The changes are modeled after Technical Specifications Task Force (TSTF) traveler TSTF–449, Revision 4, ''Steam Generator Tube Integrity,'' and the model safety evaluation prepared by the Nuclear Regulatory Commission staff and published in the **Federal Register** on March 2, 2005 (70 FR 10298). In this regard, the scope of the amendments includes changes to the definition of leakage, changes to the primary-to-secondary leakage requirements, changes to the SG tube surveillance program (SG tube integrity), and changes to the SG reporting requirements.

Date of issuance: March 14, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment Nos.: 298 and 279.

Facility Operating License Nos. DPR–58 and DPR–74: Amendments revise the Technical Specifications.

Date of initial notice in ***Federal Register***: July 5, 2006 (71 FR 38183).

The supplemental letters provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 14, 2007.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket No. 50–263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of application for amendment: March 7, 2006, as supplemented by letters dated May 30, September 7, December 15, 2006, and January 2, 2007.

Brief description of amendment: The amendment revised Section 4.3, ''Fuel Storage,'' of the Monticello Nuclear Generating Plant, technical specifications to allow for installation of an additional temporary 8x8 (64-cell) high-density spent fuel storage rack in the spent fuel pool to maintain full core off-load capability.

Date of issuance: March 9, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 150.

Facility Operating License No. DPR–22. Amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register****:* April 3, 2006 (71 FR 16599).

The supplemental letters contained clarifying information and did not change the initial no significant hazards consideration determination, and did not expand the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 9, 2007.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket Nos. 50–266 and 50–301, Point Beach Nuclear Plant, Units 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of application for amendments: March 23, 2006, as supplemented on December 19, 2006.

Brief description of amendments: The amendments revise Technical Specification (TS) 3.3.4, ''Loss of Power (LOP) Diesel Generator (DG) Start and Load Sequence Instrumentation,'' and surveillance requirement 3.3.4.3.b to modify the TS title and correct nonconservatisms in the allowable values for the degraded voltage time delay.

Date of issuance: March 21, 2007.

Effective date: As of the date of issuance and shall be implemented within 45 days.

Amendment Nos.: 225 & 231.

Renewed Facility Operating License Nos. DPR–24 and DPR–27: Amendments revised the Technical Specifications and License.

Date of initial notice in ***Federal Register****:* April 25, 2006 (71 FR 23958).

The December 19, 2006, supplement, contained clarifying information and did not change the staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 21, 2007.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota

Date of application for amendments: February 16, 2006, supplemented by letters dated July 21, and December 27, 2006.

Brief description of amendments: The amendments consist of changes to the Technical Specifications (TSs) related to steam generator tube integrity. The amendments are modeled after the U.S. Nuclear Regulatory Commission approved Technical Specification Task Force (TSTF) Standard Technical Specification Change Traveler, TSTF–449, ''Steam Generator Tube Integrity,'' Revision 4 (ML0510902003).

Date of issuance: March 20, 2007.

Effective date: As of the date of issuance and shall be implemented within 90 days.

Amendment Nos.: 177 and 167.

Facility Operating License Nos. DPR–42 and DPR–60: Amendments revised the Technical Specifications.

Date of initial notice in ***Federal Register****:* April 11, 2006 (71 FR 18376)

The supplemental letters contained clarifying information and did not change the initial no significant hazards consideration determination, and did not expand the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 20, 2007.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: May 30, 2006, as supplemented by letters dated November 22, 2006, and January 11, 2007.

Brief description of amendments: The amendments revised the existing steam generator (SG) tube surveillance program. The changes were modeled after Technical Specification Task Force (TSTF) traveler TSTF–449, Revision 4, ''Steam Generator Tube Integrity,'' and the model safety evaluation prepared by the U.S. Nuclear Regulatory Commission and published in the **Federal Register** on March 2, 2005 (70 FR 10298). The scope of the application included changes to the definition of leakage, changes to the primary-to-secondary leakage requirements, changes to the SG tube surveillance program (SG tube integrity), changes to the SG reporting requirements, and associated changes to the Technical Specification Bases.

Date of issuance: March 21, 2007.

Effective date: As of its date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: Unit 1—194; Unit 2—195.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** July 18, 2006 (71 FR 40751). The supplemental letters dated November 22, 2006, and January 11, 2007, provided additional information that clarified the application, did not expand the scope of the application as

originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 21, 2007.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: December 14, 2006.

Brief description of amendments: The amendments deleted Section 2.G of Facility Operating License Nos. DPR–80 and DPR–82, which require reporting of violations of the requirements of Sections 2.C, 2.E, and 2.F of the operating license. This operating license improvement was made available by the U.S. Nuclear Regulatory Commission on November 4, 2005, as part of the consolidated line item improvement process (CLIIP).

Date of issuance: March 19, 2007.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos.: Unit 1–193; Unit 2–194.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses.

Date of initial notice in ***Federal Register:*** January 3, 2007 (72 FR 154).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 19, 2007.

No significant hazards consideration comments received: No.

PPL Susquehanna, LLC, Docket No. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2 (SSES 1 and 2), Luzerne County, Pennsylvania

Date of application for amendments: November 18, 2005, as supplemented on November 29, 2006, December 1, 2006, December 15, 2006, January 9, 2007, and March 12, 2007 (PLA–6168 and PLA–6169).

Brief description of amendments: The amendments change the SSES 1 and 2 Technical Specifications (TSs) to implement the Average Power Range Monitor/Rod Block Monitor/TSs/ Maximum Load Line Limit Analysis by revising TS 1.1, ''Definitions,'' TS 5.6.5, ''Core Operating Limits Report,'' and the surveillance requirement sections of TS 3.3.1.1, ''Reactor Protection System Instrumentation,'' and TS 3.3.2.1, ''Control Rod Block Instrumentation.'' The amendments also delete TS 3.2.4, ''Average Power Range Monitor Gain and Setpoints,'' and its associated references in the TSs. Additionally, the amendments change the method of evaluation for the postulated recirculation line break in the reactor pressure vessel shield annulus region.

Date of issuance: March 23, 2007.

Effective date: As of the date of issuance and to be implemented prior to the startup following the SSES 1 spring 2008 15th refueling outage for Unit 1 and prior to the startup following the SSES 2 spring 2007 13th refueling outage for Unit 2.

Amendment Nos.: 242 and 220.

Facility Operating License Nos. NPF–14 and NPF–22: The amendments revised the TSs and the License.

Date of initial notice in ***Federal Register:*** February 14, 2006 (71 FR 7810).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 23, 2007.

No significant hazards consideration comments received: No.

PPL Susquehanna, LLC, Docket No. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2 (SSES 1 and 2), Luzerne County, Pennsylvania

Date of application for amendments: September 7, 2006.

Brief description of amendments: The amendments revise the SSES 1 and 2 Technical Specifications (TSs) Section 5.5.6, ''Inservice Testing Program,'' and TS 5.5.12, ''Primary Containment Leakage Rate Testing Program,'' to be consistent with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.55a(f)(4) and 10 CFR 50.55a(g)(4), respectively. The amendments implement TS Task Force (TSTF)–343, Revision 1 and TSTF–479, Revision 0.

Date of issuance: March 19, 2007.

Effective date: As of the date of issuance and to be implemented within 30 days.

Amendment Nos.: 241 and 219.

Facility Operating License Nos. NPF–14 and NPF–22: The amendments revised the License and Technical Specifications.

Date of initial notice in ***Federal Register:*** December 19, 2006 (71 FR 75997).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 19, 2007.

No significant hazards consideration comments received: No.

PPL Susquehanna, LLC, Docket No. 50–388, Susquehanna Steam Electric Station, Unit 2 (SSES 2), Luzerne County, Pennsylvania

Date of application for amendment: November 16, 2006, as supplemented on February 15, 2007.

Brief description of amendment: The amendment changes the SSES 2 Technical Specification (TS) Section 2.1.1.2 by revising the Unit 2 Cycle 14 Minimum Critical Power Ratio Safety Limit for two-loop and single-loop operation and the references listed in TS 5.6.5.b.

Date of issuance: March 19, 2007.

Effective date: As of the date of issuance and to be implemented within 30 days.

Amendment No.: 218.

Facility Operating License No. NPF–22: The amendment revised the License and Technical Specifications.

Date of initial notice in ***Federal Register:*** December 19, 2006 (71 FR 75998).

The supplement dated February 15, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 19, 2007.

No significant hazards consideration comments received: No.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of application for amendments: May 1, 2006.

Brief description of amendments: The amendments eliminate the requirement for a power range neutron flux high negative rate trip and delete the references to this trip in Salem Unit Nos. 1 and 2 Technical Specification (TS) Table 2.2–1, ''Reactor Trip System Instrumentation Trip Setpoints,'' TS Table 3.3–1, ''Reactor Trip System Instrumentation,'' TS Table 3.3–2, ''Reactor Trip System Instrumentation Response Times,'' and TS Table 4.3–1, ''Reactor Trip System Instrumentation Surveillance Requirements.'' The amendments also incorporate administrative and editorial changes to correct miscellaneous errors in the TSs for Salem Units Nos. 1 and 2.

Date of issuance: March 19, 2007.

Effective date: As of the date of issuance, to be implemented within 60 days.

Amendment Nos.: 278 and 261

Facility Operating License Nos. DPR–70 and DPR–75: The amendments revised the TSs and the License.

Date of initial notice in ***Federal Register****:* July 18, 2006 (71 FR 40752).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 19, 2007.

No significant hazards consideration comments received: No.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of application for amendments: August 4, 2006, as supplemented by letter dated February 20, 2007.

Brief description of amendments: The amendments allow the use of blind flanges for containment isolation in the containment purge system supply and exhaust lines, and make corresponding changes to the Technical Specifications (TSs). The amendments also consolidate the containment isolation requirements by moving the requirements of TS 3/4 6.1.7, ''Containment Ventilation System,'' to TS 3/4 6.3.1 (TS 3/4 6.3 for Unit No. 2), ''Containment Isolation Valves.''

Date of issuance: March 19, 2007.

Effective date: As of the date of issuance, to be implemented within 60 days.

Amendment Nos.: 277 and 260.

Facility Operating License Nos. DPR–70 and DPR–75: The amendments revised the License and the TSs.

PSEG Nuclear LLC, Docket No. 50–272, Salem Nuclear Generating Station, Unit No. 1, Salem County, New Jersey

Date of application for amendment: January 18, 2007, as supplemented on February 23, March 9, and March 22, 2007.

Brief description of amendment: The amendment approves a one-time change to the Technical Specifications (TSs) regarding the steam generator (SG) tube inspection and repair required for the portion of the SG tubes passing through the tubesheet region. Specifically, for Salem Unit No. 1 refueling outage 18 (planned for spring 2007) and the subsequent operating cycle, the TS changes limit the required inspection (and repair if degradation is found) to the portions of the SG tubes passing through the upper 17 inches of the approximate 21-inch tubesheet region.

Date of issuance: March 27, 2007.

Effective date: As of the date of issuance, to be implemented within 60 days.

Amendment No.: 279.

Facility Operating License No. DPR–70: The amendment revised the TSs and the License.

Date of initial notice in ***Federal Register****:* January 25, 2007 (72 FR 3427).

The letters dated February 23, March 9, and March 22, 2007, provided clarifying information that did not change the initial proposed no significant hazards consideration determination or expand the application beyond the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 27, 2007.

No significant hazards consideration comments received: No.

R.E. Ginna Nuclear Power Plant, LLC, Docket No. 50–244, R.E. Ginna Nuclear Power Plant, Wayne County, New York

Date of application for amendment: March 28, 2006, as supplemented by letter dated October 24, 2006.

Brief description of amendment: The amendment revises Technical Specification Surveillance Requirement 3.5.1.4 to change the method and frequency for verifying emergency core cooling system accumulator boric acid concentration.

Date of issuance: March 28, 2007.

Effective date: As of the date of issuance to be implemented within 45 days.

Amendment No.: 101.

Renewed Facility Operating License No. DPR–18: Amendment revised the License and Technical Specifications.

Date of initial notice in ***Federal Register***: April 25, 2006 (71 FR 23960) The October 24, 2006, letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 28, 2007.

No significant hazards consideration comments received: No.

TXU Generation Company LP, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: August 22, 2005, as supplemented by letters dated September 18, 2006, October 23, 2006, and February 16, 2007.

Brief description of amendments: These amendments modified Technical Specification (TS) requirements related to control room envelope habitability in TS 3.7.10, ''Control Room Emergency Filtration/Pressurization System (CREFS)'' and TS Section 5.5, ''Administrative Controls—Programs and Manuals.''

Date of issuance: March 26, 2007.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: 136/136.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: November 8, 2005 (70 FR 67754). The supplemental letters dated September 18 and October 23, 2006, and February 16, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 26, 2007.

No significant hazards consideration comments received: No.

TXU Generation Company LP, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: March 31, 2006.

Brief description of amendments: The amendments revised Technical Specification 5.0 entitled, ''ADMINISTRATIVE CONTROLS.'' Specifically, the change deleted the Vice President, Nuclear Operations, as an alternative to the Plant Manager for certain functions.

Date of Issuance: March 20, 2007.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: Unit 1–134; Unit 2–134.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: September 12, 2006 (71 FR 53722).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 20, 2007.

No significant hazards consideration comments received: No.

TXU Generation Company LP, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station (CPSES), Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: February 21, 2006, as supplemented by letter dated March 19, 2007.

Brief description of amendments: The amendments revise TS 5.6.5 entitled, ''Core Operating Limits Report (COLR),'' by adding two reports providing Loss-of-Coolant Accident (LOCA) and non-LOCA analysis methodologies for CPSES Unit 1.

Date of issuance: March 26, 2007.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance, but no later than the entry into Mode 5 in the restart of Unit 1 from its spring 2007 refueling outage.

Amendment Nos.: 135/135.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: June 6, 2006 (71 FR 32609). The supplemental letter dated March 19, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 26, 2007.

No significant hazards consideration comments received: No.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: May 25, 2006, as supplemented by letter dated March 12, 2007.

Brief description of amendment: The amendment revised Technical Specifications 3.1.7, ''Rod Position Indication,'' 3.2.1, ''Heat Flux Hot Channel Factor ($F_Q(Z)$) (F_Q Methodology),'' 3.2.4, ''Quadrant Power Tilt Ratio (QPTR),'' and 3.3.1, ''Reactor Trip System (RTS) Instrumentation,'' to allow use of the Westinghouse proprietary computer code, the Best Estimate Analyzer for Core Operations—Nuclear (BEACON). Certain required actions, for when a limiting condition for operation is not met, and certain surveillance requirements are being changed to refer to power distribution measurements or measurement information of the core.

Date of issuance: March 21, 2007.

Effective date: As of its date of issuance and shall be implemented before entry into Mode 2 in the plant restart from the refueling outage scheduled for the spring of 2007. This includes the incorporation of the identified changes to the Final Safety Analysis Report (FSAR) in Attachment 6 of the licensee's application dated May 25, 2006, into the FSAR.

Amendment No.: 182.

Facility Operating License No. NPF–30: The amendment revised the Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: July 18, 2006 (71 FR 40756) The supplemental letter dated March 12, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination published in the **Federal Register** on July 18, 2006.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 21, 2007.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 3rd day of April 2007.

For the Nuclear Regulatory Commission.

Catherine Haney,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E7–6632 Filed 4–9–07; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Submission for OMB Review; Comment Request

AGENCY: Overseas Private Investment Corporation (OPIC)

ACTION: Request for comments.

SUMMARY: Under the provision of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that Agency is preparing an information collection request for OMB review and approval and to request public review and comment on the submission.

Comments are being solicited on the need for the information, its practical utility, the accuracy of the Agency's burden estimate, and on ways to minimize the reporting burden, including automated collection techniques and uses of other forms of technology. The proposed form under review is summarized below.

DATES: Comments must be received within 30 calendar days of this notice.

ADDRESSES: Copies of the subject form and the request for review prepared for submission to OMB may be obtained from the Agency submitting officer. Comments on the form should be submitted to the Agency Submitting Officer.

FOR FURTHER INFORMATION CONTACT: OPIC Agency Submitting Officer: Essie Bryant, Record Manager, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527; 202–336–8563.

Summary Form Under Review

Type of Request: Revised form.

Title: OPIC Self-Monitoring Questionnaire.

Form Number: OPIC–162.

Frequency of Use: Annually for duration of project.

Type of Respondents: Business or other institution (except farms); individuals.

Standard Industrial Classification Codes: All.

Description of Affected Public: U.S. companies or citizens investing overseas.

Reporting Hours: 6.5 hours per project.

Number of Responses: 350 per year.

Federal Cost: $35,000.

Authority for Information Collection: Sections 231, 234(a), 239(d), and 240A of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The questionnaire is completed by OPIC-assisted investors annually. The questionnaire allows OPIC's assessment of effects of OPIC-assisted projects on the U.S. economy and employment, as well as on the environment and economic development abroad.

Dated: April 5, 2007.

John P. Crowley, III,

Senior Administrative Counsel, Department of Legal Affairs.

[FR Doc. 07–1771 Filed 4–9–07; 8:45 am]

BILLING CODE 3210–01–M

PENSION BENEFIT GUARANTY CORPORATION

Approval of Exemption From the Bond/Escrow Requirement Relating to the Sale of Assets by an Employer Who Contributes to a Multiemployer Plan; Washington Nationals Baseball Club, LLC

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of approval.

SUMMARY: The Pension Benefit Guaranty Corporation has granted a request from the Washington Nationals Baseball Club, LLC for an exemption from the bond/escrow requirement of section 4204(a)(1)(B) of the Employee Retirement Income Security Act of 1974, as amended, with respect to the Major League Baseball Players Benefit Plan. A notice of the request for exemption from the requirement was published on January 31, 2007 (72 FR 4538). The effect of this notice is to advise the public of the decision on the exemption request.

ADDRESSES: The non-confidential portions of the request for an exemption and any PBGC response to the request may be obtained by writing PBGC's Communications and Public Affairs Department (CPAD) at Suite 1200, 1200 K Street, NW., Washington, DC 20005–4026, or by visiting or calling CPAD during normal business hours (202–326–4040).

FOR FURTHER INFORMATION CONTACT: Eric Field, Office of the Chief Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; telephone 202–326–4020. (For TTY/TDD users, call the Federal Relay Service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4020).

SUPPLEMENTARY INFORMATION:

Background

Section 4204 of the Employee Retirement Income Security Act of 1974, as amended by the Multiemployer Pension Plan Amendments Act of 1980 (''ERISA'' or ''the Act''), provides that a bona fide arm's-length sale of assets of a contributing employer to an unrelated party will not be considered a withdrawal if three conditions are met. These conditions, enumerated in section 4204(a)(1)(A)–(C), are that—

(A) The purchaser has an obligation to contribute to the plan with respect to the operations for substantially the same number of contribution base units for which the seller was obligated to contribute;

(B) The purchaser obtains a bond or places an amount in escrow, for a period of five plan years after the sale, in an amount equal to the greater of the seller's average required annual contribution to the plan for the three plan years preceding the year in which the sale occurred or the seller's required annual contribution for the plan year preceding the year in which the sale occurred (the amount of the bond or escrow is doubled if the plan is in reorganization in the year in which the sale occurred); and

(C) The contract of sale provides that if the purchaser withdraws from the plan within the first five plan years beginning after the sale and fails to pay any of its liability to the plan, the seller shall be secondarily liable for the liability it (the seller) would have had but for section 4204.

The bond or escrow described above would be paid to the plan if the purchaser withdraws from the plan or fails to make any required contributions to the plan within the first five plan years beginning after the sale. Additionally, section 4204(b)(1) provides that if a sale of assets is covered by section 4204, the purchaser assumes by operation of law the contribution record of the seller for the plan year in which the sale occurred and the preceding four plan years.

Section 4204(c) of ERISA authorizes the Pension Benefit Guaranty Corporation (''PBGC'') to grant individual or class variances or exemptions from the purchaser's bond/escrow requirement of section 4204(a)(1)(B) when warranted. The legislative history of section 4204 indicates a Congressional intent that the sales rules be administered in a manner that assures protection of the plan with the least practicable intrusion into normal business transactions. Senate Committee on Labor and Human Resources, 96th Cong., 2nd Sess., S. 1076, The Multiemployer Pension Plan Amendments Act of 1980: Summary and Analysis of Considerations 16 (Comm. Print, April 1980); 128 Cong. Rec. S10117 (July 29, 1980). The granting of an exemption or variance from the bond/escrow requirement does not constitute a finding by the PBGC that a particular transaction satisfies the other requirements of section 4204(a)(1).

Under the PBGC's regulation on variances for sales of assets (29 CFR Part 4204), a request for a variance or waiver of the bond/escrow requirement under any of the tests established in the regulation (sections 4204.12 & 4204.13) is to be made to the plan in question. The PBGC will consider waiver requests only when the request is not based on satisfaction of one of the three regulatory tests or when the parties assert that the financial information necessary to show satisfaction of one of the regulatory tests is privileged or confidential financial information within the meaning of 5 U.S.C. 552(b)(4) of the Freedom of Information Act.

Under section 4204.22 of the regulation, the PBGC shall approve a request for a variance or exemption if it determines that approval of the request is warranted, in that it—

(1) Would more effectively or equitably carry out the purposes of Title IV of the Act; and

(2) Would not significantly increase the risk of financial loss to the plan.

Section 4204(c) of ERISA and section 4204.22(b) of the regulation require the PBGC to publish a notice of the pendency of a request for a variance or exemption in the **Federal Register**, and to provide interested parties with an opportunity to comment on the proposed variance or exemption. The PBGC received no comments on the request for exemption.

Decision

On January 31, 2007, the PBGC published a notice of the pendency of a request by the Washington Nationals Baseball Club, LLC (the ''Buyer'') for an exemption from the bond/escrow requirement of section 4204(a)(1)(B) with respect to its purchase of the Washington Nationals Baseball Team from Baseball Expos, L.P. (the ''Seller'') (72 FR 4538). According to the request, the Major League Baseball Players Benefit Plan (the ''Plan'') was established and is maintained pursuant to a collective bargaining agreement between the professional major league baseball teams (the ''Clubs'') and the Major League Baseball Players Association (the ''Players Association'').

According to the Buyer's representations, the Seller was obligated to contribute to the Plan for certain employees of the sold operations. Pursuant to an agreement dated April 24, 2006, the Buyer and Seller entered into an agreement under which the Buyer agreed to purchase substantially all of the assets and assume substantially all of the liabilities of the Seller relating to the business of employing employees under the Plan. The Buyer agreed to contribute to the Plan for substantially the same number of contribution base units as the Seller. The Seller agreed to be secondarily liable for any withdrawal liability it would have had with respect to the sold operations (if not for section 4204) should the Buyer withdraw from the Plan within the five plan years following the sale and fail to pay its withdrawal liability. The amount of the bond/escrow required under section 4204(a)(1)(B) of ERISA is $2,803,040. The estimated amount of the unfunded vested benefits allocable to the Seller with respect to the operations subject to the sale is $14,454,124. While the separate major league clubs are the nominal contributing employers to the Plan, the Major League Central Fund

under the Office of the Commissioner receives the revenues and makes the payments for certain common expenses, including each club's contribution to the Plan. In support of the waiver request, the requester asserts that: ''The Plan is funded directly from Revenues which are paid from the Central Fund directly to the Plan without passing through the hands of any of the clubs. Therefore, the Plan enjoys a substantial degree of security with respect to contributions on behalf of the clubs. A change in ownership of a club does not affect the obligation of the Central Fund to fund the Plan out of the Revenue. As such, approval of this exemption request would not significantly increase the risk of financial loss to the Plan.''

Based on the facts of this case and the representations and statements made in connection with the request for an exemption, the PBGC has determined that an exemption from the bond/escrow requirement is warranted, in that it would more effectively carry out the purposes of Title IV of ERISA and would not significantly increase the risk of financial loss to the Plan. Therefore, the PBGC hereby grants the request for an exemption for the bond/escrow requirement. The granting of an exemption or variance from the bond/escrow requirement of section 4204(a)(1)(B) does not constitute a finding by the PBGC that the transaction satisfies the other requirements of section 4204(a)(1).

The determination of whether the transaction satisfies such other requirements is a determination to be made by the Plan sponsor.

Issued at Washington, DC, on this 30th day of March, 2007.

Vincent K. Snowbarger,

Interim Director, Pension Benefit Guaranty Corporation.

[FR Doc. E7–6706 Filed 4–9–07; 8:45 am]

BILLING CODE 7708–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55570; File No. SR–CBOE–2007–15]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Proposed Rule Change To Amend CBOE's Membership Application Procedures To Incorporate Individuals Who Are Acting in an Exchange Trading Floor Capacity

April 2, 2007.

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 February 14, 2007, The Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its membership application procedures to incorporate those individuals who are acting in an Exchange trading floor capacity. Set forth below are the proposed changes to the rule text with additions in *italic*.

Chicago Board Options Exchange, Incorporated

Rules

* * * * *

Rule 3.9. Application Procedures and Approval or Disapproval

(a)–(f) No Change.

(g) Any person applying pursuant to paragraph (a) of this Rule to have an authorized trading function is required to have completed the Exchange's Member Orientation Program and to have passed an Exchange Trading Member Qualification Exam. Additionally, any person who has completed the Member Orientation Program and taken and passed the applicable Trading Member Qualification Exam and who then does not possess an authorized trading function *or Exchange trading floor capacity* for more than 1 year is required to complete the Member Orientation Program and to re-pass the applicable Trading Member Qualification Exam in order to once again become eligible to have an authorized trading function. A person must score 75% or better on the applicable Trading Member Qualification Exam in order to pass the Exam. Any person who fails the applicable Trading Member Qualification Exam must wait 30 days to re-take the Exam after failing the Exam for the first time, must wait 60 days to re-take the Exam after failing the Exam for the second time, and must wait 120 days to re-take the Exam after failing the Exam for a third or subsequent time. The Exchange may not waive any of the requirements set forth in this paragraph (g).

(h)–(l) No Change.

* * * Interpretations and Policies:

.01 No Change.

.02 No Change.

.03 *For purposes of this rule, ''Exchange trading floor capacity'' means any person who is acting on behalf of the Exchange in an Exchange trading floor capacity, such as a PAR Official, Order Book Official, or other similar function.*

* * * * *

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

Exchange Rule 3.9, entitled ''Application Procedures and Approval or Disapproval,'' outlines, among other things, the application procedures for an individual who desires to become a member of the Exchange. Paragraph (g) of Exchange Rule 3.9 currently requires any person applying to the Exchange to (i) have completed the Exchange's Member Orientation Program (''Orientation Program'') and (ii) passed an Exchange Trading Member Qualification Exam (''Qualification Exam''). However, a person who has completed the Orientation Program and taken and passed the Qualification Exam but does not possess an authorized trading function for more than one year must again complete the Orientation Program and re-pass the Qualification Exam.

This filing proposes to amend CBOE's rules to provide that PAR Officials and Order Book Officials, as described in CBOE's rules and discussed below, as well as others acting in a similar capacity (*i.e.*, an Exchange trading floor capacity), shall be included in the rule, in addition to those who possess an authorized trading function, since both functions are similar.

On November 18, 2005, the Commission approved a filing which

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

created a new category of market participant called ''PAR Officials.'' [3] The PAR Official was established in response to the elimination of CBOE's rules as applied to Designated Primary Market-Makers (''DPMs'') executing orders as agents or Floor Brokers in their allocated option classes. The PAR Official is responsible for operating the PAR workstation trading stations, including handling and executing orders that are routed to the PAR workstation.

Specifically, the PAR Official is an Exchange employee or independent contractor designated by the Exchange to be responsible for (i) operating the PAR workstation; (ii) when applicable, maintaining the customer limit order book for the assigned option classes; [4] and (iii) effecting proper executions of orders placed with him.

In addition to PAR Officials, the Exchange also employs ''Order Book Officials'' (''OBOs'') whose responsibilities include, among other things, (i) maintaining the book with respect to the classes of options assigned to him, (ii) effecting proper executions of orders placed with him, (iii) displaying bids and offers, and (iv) monitoring the market for the classes of options assigned to him.

The Exchange may employ former members, who previously acted in the capacity of a DPM before the initiation of the PAR Official, to act on behalf of the Exchange in a trading floor capacity. If these PAR Officials and OBOs become members of the Exchange after working for the Exchange in a trading floor capacity for longer than one year, these individuals would have to again complete the Orientation Program and re-pass the Qualification Exam under current CBOE Rule 3.9, since they would have not possessed an authorized trading function for longer than one year.

These PAR Officials and OBOs, while acting in an Exchange trading floor capacity, are ultimately acting in the same capacity as when they were operating in a DPM capacity prior to the initiation of the PAR Official trading floor capacity. Therefore, the Exchange feels that it is appropriate to amend its procedures to allow for the one year period under CBOE Rule 3.9(g) to be applied to not only an individual who has possessed an authorized trading function, but also to an individual who has acted in an Exchange trading floor capacity, since both functions are similar.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it should promote just and equitable principles of trade, serve to remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

This proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 CBOE consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2007–15 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–2007–15. 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. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2007–15 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6671 Filed 4–9–07; 8:45 am]

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[3] *See* Securities Exchange Act Release No. 52798 (November 18, 2005), 70 FR 71344 (November 28, 2005) (SR–CBOE–2005–46).

[4] This provision will not apply to option classes that are on the CBOE's Hybrid System.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55575; File No. SR–ISE–2006–59]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing of Amendment No. 2 to and Order Granting Accelerated Approval of a Proposed Rule Change as Modified by Amendment Nos. 1 and 2 Thereto Relating to Foreign Currency Options

April 3, 2007.

I. Introduction

On September 29, 2006, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt rules for the listing and trading of cash-settled rate-modified foreign currency options (''FCOs'').[3] On February 23, 2007, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on March 1, 2007.[5] The Commission received no comments on the proposal. On April 3, 2007, the Exchange filed Amendment No. 2 to the proposed rule change.[6] This order provides notice of Amendment No. 2 to the proposed rule change and approves the proposed rule change, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

II. Description of the Proposal

A. Product Specifications

The Exchange proposes to adopt rules for the listing and trading of FCOs[7] on the following currencies: The euro, the British pound, the Australian dollar, the New Zealand dollar, the Japanese yen, the Canadian dollar, the Swiss franc, the Chinese renminbi, the Mexican peso, the Swedish krona, the Russian ruble, the South African rand, the Brazilian real, the Israeli shekel, the Norwegian krone, the Polish zloty, the Hungarian forint, the Czech koruna and the Korean won (individually, a ''Currency'' and collectively, the ''Currencies'').[8] The Exchange proposes to list and trade FCOs that include the U.S. Dollar on one side of the underlying currency pair, as well as certain cross-rate FCOs that include two of the aforementioned Currencies in the underlying currency pair (''cross-rate FCOs'').[9]

The Exchange proposes to list and trade FCOs based on the Reuters Composite Currency Rate[10] as modified by ISE in a way that permits the underlying price of the FCO contract to resemble a price level similar to that of an index option.[11] The Exchange proposes to use fixed, pre-assigned modifiers of 1, 10, or 100 depending on the exchange rate level of the underlying foreign currency.[12] The Exchange would disseminate the current modified exchange rate[13] at least once every fifteen seconds through the Options Price Reporting Authority (''OPRA'') or one or more major market data vendors during the time FCOs are traded on the Exchange.[14] FCOs would be quoted in U.S. Dollars and would be European-style exercise.

FCOs listed by the Exchange would be cleared by The Options Clearing Corporation (''OCC''),[15] and holders of options contracts would receive U.S. Dollars representing the difference between the modified exchange rate and the exercise price[16] of the option, which would be multiplied by 100. Specifically, upon exercise of an in-the-money FCO call option, the holder would receive from OCC, U.S. Dollars representing the difference between the exercise price and the closing settlement value of the FCO contract multiplied by 100. Upon exercise of an in-the-money FCO put option, the holder would receive from OCC, U.S. Dollars representing the excess of the exercise price over the closing settlement value of the cash-settled FCO contract multiplied by 100. Additionally, FCOs that are in-the-money by any amount on the expiration date would be exercised automatically by OCC, while FCOs that are out-of-the-money on the expiration date would expire worthless.

Minimum Increments. The interval between exercise prices of series of FCOs would be no less than $0.10.[17] Additionally, under the Exchange's current rules, the minimum trading increment for a FCO contract trading at less than $3.00 would be $0.05, and for a FCO contract trading at $3.00 or higher, the minimum trading increment would be $0.10.

Expirations. The Exchange proposes to permit FCOs to be listed with expirations that are the same as the expirations permitted for index options,[18] except that FCOs would be permitted to have expirations only up to 36 months.[19] Accordingly, after a class of options contracts involving any of the Currencies has been approved for listing and trading, the Exchange could open for trading series of FCOs that expire in consecutive monthly intervals, that expire in three or ''cycle'' month

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that the cash-settled FCOs that ISE proposes to list and trade pursuant to this proposed rule change are rate-modified. Cash-settled foreign currency options that trade on the Philadelphia Stock Exchange (''Phlx'') are not rate-modified. *See* Securities Exchange Act Release No. 54989 (December 21, 2006), 71 FR 78506 (December 29, 2006) (SR–PHLX–2006–34). *See also* Phlx Rules 1000–1093. Accordingly, the term ''FCO'' used throughout this Order refers only to ISE's proposed cash-settled rate-modified foreign currency options. FCOs listed and traded by ISE pursuant to this proposed rule change will not be fungible with those listed and traded by Phlx.

[4] Amendment No. 1 replaced and superseded the original filing in its entirety.

[5] *See* Securities Exchange Act Release No. 55336 (February 23, 2007), 72 FR 09364 (''Notice'').

[6] The text of Amendment No. 2 is available at the Exchange, on the Exchange's Web site (*http://www.iseoptions.com*), and at the Commission's Public Reference Room. In Amendment No. 2, ISE clarified its plans to list cross-rate FCOs by specifying the cross-rate pairs it intends to offer as well as the applicable modifier and position limits for each proposed cross-rate pair. ISE also made a non-substantive change to the title of the proposed rule text and to the text of proposed ISE Rule 2200.

[7] The Commission notes that ISE refers to these FCO products in its marketing literature as ''FX Options™.''

[8] The Exchange's existing rules and procedures would also be applicable to FCOs, unless such rules are specifically replaced or are supplanted by the proposed new rules governing FCOs. *See* Proposed ISE Rule 2200. The Commission notes that futures contracts, and options on such futures contracts, are currently traded by the Chicago Mercantile Exchange (''CME'') on all of the Currencies.

[9] *See* Amendment No. 2. In other words, a cross-rate FCO would not involve the U.S. Dollar on one side of the underlying currency pair (*e.g.*, EUR/GBP).

[10] The Reuters data is based on an amalgamation of midpoint dealer quotes on its foreign exchange dealing system.

[11] *See* Proposed ISE Rule 2201(8) (defining ''modified exchange rate'').

[12] For example, if one U.S. Dollar buys .84177 euros, a modifier of 100 would be used so that the modified exchange rate would become 84.18. Modifiers used for creating underlying values will be posted on the Exchange's Web site no later than the first day on which FCOs begin trading on ISE. Once a modifier has been assigned to a currency pair, it can only be changed upon a filing of a proposed rule change with the Commission.

[13] *See* Proposed ISE Rule 2201(8).

[14] *See* Proposed ISE Rule 2207. The Exchange will also disseminate FCO quotes and trades through OPRA.

[15] *See* File No. SR–OCC–2007–02 (proposing to amend OCC's by-laws and rules to accommodate the clearance and settlement of ISE's FCOs).

[16] *See* Proposed ISE Rule 2201(3) (defining ''exercise price'').

[17] *See* Proposed ISE Rule 2206(a)(4).

[18] *See* ISE Rules 2000 and 2001.

[19] *See* Proposed ISE Rule 2205. While the proposed rules would permit the Exchange to list FCOs that have up to 36 months to expiration, the Exchange has stated that it does not anticipate listing these long-term series initially.

intervals,[20] or that have up to 36 months to expiration.[21] The expiration date for the consecutive and cycle month options would be 11:59 p.m. Eastern Time on the Saturday immediately following the third Friday of the expiration month.

Settlement Value. The closing settlement value would be based on the Noon Buying Rate (to the extent it is maintained for the applicable Currency), as determined by the Federal Reserve Bank of New York, on the last trading day during expiration week,[22] and would be modified using the applicable modifier that is used in calculating the respective modified exchange rate.[23] If the Noon Buying Rate is not announced by 2 p.m. Eastern Time, the closing settlement value would be the most recently announced Noon Buying Rate, as modified by the applicable modifier, unless the Exchange determines to apply an alternative closing settlement value as a result of extraordinary circumstances.[24] In the event that the Noon Buying Rate is not published for an underlying Currency, the Exchange proposes to apply the WM/Reuters Closing Spot rate to determine the closing settlement value.[25] Like the Noon Buying Rate, in determining the closing settlement value, the WM/Reuters Closing spot rate would be modified using the applicable modifier that is used in calculating the respective modified exchange rate. The Exchange proposes to post closing settlement values on its Web site, but such values would not be disseminated through OPRA.[26]

Position Limits. The Exchange proposes to impose the following position limits for FCOs involving the U.S. Dollar on the same side of the market: 1,200,000 contracts for the euro; 600,000 contracts for the Australian dollar, the British pound, the Canadian dollar, the Israeli shekel, the Japanese yen, the Swedish krona and the Swiss franc; 300,000 contracts for the remaining Currencies.[27] Position limits for each of the proposed cross-rate FCOs are specified in proposed ISE Rule 2008.[28] Exercise limits for FCOs over any five consecutive business days would be equivalent to the position limits prescribed to that FCO.[29]

Hours of Trading. The Exchange proposes to permit trading of FCOs on the Exchange between the hours of 9:30 a.m. and 4:15 p.m. Eastern Time, except that on the last trading day of the week during which a FCO is set to expire, trading would cease at 12 p.m. Eastern Time.[30] The opening rotation for FCOs would be held at or as soon as practicable after the Exchange's market opens, unless an Exchange official determines to delay the opening rotation in the interest of maintaining a fair and orderly market.[31] Trading in FCOs would follow the holiday schedule of the U.S. equity markets.

B. Market Makers

The Exchange proposes to create two new classes of market makers on the Exchange that may quote and trade FCOs: FXPMMs (*i.e.*, primary market makers) and FXCMMs (*i.e.*, competitive market makers).[32] The Exchange states that such market makers would have similar obligations to the PMMs and CMMs on the Exchange's equity and index markets. The proposed rule sets forth the rules and the obligations of such market makers and the procedures under which an FXPMM and/or FXCMM would be able to purchase a trading license from the Exchange.[33] Market maker trading licenses for a calendar year would be sold annually through an auction conducted during the fourth quarter of the preceding year.[34]

FXPMM. The Exchange proposes to offer one FXPMM trading license per currency pair by a sealed bid auction, and prospective FXPMMs would be required to submit a bid amount with a market quality commitment using parameters similar to those currently used by the Exchange for ETF and index options.[35] An FXPMM's trading license would have a three year term,[36] and at the end of the three year term, the incumbent FXPMM would have the right of first refusal to match the highest bid and market quality commitment from another bidding firm. An FXPMM that continuously fails to meet its stated market quality commitments would have its trading license terminated.

FXCMM. The Exchange proposes to initially sell ten FXCMM trading licenses per currency pair, with each trading license having a term of one year.[37] The Exchange proposes to conduct a ''Dutch'' auction to sell FXCMM trading licenses.[38] An FXCMM would have the ability to terminate its trading license prior to its scheduled expiration, so long as the FXCMM provides the requisite written notice and pays a termination fee.[39]

C. Margin

The Exchange is also proposing to amend its existing margin requirements

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[20] Consecutive month and cycle month expirations of a given series will never overlap. *See* Proposed ISE Rule 2205(a)(1).

[21] *See* Proposed ISE Rule 2205; *see also* Notice, *supra* note 5 (describing the proposed provisions governing the listing and trading of series of FCOs).

[22] If Friday is an Exchange holiday, the settlement value for FCOs would be determined on the preceding trading day, which will also be the last trading day for the expiring option.

[23] *See* Proposed ISE Rule 2212; *see also supra* note 12 and accompanying text (discussing rate modifiers).

[24] In such cases, the Exchange has stated that it may use the WM/Reuters Closing Spot rate.

[25] *See* Notice, *supra* note 5 (providing a detailed discussion of how the WM/Reuters Closing Spot rate is calculated and providing a list of the Currencies for which the Federal Reserve Bank of New York does not currently publish a Noon Buying Rate). In the event the Federal Reserve Bank of New York begins to publish a Noon Buying Rate for any of the Currencies for which it currently does not publish a Noon Buying Rate, the Exchange would resort to the Noon Buying Rate in place of the WM/Reuters Composite Spot rate to determine the closing settlement value for the applicable FCO.

[26] The Commission notes that, as discussed above, modified exchange rates will be disseminated through OPRA, as will FCO quotes and trades, while closing settlement values will only be posted on the Exchange's Web site. Investors should consult these values when trading FCOs.

[27] *See* Proposed ISE Rule 2208. For the purpose of determining which positions are on the same side of the market, long call positions would be aggregated with short put positions and short call positions would be aggregated with long put positions.

[28] *See* Amendment No. 2 and proposed ISE Rule 2208(a).

[29] *See* Proposed ISE Rule 2209.

[30] *See* Proposed ISE Rule 2210(a).

[31] *See* Proposed ISE Rule 2210(b); *see also* Notice, *supra* note 5 (providing further details regarding trading rotations and instituting halts and suspensions in the trading of an FCO).

[32] *See* Proposed ISE Rule 2213.

[33] *See* Proposed ISE Rule 2213; *see also* Notice, *supra* note 5 (providing a detailed discussion of rules governing market maker trading licenses). Under the proposed rules, a firm would not be permitted to hold more than four FXPMM trading licenses across all currencies or more than one FXCMM trading license per currency pair. Additionally, market makers would not be permitted to hold and act as both a FXPMM and FXCMM in the same currency pair. Market maker trading licenses would generally not be able to be leased or transferred, although they would be permitted to be transferred to an affiliated Member, or to another qualified Member which continues substantially the same business as the Member that currently holds the market maker trading license.

[34] *See* Proposed ISE Rule 2213; *see also* Notice, *supra* note 5 (describing the rules governing the auction processes). The Exchange proposes to assess market maker trading licenses that are sold between annual auctions a premium of ten percent of the price at which the market maker trading license was sold during the preceding auction.

[35] *See* Proposed ISE Rule 2213(f).

[36] The proposed rule provides that an FXPMM generally would not be permitted to terminate its trading license. In the event a FXPMM is unable to fulfill its obligations, a backup FXPMM would be designated by the Exchange; however, the FXPMM would be required to continue to pay its trading license price until the license expires. *See* Proposed ISE Rule 2213(f)(6).

[37] *See* Proposed ISE Rule 2213(g). Based on market demand, the Exchange may increase the number of FXCMM trading licenses available at the next regularly scheduled auction.

[38] *See* Proposed ISE Rule 2213(g)(2) (setting forth the manner in which the Exchange will conduct the ''Dutch'' auction).

[39] *See* Proposed ISE Rule 2213(g)(4).

by adopting a provision for FCOs that is substantially similar to the Phlx's margin rules for foreign currency options.[40] Accordingly, FCOs would have the same customer margin requirements as are provided in Phlx Rule 722, ''Margin Accounts,'' Commentary .16.[41] The Exchange would inform Members and the public of the margin levels for each currency option immediately following the quarterly reviews described in the proposed rule.

D. Customer Protection and Surveillance

The Exchange's existing rules designed to protect public customer trading would apply to trading in FCOs. Specifically, ISE Rules 608(a) and (b) prohibit Members from accepting a customer order to purchase or write an option unless such customer's account has been approved in writing by a designated Options Principal of the Member. Additionally, ISE Rule 610 regarding suitability provides that options should only be sold to customers capable of evaluating and bearing the risks associated with trading in this instrument. Further, ISE Rule 611 permits members to exercise discretionary power with respect to trading options in a customer's account only if the Member has received prior written authorization from the customer and the account had been accepted in writing by a designated Options Principal. ISE Rule 611 also requires designated Options Principals or Representatives of a Member to approve and initial each discretionary order on the day the discretionary order is entered. These customer protection rules, as well as ISE Rule 609, ''Supervision of Accounts,'' ISE Rule 612, ''Confirmation to Customers,'' and ISE Rule 616, ''Delivery of Current Options Disclosure Documents and Prospectus,''[42] would apply to trading in FCOs.

FCOs would be covered under the ISE's existing surveillance program. Specifically, the Exchange has represented that it has an adequate surveillance program in place for FCOs, and intends to apply the same program procedures that it applies to the Exchange's index options.[43] The Exchange has also noted that it is a member of the Intermarket Surveillance Group (''ISG'') and may obtain trading information via the ISG from other exchanges who are members or affiliates of the ISG.[44]

III. Discussion

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b)(5) of the Act,[45] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to 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.[46]

The Commission believes that FCOs may provide investors with additional strategic investment and hedging tools. As such, the Commission believes that the availability of FCOs may provide investors with greater flexibility in meeting their investment objectives. The Commission notes that, while ISE's FCOs differ in some respects from other foreign currency option products, the Commission has recently approved the trading of cash-settled foreign currency options on another national securities exchange.[47] As discussed further below, the Commission believes that ISE's proposed rules adequately address any concerns raised by the listing and trading of FCOs (*e.g.*, transparency, customer protection, surveillance) and provide for adequate and proper regulation of the listing and trading of FCOs on ISE.

A. Dissemination of Information

The Commission notes that the underlying value of ISE's proposed FCOs are intended to ''look and feel'' like index options. To achieve this, ISE will base each FCO on a modified exchange rate (*i.e.*, ISE will multiply the Reuters Composite Currency Rate by a pre-determined, fixed amount of 1, 10, or 100).[48] The purpose of the modifier is to bring the underlying value of an FCO up to a level that more closely resembles the value an investor would customarily see for an index option. Accordingly, dissemination of the modified exchange rates by ISE is essential to inform investors' trading of FCOs. In this respect, ISE will disseminate current modified exchange rates for each FCO at least once every fifteen seconds over OPRA or one or more major market data vendors for all the currency rates on which it intends to list options.[49]

With respect to the underlying components that make up an FCO, the Commission notes that an investor can access a list of the modifiers that are used in creating each of the modified exchange rates upon which the FCOs are based by consulting ISE's Web site. Further, the Commission believes that sufficient venues exist for obtaining reliable information on the Currencies so that investors in FCOs can monitor the underlying spot market in the Currencies. These foreign exchange rates are widely available via public Web sites, broker Web sites, as well as in print publications.[50]

[40] *See* Proposed ISE Rule 1202(d).

[41] Similar to Phlx Rule 722, Commentary .16, the Exchange would calculate the margin requirement for customers that assume short FCO positions by adding a percentage of the current market value of the underlying foreign currency contract to the option premium price less an adjustment for the out-of-the-money amount of the option contract. On a quarterly calendar basis, ISE would review five-day price changes over the preceding three-year period for each underlying currency and set the add-on percentage at a level which would have covered those price changes at least 97.5% of the time (the ''confidence level''). If the results of subsequent reviews show that the current margin level provides a confidence level below 97%, ISE would increase the margin requirement for that individual currency up to a 98% confidence level. If the confidence level is between 97% and 97.5%, the margin level would remain the same but will be subject to monthly follow-up reviews until the confidence level exceeds 97.5% for two consecutive months. If during the course of the monthly follow-up reviews, the confidence level drops below 97%, the margin level would be increased to a 98% level and if it exceeds 97.5% for two consecutive months, the currency would be taken off monthly reviews and will be put back on the quarterly review cycle. If the currency exceeds 98.5%, the margin level would be reduced to a 98% confidence level during the most recent 3 year period. Finally, in order to account for large price movements outside the established margin level, if the quarterly review shows that the currency had a price movement, either positive or negative, greater than two times the margin level during the most recent 3 year period, the margin requirement would be set at a level to meet a 99% confidence level (''Extreme Outlier Test'').

[42] The OCC, together with the Exchange, has prepared an amendment to the Options Disclosure Document (''ODD''), to include characteristics of the Exchange's FCOs and trading examples.

[43] *See* Notice, *supra* note 5, at 72 FR 9368.

[44] *See id.*

[45] 15 U.S.C. 78f(b)(5).

[46] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[47] *See* Securities Exchange Act Release No. 54989 (December 21, 2006), 71 FR 78506 (December 29, 2006) (SR–PHLX–2006–34); *see also* Phlx Rules 1000–1093. As noted above, ISE's FCOs will be rate-modified, whereas Phlx lists and trades cash-settled foreign currency options that are not rate-modified.

[48] *See supra* note 12 and accompanying text (discussing the use of rate modifiers).

[49] *See* Proposed ISE Rule 2207. The Exchange will also disseminate FCO quotes and trades over OPRA.

[50] For example, Web sites such as Bloomberg.com, Reuters.com, Yahoo! Finance, CNBC.com, OANDA.com, and Nasdaq.com provide free currency data. In addition, Investors Business Daily, Wall Street Journal, and the New York Times all provide currency data as part of their daily coverage.

The Commission also notes that investors can readily obtain information regarding futures trading on the Currencies, as the Exchange proposes to trade FCOs only on those Currencies whose futures contracts, and options on such futures contracts, are currently traded on the CME.

B. Settlement Value

An FCO's closing settlement value will be the Noon Buying Rate or the WM/Reuters Closing Spot rate, as applicable,[51] on the trading day prior to expiration,[52] as modified by the applicable modifier. Settlement values will be posted on the Exchange's Web site, and will be publicly available to all visitors to the ISE's Web site. The Commission believes that the Exchange's procedures and the competitive nature of the spot market for the Currencies should help to ensure that the settlement values for FCO contracts will accurately reflect the spot price for foreign currencies.

C. Customer Protection

The Commission believes that a regulatory system designed to protect public customers must be in place before the trading of sophisticated financial instruments, such as ISE's proposed FCOs, can commence trading on a national securities exchange. The Commission believes that this goal has been satisfied by the application of ISE's existing customer protection rules to FCOs.[53] As noted above, the Exchange's customer protection rules regarding customer suitability, discretionary accounts, supervision of accounts, confirmation to customers, and delivery of the ODD, among others, will extend to the trading of FCOs. The Commission also notes that the ODD is being amended to include characteristics and trading examples of the Exchange's FCOs and that the Exchange plans to deliver a circular to its members describing the specific risks associated with FCOs. Accordingly, the Commission believes that ISE has provided adequate safeguards to help ensure the protection of investors in FCOs.

D. Surveillance

The Commission notes that ISE will integrate FCOs into its existing market surveillance program and that it intends to apply the same program procedures to FCOs that it applies to the Exchange's index options. Further, ISE will have the ability to obtain trading information via the ISG from other exchanges who are members or affiliates of the ISG.[54] In addition, the major futures exchanges are affiliate members of the ISG, which will allow ISE to obtain surveillance information regarding potential intermarket trading abuses from futures exchanges (such as the CME). Therefore, the Commission believes that ISE should have the tools necessary to allow it to adequately surveil trading in FCOs.

E. Position and Exercise Limits and Margin Requirements

The Commission believes that the position and exercise limits proposed by the Exchange for FCOs are reasonably designed to protect the options and related markets from disruptions or manipulation.[55] At the same time, the Commission believes that such position and exercise limits should not hamper the depth and liquidity of the market for FCOs. The Commission also notes that the margin requirements that ISE proposes to adopt for FCOs are substantially similar to Phlx's margin requirements for foreign currency options, which has been approved by the Commission.[56] Accordingly, the Commission believes that the proposed position and exercise limits and margin requirements are appropriate and consistent with the Act.

F. Market Maker Trading Licenses

The Commission believes that the provisions governing the two new classes of market makers that will be permitted to trade FCOs on the Exchange, FXPMMs and FXCMMs, are consistent with the Act. The Commission notes that FXPMMs and FXCMMs will be bound by similar obligations as the PMMs and CMMs of the Exchange's equity markets.[57] In addition, the Commission notes that, in order to obtain a trading license, FXPMMs will be required provide the Exchange with market quality commitments along with a bid.[58] If an FXPMM continuously fails to meet its stated market quality comments, it will have its trading license terminated by the Exchange.[59]

The Commission believes that the procedures under which the Exchange proposes to offer market maker trading licenses are reasonably calculated to provide fair access to the Exchange. Specifically, the Commission believes that the provisions governing the Dutch auction, by which FXCMM trading licenses will be sold, are designed to ensure that market maker trading licenses are widely available.[60] For example, the proposed rule permits the Exchange to increase the number of FXCMM trading licenses available at the next regularly scheduled auction based on market demand; specifies a reasonable minimum Reserve Price; limits the number of market maker trading licenses that may be bid by a single Member; and gives the Exchange the ability to sell additional unsold market maker trading licenses during the year at a 10% premium.[61] In addition, the Commission believes that the proposed sealed bid auction for FXPMM trading licenses is reasonably calculated to award trading licenses in a fair and reasonable manner and provide fair access to the Exchange.[62] The requirement that bidders provide a quality market commitment in addition to their bid will allow the Exchange to grant FXPMM trading licenses in an objective manner without awarding a trading license solely based on the highest bid.

G. Other Rules

The Commission believes that the other rule changes proposed by ISE to accommodate the trading of FCOs also are consistent with the Act. Further, the Commission notes that the Exchange has represented that it has the necessary systems capacity to support the additional quotations and messages that will result from listing and trading of FCOs.[63]

In particular, the Commission believes that it is reasonable and consistent with the Act for the Exchange to apply its current minimum trading increment requirements to FCOs, so that the minimum trading increment for an FCO trading at less than $3.00 will be $0.05 and the minimum trading

[51] *See* Proposed ISE Rule 2212. As noted above, in the event that the Federal Reserve Bank of New York does not maintain or publish a Noon Buying Rate for an underlying Currency, the Exchange will apply the WM/Reuters Closing Spot rate to determine the closing settlement value for a particular FCO.

[52] If the Noon Buying Rate is not announced by 2 p.m. Eastern Time, the closing settlement value would be the most recently announced Noon Buying Rate, as modified by the applicable modifier, unless the Exchange determines to apply an alternative closing settlement value as a result of extraordinary circumstances. The WM/Reuters Closing Spot rate would be one of the alternative closing settlement values available to ISE for use in such a situation.

[53] *See supra* Section II.D (Customer Protection and Surveillance).

[54] The members of the ISG include all of the U.S. registered stock and options markets.

[55] *See* Proposed ISE Rules 2208 and 2209.

[56] *See supra* notes 40 and 41 and accompanying text (discussing the proposed margin requirements).

[57] *See* Notice, *supra* note 5.

[58] *See* Proposed ISE Rule 2213(f)(2).

[59] *See* Proposed ISE rule 2213(f)(4).

[60] *See* Proposed ISE Rule 2213(g).

[61] *Id.*

[62] *See* Proposal ISE Rule 2213(f).

[63] *See* Letter from Michael Simon, General Counsel, ISE, to John Roeser, Assistant Director, Commission, dated February 23, 2007.

increment for an FCO trading at $3.00 or higher will be $0.10.[64] In addition, the Commission believes that it is reasonable for the Exchange to list exercise prices of series at intervals no less than $0.10.[65] Further, the Exchange believes that it appropriate for the Exchange to list FCOs with expirations that are the same as the expirations currently permitted for index options, with the exception that FCO long-term series will only have expirations up to 36 months.[66]

The Commission also notes that, consistent with the Act, the proposed rules provide that the Exchange will have the ability to withdraw approval of the trading of a FCO if advisable in the public interest or for the protection of investors,[67] and an Exchange official will have the authority to halt or suspend trading in an FCO under certain circumstances in the interest of a fair and orderly market.[68]

H. Accelerated Approval

The Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after publishing notice of Amendment No. 2 in the **Federal Register**. The Commission notes that the proposal, as modified by Amendment No. 1, was published for notice and comment,[69] and that the Commission received no comment letters on the proposal. Amendment No. 2 proposes to amend the proposed rules to specify the 47 cross-rate FCOs that ISE proposes to list and trade, as well as specify the position and exercise limits and the applicable rate modifiers for each proposed cross-rate FCO. The Commission notes that the Exchange expressed its intention to list cross-rate FCOs in its Exhibit 3 to the original proposed rule change, and that Amendment No. 2 provided the additional clarification necessary to allow the Exchange to do so. The Commission also notes that the proposed cross-rate FCOs are based on the same Currencies set forth in the original proposal, as modified by Amendment No. 1 and published in the **Federal Register**, and they are subject to the same rules and requirements as other FCOs. As such, the Commission believes that Amendment No. 2 does not raise any new or novel issues. Accordingly, the Commission finds good cause, consistent with Section 19(b)(2) of the Act,[70] to approve the proposal, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

[64] *See* ISE Rule 710.

[65] *See* Proposed ISE Rule 2206(a)(4).

[66] *See* Proposed ISE Rule 2205.

[67] *See* Proposed ISE Rule 2204.

[68] *See* Proposed ISE Rule 2210.

[69] *See* Notice, *supra* note 5.

[70] 15 U.S.C. 78s(b)(2).

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–ISE–2006–59 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–ISE–2006–59. 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. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2006–59 and should be submitted on or before May 1, 2007.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[71] that the proposed rule change (SR–ISE–2006–59), as modified by Amendment Nos. 1 and 2, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[72]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6655 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

[71] 15 U.S.C. 78s(b)(2).

[72] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55571; File No. SR–ISE–2007–21]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fee Changes

April 3, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 26, 2007, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the ISE. The ISE has designated this proposal as one establishing or changing a due, fee, or other charge applicable only to a member under Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE is proposing to amend its Schedule of Fees to establish fees for transactions in options on seven Premium Products.[5] The text of the proposed rule change is available on the ISE's Web site (*http://*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] ''Premium Products'' is defined in the Schedule of Fees as the products enumerated therein.

www.iseoptions.com/legal/proposed_rule_changes.asp), at the ISE, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the ISE 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 ISE 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 is proposing to amend its Schedule of Fees to establish fees for transactions in options on the following seven Premium Products: iShares Dow Jones U.S. Basic Materials Sector Index Fund (''IYM''),[6] iShares MSCI Germany Index Fund (''EWG''), iShares MSCI Australia Index Fund (''EWA''), iShares S&P 500 Growth Index Fund (''IVW''), iShares S&P 500 Value Index Fund (''IVE''),[7] iShares KLD Select Social Index Fund (''KLD''), and iShares KLD 400 Social Index Fund (''DSI'').[8]

All of the applicable fees covered by this filing are identical to fees charged by the Exchange for all other Premium Products.[9] Specifically, the Exchange is proposing to adopt an execution fee and a comparison fee for all transactions in options on IYM, EWG, EWA, IVW, IVE, KLD and DSI.[10] The amount of the execution fee and comparison fee for products covered by this filing shall be $0.15 and $0.03 per contract, respectively, for all Public Customer Orders[11] and Firm Proprietary orders. The amount of the execution fee and comparison fee for all ISE Market Maker transactions shall be equal to the execution fee and comparison fee currently charged by the Exchange for ISE Market Maker transactions in equity options.[12] Finally, the amount of the execution fee and comparison fee for all non-ISE Market Maker transactions shall be $0.16 and $0.03 per contract, respectively. Further, since options on IYM, EWG, EWA, IVW, IVE, KLD and DSI are multiply-listed, the Payment for Order Flow fee shall also apply. The Exchange believes the proposed rule change will further the Exchange's goal of introducing new products to the marketplace that are competitively priced.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[13] in general, and furthers the objectives of Section 6(b)(4),[14] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing 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[15] and Rule 19b–4(f)(2)[16] thereunder. 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 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,

[6] iShares® is a registered trademark of Barclays Global Investors, N.A. (''BGI''), a wholly owned subsidiary of Barclays Bank PLC. ''Dow Jones,'' and ''Dow Jones U.S. Basic Materials Sector Index Fund'' are trademarks and service marks of Dow Jones & Company, Inc. (''Dow Jones'') and have been licensed for use for certain purposes by BGI. All other trademarks and service marks are the property of their respective owners. IYM is not sponsored, endorsed, issued, sold or promoted by Dow Jones. BGI and Dow Jones have not licensed or authorized ISE to: (i) Engage in the creation, listing, provision of a market for trading, marketing, and promotion of options on IYM; or (ii) use and refer to any of their trademarks or service marks in connection with the listing, provision of a market for trading, marketing, and promotion of options on IYM or with making disclosures concerning options on IYM under any applicable federal or state laws, rules or regulations. BGI and Dow Jones do not sponsor, endorse, or promote such activity by ISE, and are not affiliated in any manner with ISE.

[7] iShares® is a registered trademark BGI, a wholly owned subsidiary of Barclays Bank PLC. ''Standard & Poor's®,'' ''S&P®,'' ''S&P 500®,'' are trademarks of The McGraw-Hill Companies, Inc. (''McGraw-Hill''), and have been licensed for use for certain purposes by BGI. Neither IVW nor IVE are sponsored, sold or endorsed by Standard & Poor's, (''S&P''), a division of McGraw-Hill, and S&P makes no representation regarding the advisability of investing in IVW and IVE. ''MSCI Germany Index'' and ''MSCI Australia Index'' are service marks of Morgan Stanley Capital International (''MSCI'') and have been licensed for use for certain purposes by BGI. All other trademarks and service marks are the property of their respective owners. Neither EWG nor EWA are sponsored, endorsed, issued, sold or promoted by MSCI. BGI, S&P and MSCI have not licensed or authorized ISE to: (i) engage in the creation, listing, provision of a market for trading, marketing, and promotion of options on IVW, IVE, EWG and EWA; or (ii) use and refer to any of their trademarks or service marks in connection with the listing, provision of a market for trading, marketing, and promotion of options on IVW, IVE, EWG and EWA or with making disclosures concerning options on IVW, IVE, EWG and EWA under any applicable federal or state laws, rules or regulations. BGI, S&P and MSCI do not sponsor, endorse, or promote such activity by ISE, and are not affiliated in any manner with ISE.

[8] iShares® is a registered trademark of BGI, a wholly owned subsidiary of Barclays Bank PLC. ''KLD Select Social℠ Index'' and ''Domini 400 Social℠ Index'' are service marks of KLD Research & Analytics, Inc. and have been licensed for use for certain purposes by BGI. All other trademarks and service marks are the property of their respective owners. Neither KLD nor DSI are sponsored, endorsed, issued, sold or promoted by KLD Research & Analytics, Inc. BGI and KLD Research & Analytics, Inc. have not licensed or authorized ISE to: (i) Engage in the creation, listing, provision of a market for trading, marketing, and promotion of options on KLD and DSI; or (ii) use and refer to any of their trademarks or service marks in connection with the listing, provision of a market for trading, marketing, and promotion of options on KLD and DSI or with making disclosures concerning options on KLD and DSI under any applicable federal or state laws, rules or regulations. BGI and KLD Research & Analytics, Inc. do not sponsor, endorse, or promote such activity by ISE, and are not affiliated in any manner with ISE.

[9] The Exchange represents that IYM, EWG, EWA, IVW, IVE, KLD and DSI constitute ''Fund Shares,'' as defined by ISE Rule 502(h).

[10] These fees will be charged only to Exchange members. Under a pilot program that is set to expire on July 31, 2007, these fees will also be charged to Linkage Orders (as defined in ISE Rule 1900). *See* Securities Exchange Act Release No. 54204 (July 25, 2006), 71 FR 43548 (August 1, 2006) (SR–ISE–2006–38).

[11] ''Public Customer Order'' is defined in Exchange Rule 100(a)(39) as an order for the account of a Public Customer. ''Public Customer'' is defined in Exchange Rule 100(a)(38) as a person that is not a broker or dealer in securities.

[12] The execution fee is currently between $0.21 and $0.12 per contract side, depending on the Exchange Average Daily Volume, and the comparison fee is currently $0.03 per contract side.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 19b–4(f)(2).

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 No. SR–ISE–2007–21 on the subject line.

Paper Comments:

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2007–21. 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. Copies of such filing also will be available for inspection and copying at the principal office of the ISE. 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–ISE–2007–21 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

Florence E. Harmon,

Deputy Secretary.

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BILLING CODE 8010–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55576; File No. SR–NASDAQ–2007–026]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Pricing for Nasdaq Members Using the Nasdaq Market Center

April 3, 2007.

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 22, 2007, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by Nasdaq. Nasdaq has designated this proposal as one establishing or changing a due, fee, or other charge under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective immediately upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to modify the pricing for Nasdaq members using the Nasdaq Market Center. The text of the proposed rule change is available at Nasdaq, on the Exchange's Web site at *http://www.nasdaq.com*, and in 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, Nasdaq 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. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to conform its execution fees and liquidity-provider rebates for transactions in non-Nasdaq-listed securities priced under $1 to the current fees and rebates for Nasdaq-listed securities priced under $1. The execution fees for such transactions will be 0.1% of the total transaction cost, and the liquidity-provider rebate will be zero.[5] Thus, for example, the execution fee for a trade of 100 shares in a stock priced at $0.70 would be $0.07, with no rebate to the liquidity provider.

Nasdaq is also proposing to modify the routing fee for Nasdaq-listed and non-Nasdaq-listed securities priced under $1 to 0.3% of the total transaction cost.[6] The change reflects the fact that under Rule 610 of Regulation NMS,[7] market centers to which Nasdaq routes may charge Nasdaq only up to 0.3% of the transaction cost for executing routed orders in securities priced under $1.

Nasdaq recently began trading non-Nasdaq-listed securities priced under $1 in sub-penny increments. As a result, Nasdaq has seen an increase in its share volume in these securities. Nasdaq believes that, as is true for Nasdaq-listed securities, the pricing structure for these securities ensures that market participants do not pay execution or routing fees, or receive rebates, that are disproportionately large when compared with the dollar value of a particular transaction. Nasdaq believes that the changes also ensure that execution fees are in compliance with Rule 610 of Regulation NMS. Separately, Nasdaq has filed a proposal for a retroactive reduction in the fees charged for executions of non-Nasdaq-listed securities priced under $1 for the period from March 5 through March 21, 2007, to ensure that these fees are also in compliance with the requirements of Rule 610.

[5] For an order in a non-Nasdaq security through which a member accesses liquidity, this change will result in a fee reduction; for a quote or order through which a member acts as a liquidity provider, this change will eliminate the rebate previously paid to the member. *See* e-mail from John Yetter, Vice President and Deputy General Counsel, Nasdaq, to Sara Gillis, Attorney, Division of Market Regulation, Commission, on April 2, 2007 (''April 2, 2007 E-mail'').

[6] Depending on the price of the transaction and a member's average daily share volume during the month, this change may either constitute a fee increase or a fee reduction for a particular routed order. *See* April 2, 2007 E-mail, *supra* note 5.

[7] 17 CFR 242.610.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[8] in general, and with Section 6(b)(4) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system which Nasdaq operates or controls. Nasdaq believes that this change will ensure that the level of fees and rebates associated with trading securities at prices under $1 is consistent with the value of these securities, the costs of routing orders to other market centers for execution, and the requirements of Rule 610 of Regulation NMS.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change establishes or changes a due, fee, or other charge applicable only to a member imposed by Nasdaq, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and subparagraph (f)(2) of Rule 19b–4 thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–026 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–NASDAQ–2007–026. 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. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. 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–NASDAQ–2007–026 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6674 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55567; File No. SR–NYSE–2007–35]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Technical Amendments to the Amended and Restated Certificate of Incorporation of NYSE Euronext

April 2, 2007.

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 29, 2007, New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared substantially by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make certain technical changes to the amended and restated certificate of incorporation of NYSE Euronext to remove all references to ''Year 1 NYSE Shares'' and ''Year 1 NYSE Group Shares'' from the provisions regarding transfer restrictions and to clarify that it is the currently operative certificate of incorporation of NYSE Group, Inc. (and not the certificate of incorporation of NYSE Group, Inc. that will be operative after the closing of the Combination (as defined below)) which contains the definitions of the terms ''Year 2 NYSE Share'' and ''Year 3 NYSE Share.'' The text of the proposed rule change is available at the Exchange, *http://www.nyse.com*, and the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange, a New York limited liability company, registered national securities exchange, and self-regulatory organization, is submitting this rule filing to the Commission in connection with the proposed business combination (''Combination'') of NYSE Group, Inc., a Delaware corporation (''NYSE Group''), with Euronext N.V., a company organized under the laws of The Netherlands (''Euronext''). As a result of the Combination, the businesses of NYSE Group (including that of the Exchange and NYSE Arca, Inc., a Delaware corporation, registered national securities exchange, and self-regulatory organization) and Euronext will be held under a single, publicly traded holding company named NYSE Euronext, a Delaware corporation (''NYSE Euronext''). Following the Combination, each of NYSE Group and Euronext (or a successor Dutch holding company) will be a separate subsidiary of NYSE Euronext, and their respective businesses and assets will continue to be held as they are currently held (subject to any post-closing reorganization of Euronext). The Commission has approved the Exchange's rule filing in connection with the Combination (''Combination Filing'') [5] and the Combination is scheduled to close on April 4, 2007.

Subsequent to the Combination Filing's approval, the transfer restrictions on the Year 1 NYSE Shares, as defined in the currently operative certificate of incorporation of NYSE Group, expired, causing the references to ''NYSE Year 1 Shares'' and ''NYSE Group Year 1 Shares'' in the amended and restated certificate of incorporation of NYSE Euronext to become obsolete and potentially confusing. Additionally, the Exchange wishes to clarify that it is the currently operative certificate of incorporation of NYSE Group (and not the certificate of incorporation of NYSE Group that will be operative after the closing of the Combination) in which the terms ''Year 2 NYSE Share'' and ''Year 3 NYSE Share'' are defined. The Exchange is also adding the date on which the amended and restated certificate of incorporation of NYSE Euronext is being filed. The proposed changes do not affect the substance of the amended and restated certificate of incorporation of NYSE Euronext in any way. The Exchange needs the proposed rule change to be effective and operative prior to the consummation of the Combination, as it must file the amended and restated certificate of incorporation of NYSE Euronext with the Delaware Secretary of State before the closing of the Combination,[6] as contemplated by the Combination Filing.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirement under Section 6(b)(5) [7] of the Act that an exchange have rules that are designed to promote just and equitable principles of trade, 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.

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

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (A) Significantly affect the protection of investors or the public interest; (B) impose any significant burden on competition; and (C) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) thereunder.[9]

A proposed rule change filed under Rule 19b–4(f)(6) [10] normally may not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) [11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay, and designate the proposed rule change immediately operative.[12] The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[13] The Exchange has stated that the amended and restated certificate of incorporation of NYSE Euronext as modified by this proposed rule change must be filed with the Delaware Secretary of State before the closing of the Combination that is scheduled for April 4, 2007. The Commission notes that the proposed modifications to the amended and restated certificate of incorporation of NYSE Euronext are technical changes that are non-substantive. Accordingly, the Commission designates that the proposed rule change become operative immediately.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and

[5] Securities Exchange Act Release No. 55293 (February 14, 2007), 72 FR 8033 (February 22, 2007) (SR–NYSE–2006–120).

[6] The Commission notes that the Exchange included references in the proposed rule change to filing the amended and restated certificate of incorporation of NYSE Euronext with the Delaware Secretary of State and the Secretary of State of New York, before and at the closing of the Combination. The Commission staff clarified with the Exchange that the correct reference should be to filing with the Delaware Secretary of State before the closing of the Combination. Telephone conversation between Janet Kissane, Vice President and Associate General Counsel, NYSE Group, and Kim M. Allen, Special Counsel, Division of Market Regulation, Commission, on March 29, 2007.

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] *Id.*

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] The Exchange also asked the Commission to waive the five-business day pre-filing notice requirement. *See* Rule 19b–4(f)(6)(iii), 17 CFR 240.19b–4(f)(6)(iii). The Commission is exercising its authority to designate a shorter time, and notes that the Exchange provided the Commission with written notice of its intention to file the proposed rule change on March 26, 2007.

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

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–NYSE–2007–35 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–NYSE–2007–35. 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. 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–NYSE–2007–35 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6669 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55574; File No. SR–NYSE–2007–36]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Section 802.01C of the Listed Company Manual, Clarifying That the Exchange Uses the Closing Price Reported on the Consolidated Tape To Determine Compliance With Its Price Test

April 3, 2007.

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 29, 2007, the New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change is described in Items I, II, and III below, which Items have been substantially prepared by the Exchange. The NYSE filed this proposal pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(1) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NYSE proposes to amend Section 802.01C of its Listed Company Manual (the ''Manual'') to clarify that, for purposes of determining whether a company is below the $1.00 share price compliance standard, the Exchange uses the closing price reported on the consolidated tape. The text of the proposed rule change is available at the Exchange, on the Exchange's Web site at *http://www.nyse.com*, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 802.01C of the Manual provides that a company will be considered to be below compliance standards if the average closing price of a security is less than $1.00 over a consecutive 30 trading-day period. The Exchange proposes to amend Section 802.01C to clarify that the pricing information that it uses for this purpose is the closing price reported on the consolidated tape. The Exchange states that this is consistent with its longstanding practice in applying this rule.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) of the Act[5] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and, in general, 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 were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(i) of the Act[6] and Rule 19b–4(f)(1) thereunder[7] because it constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule. At any

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 5 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(1).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(i).

[7] 17 CFR 19b–4(f)(1).

time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2007–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2007–36. 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. Copies of such filing also will be available for inspection and copying at the principal offices 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–NYSE–2007–36 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6673 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55577; File No. SR–NYSEArca–2007–32]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to NYSE Arca Marketplace Trading Sessions

April 3, 2007.

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 23, 2007, 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 and II below, which Items have been substantially prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes, through NYSE Arca Equities, to update the list in NYSE Arca Equities Rule 7.34 of securities eligible to trade in one or more, but not all three, of the Exchange's trading sessions. The Exchange proposes to add to the list shares of certain Funds (''Shares'') that are traded on NYSE Arca, L.L.C. (''NYSE Arca Marketplace''), the equities trading facility of NYSE Arca Equities, pursuant to unlisted trading privileges (''UTP''). The text of the proposed rule change is available on the Exchange's Web site (*http://www.nysearca.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change. 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

NYSE Arca Equities Rule 7.34 currently provides, in part, that NYSE Arca Marketplace shall have three trading sessions each day: an Opening Session (1 a.m. Pacific Time (''PT'') to 6:30 a.m. PT), a Core Trading Session (6:30 a.m. PT to 1 p.m. PT) and a Late Trading Session (1 p.m. PT to 5 p.m. PT), and that the Core Trading Session for securities described in NYSE Arca Equities Rules 5.1(b)(13), 5.1(b)(18), 5.2(j)(3), 8.100, 8.200, 8.201, 8.202, 8.203, 8.300, and 8.400 (each, a ''Derivative Securities Product'') shall conclude at 1:15 p.m. PT.[5]

NYSE Arca Equities Rule 7.34 includes a list of those securities which are eligible to trade in one or more, but not all three, of the Exchange's trading sessions. The Exchange maintains on its Internet Web site (*http://www.nysearca.com*) a list that identifies all securities traded on the NYSE Arca Marketplace that do not trade for the duration of each of the three sessions specified in NYSE Arca Equities Rule 7.34. The Exchange proposes to add the following securities to these list: (1) PowerShares DB Agriculture Fund; (2) PowerShares DB Base Metals Fund; (3) PowerShares DB Energy Fund; (4) PowerShares DB Gold Fund; (5) PowerShares DB Oil Fund; (6) PowerShares DB Precious Metals Fund; (7) PowerShares DB Silver Fund; (8) PowerShares DB U.S. Dollar Index Bearish Fund; and (9) PowerShares DB

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] NYSE Arca Equities Rules 5.1(b)(13), 5.2(j)(3), 8.100, 8.200, 8.201, 8.202, 8.203, 8.300, and 8.400 relate to Unit Investment Trusts, Investment Company Units, Portfolio Depositary Receipts, Trust Issued Receipts, Commodity-Based Trust Shares, Currency Trust Shares, Commodity Index Trust Shares, Partnership Units, and Paired Trust Shares, respectively. *See* Securities Exchange Act Release No. 54997 (December 21, 2006), 71 FR 78501 (December 29, 2006) (SR–NYSEArca–2006–77) (amending NYSE Arca Equities Rule 7.34).

U.S. Dollar Index Bullish Fund.[6] These securities, which are Trust Issued Receipts as described in NYSE Arca Equities Rule 8.200 Commentary .02, are traded on the NYSE Arca Marketplace pursuant to UTP.

The Exchange proposes to delete the iShares® FTSE/Xinhua China 25 Index Fund from the lists since these securities are eligible to trade in all three of the Exchange's trading sessions.[7] These securities, which are Investment Company Units described in NYSE Arca Equities Rule 5.2(j)(3), are traded on the NYSE Arca Marketplace pursuant to UTP.

The Exchange proposes to change the trading sessions of iShares® COMEX Gold Trust trading session to accurately reflect that they are traded in the core trading session only.[8] The securities, which are Commodity-Based Trust Shares as described in NYSE Arca Equities Rule 8.201, are traded on the Exchange pursuant to UTP.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5),[10] in particular, in that it is designed to facilitate transactions in securities, to promote just and equitable principles of trade, to enhance competition, and 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

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12]

The Exchange has asked the Commission to waive the 30-day operative delay. The Commission believes that such waiver is consistent with the protection of investors and the public interest because the proposed rule change should provide transparency and more clarity with respect to the trading hours eligibility of certain derivative securities products and should promote consistency in the trading halts of derivative securities. The Commission notes that this filing does not change the trading hours of the Derivative Securities Products listed in NYSE Arca Equities Rule 7.34, but codifies trading hour sessions that have been established through other rule changes or through the use of the Exchange's generic listing standards pursuant to Rule 19b–4(e) under the Act. For these reasons, the Commission designates the proposed rule change as operative immediately.[13]

At any time within 60 days of the filing of the proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2007–32 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–NYSEArca–2007–32. 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. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File number SR–NYSEArca–2007–32 and should be submitted by or before May 1, 2007.

[6] The Commission has approved the trading of Shares of the PowerShares DB Agriculture Fund, PowerShares DB Base Metals Fund, PowerShares DB Energy Fund, PowerShares DB Gold Fund, PowerShares DB Oil Fund, PowerShares DB Precious Metals Fund, and PowerShares DB Silver Fund on the NYSE Arca Marketplace pursuant to UTP. *See* Securities Exchange Act Release No. 55453 (March 13, 2007), 72 FR 13333 (March 21, 2007) (SR–NYSEArca–2006–62). The Commission has approved the trading of Shares of the PowerShares DB U.S. Dollar Index Bearish Fund and PowerShares DB U.S. Dollar Index Bullish Fund on the NYSE Arca Marketplace pursuant to UTP. *See* Securities Exchange Act Release No. 55484 (March 16, 2007), 72 FR 13847 (March 23, 2007) (SR–NYSEArca–2006–67).

[7] The Commission has approved trading of these securities on the NYSE Arca Marketplace pursuant to UTP. *See* Securities Exchange Act Release No. 50799 (December 6, 2004), 69 FR 72242 (December 13, 2004) (SR–PCX–2004–99).

[8] The Commission has approved the trading of these securities on the NYSE Arca Marketplace pursuant to UTP. *See* Securities Exchange Act Release No. 51067 (January 21, 2005), 70 FR 3952 (January 27, 2005) (SR–PCX–2004–132).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires an exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has determined to waive the five-day pre-filing notice requirement in this case.

[13] For purposes only of waiving the operative date of this proposal, the Commission has considered the rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6675 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55578; File No. SR–NYSEArca–2007–29]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to NYSE Arca Rule 7.20 and 7.31

April 4, 2007.

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 20, 2007, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder, which renders it effective upon filing with the Commission.[4] 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

NYSE Arca, through its wholly owned subsidiary, NYSE Arca Equities, Inc. (''NYSE Arca Equities''), is proposing to amend its rules governing NYSE Arca, LLC (''NYSE Arca Marketplace''), the equities trading facility of NYSE Arca Equities. With this filing, the Exchange proposes to clarify: (1) That Equity Trading Permit (''ETP'') Holders who are not registered Market Makers[5] are prohibited from entering Q Orders pursuant to NYSE Arca Equities Rule 7.20(a), and (2) when Q Orders will automatically repost pursuant to NYSE Arca Equities Rule 7.31(*l*). 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 NYSE Arca 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 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

Pursuant to NYSE Arca Equities Rule 7.23(a)(1) (Obligations of Market Makers), Market Makers are required to maintain continuous, two-sided Q Orders in those securities in which the Market Maker is registered to trade. NYSE Arca Equities Rule 7.31(k)(1)(A) provides that a Market Maker may instruct the NYSE Arca Marketplace before 6:28 a.m. (Pacific Time) to enter a Q Order on its behalf at price levels set forth in Rule 7.31(k)(1)(A).[6] Furthermore, Rule 7.31(k) provides that upon execution, the Q Order entered pursuant to the Market Maker's instructions will automatically repost with the original size at $10 below the original bid or $10 above the original offer, but never below $0.01.

The amendment to Rule 7.31 reflected in this rule filing is consistent with the intent of the rule and how the system currently operates. Specifically, such automatic reposting will not occur if the Market Maker initially enters the Q Order without a reserve size, or if the Market Maker initially enters the Q Order with a reserve size and such reserve size is exhausted. The proposed amendment clarifies that under such circumstances, a Market Maker will be responsible for reposting a new Q Order in the security in order to remain in compliance with its continuous Q Order obligation pursuant to Rule 7.23(a)(1).

In addition, due to the broad definition of ''Q Order'' in Rule 7.31(k)(1), ETP Holders, who are not registered Market Makers, have been improperly acting as Market Makers by entering Q Orders on the NYSE Arca Marketplace. In order to prevent this practice, the Corporation is clarifying the language in NYSE Arca Equities Rule 7.20(a) to prohibit specifically ETP Holders not registered as Market Makers from acting as Market Markers (*i.e.,* submitting Q Orders) and make Rule 7.20(a) more consistent with the proposed changes to Rule 7.31(k)(l).

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[7] of the Act, in general, and furthers the objectives of Section 6(b)(5)[8] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

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

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)[9] and Rule 19b–4(f)(6) thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors,

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* NYSE Arca Rule 1.1(u).

[6] These price levels are: (1) At the last price and size entered by the Market Maker during the previous trading day, either including or excluding reserve size; (2) at a specified percentage from the best bid or offer; or (3) at the standard Q defined as $0.01 bid and 2 times the previous day's close for the offer with specified display and reserve sizes.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

or otherwise in furtherance of the purposes of the Act.

NYSE Arca has asked the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay. The Commission believes such waivers are consistent with the protection of investors and the public interest because they would permit the Exchange to codify the proposed clarifications without further delay.[11] For this reason, the Commission designates the proposal to be operative upon filing with the Commission.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2007–29 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–NYSEArca–2007–29. 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. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE Arca. 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–2007–29 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6710 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

[11] For purposes only of waiving the 30-day pre-operative period, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55579; File No. SR–OCC–2007–02]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Rate-Modified Foreign Currency Options

April 4, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on March 5, 2007, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared primarily by OCC. The Commission is publishing this notice and order to solicit comments on the proposed rule change from interested persons and to grant accelerated approval of the proposal.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change will allow OCC to clear and settle rate-modified foreign currency options (''Rate-Modified FCOs'') which have been proposed and approved for trading by the International Securities Exchange (''ISE'').[2]

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 55575 (April 3, 2007) (File No. SR–ISE–2006–59). For notice of the proposal, see Securities Exchange Act Release No. 55336 (February 23, 2007), 72 FR 9364 (March 1, 2007).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this rule change is to accommodate a request from ISE that OCC clear and settle Rate-Modified FCOs. OCC's By-Laws and Rules currently provide for the clearance and settlement of cash-settled foreign currency options (''Cash-Settled FCOs'').[4] However, unlike the Cash-Settled FCOs currently covered by OCC's By-Laws and Rules, the underlying interest for Rate-Modified FCOs is stated in terms of the exchange rate between a ''currency pair,'' one of which may be the U.S. dollar or both of which may be non-U.S. currencies, as modified by a ''rate modifier'' determined by ISE.

The rate modifier for Rate-Modified FCOs is selected so that the underlying modified rate looks similar to an index. The exchange rates underlying Rate-Modified FCOs may or may not be stated in the same way that they are conventionally quoted in the spot market. For example, exchange rates between the U.S. dollar and the euro are generally quoted as dollars per euro on the spot market, but the rate modifying a Rate-Modified FCO could be stated as euros per dollar. The number by which the exchange rate is multiplied to determine the modified rate for a particular class of options will be 1, 10 or 100 depending on the level of the exchange rate in question.

For purposes of determining an exercise settlement amount, Rate-Modified FCOs would use a multiplier

[3] The Commission has modified parts of these statements.

[4] The Commission recently approved a proposed rule change filed by OCC to accommodate Cash-Settled FCOs traded on the Philadelphia Stock Exchange (''Phlx''). Securities Exchange Act Release No. 54935 (December 13, 2006), 71 FR 76417 (December 20, 2006) (File No. SR–OCC–2006–10). The rule changes that were made with respect to the Phlx Cash-Settled FCOs will also apply to Rate-Modified FCOs.

of $100 (*i.e.*, the exercise settlement amount will be the difference between the strike price and the exercise settlement value of the underlying modified rate times the multiplier). The multiplier, which always has a value of $100, is not the same thing as the rate modifier. Similarly, premium quotations would be multiplied by $100 to obtain the aggregate premium amount for a single option.

The exercise settlement amount for Rate-Modified FCOs will be based on the noon buying rates for the underlying currencies as published by the Federal Reserve Bank of New York. If the Federal Reserve Bank does not publish a noon buying rate for a particular currency pair, ISE will use a rate obtained by a market data vendor. OCC will ordinarily look to ISE to supply the final value of the underlying for exercise settlement purposes, but OCC will retain its customary authority to set a value if none is available from ISE. Trading of Rate-Modified FCOs will ordinarily cease at 12:00 noon Eastern Time on the business day before the expiration date.

Rate-Modified FCOs are to be European style and will expire on the Saturday following the third Friday of the expiration month. Rate-Modified FCOs will have up to three near-term expiration months followed by three calendar quarter-end expiration months.

To accommodate Rate-Modified FCOs, OCC is proposing to add or modify certain defined terms in Article XXII of the By-Laws. Definitions of ''multiplier,'' ''rate-modified foreign currency options,'' ''underlying currency pair,'' and ''underlying modified rate'' will be added, and the definitions of ''call,'' ''exercise price,'' ''exercise settlement amount,'' ''premium,'' ''put,'' ''reporting authority,'' ''series of options'' and ''spot price'' will be amended to reflect the use of a modified exchange rate as the underlying interest for Rate-Modified FCOs. In addition, Section 5 of Article XXII of the By-Laws relating to the time for determination of the spot price will be amended for clarification. OCC will delete the definition of ''aggregate exercise price,'' which is no longer used in OCC's By-Laws or Rules with respect to Cash-Settled FCOs.

The introduction to Chapter XXIII of the Rules will be amended to make a non-substantive change to conform to the terminology in Article XXII of the By-Laws.

The proposed rule change is consistent with Section 17A of the Act because it is designed to promote the prompt and accurate clearance and settlement of transactions in Rate-Modified FCOs by applying the same basic rules and procedures to such options as are applied to other cash-settled foreign currency options. The proposed rule change is not inconsistent with the existing rules of OCC, including those rules proposed to be amended.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[5] The purpose of the proposed rule change is to amend OCC's By-Laws and Rules so that OCC may clear and settle the new Rate-Modified FCO product to be listed and traded on ISE. Accordingly, the proposed rule change should promote the prompt and accurate clearance and settlement of securities transactions.

OCC has requested that the Commission approve the proposed rule prior to the thirtieth day after publication of the notice of the filing. The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the publication of notice because such approval will allow ISE to commence trading of Rate-Modified FCOs without any unnecessary delay.

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–OCC–2007–02 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–OCC–2007–02. 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. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.optionsclearing.com.*

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–OCC–2007–02 and should be submitted on or before May 1, 2007.

V. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.[6]

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–2007–02) be and hereby is approved.

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6668 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55582; File No. SR–ODD–2007–01]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Approval of Accelerated Delivery of Supplement to the Options Disclosure Document Reflecting Certain Changes to Disclosure Regarding Rate-Modified Cash-Settled Foreign Currency Options

April 4, 2007.

On March 13, 2007, The Options Clearing Corporation (''OCC'') submitted to the Securities and Exchange Commission (''Commission''), pursuant to Rule 9b–1 under the Securities Exchange Act of 1934 (''Act''),[1] five preliminary copies of a supplement to its options disclosure document (''ODD'') reflecting certain changes to disclosure regarding rate-modified cash-settled foreign currency options (''Rate-Modified FCOs'').[2] On April 3, 2007, the OCC submitted to the Commission five definitive copies of the supplement.[3]

The ODD currently provides general disclosures on the characteristics and risks of trading standardize options. Recently, an options exchange amended its rules to permit the listing and trading of Rate-Modified FCOs.[4] The proposed supplement, which supersedes and replaces the January 2007 Supplement to the ODD,[5] provides disclosure on the characteristics of non-rate modified cash-settled foreign currency options (''Non-Rate Modified FCOs'') and adds new disclosure on the characteristics of Rate-Modified FCOs.

In addition to providing new disclosure on the characteristics of Rate-Modified FCOs, the proposed supplement to the ODD also reorganizes the January 2007 Supplement to distinguish disclosures regarding Non-Rate Modified FCOs from Rate-Modified FCOs, as well as providing a separate heading for certain disclosures pertaining to all dollar-denominated cash-settled foreign currency options. Further, the proposed supplement adds new clarification regarding exercise settlement values of Rate-Modified FCOs. The proposed supplement is intended to be read in conjunction with the more general ODD, which, as described above, discusses the characteristics and risks of options generally.[6]

Rule 9b–1(b)(2)(i) under the Act[7] provides that an options market must file five copies of an amendment or supplement to the ODD with the Commission at least 30 days prior to the date definitive copies are furnished to customers, unless the Commission determines otherwise, having due regard to the adequacy of information disclosed and the public interest and protection of investors.[8] In addition, five copies of the definitive ODD, as amended or supplemented, must be filed with the Commission not later than the date the amendment or supplement, or the amended options disclosure document, is furnished to customers. The Commission has reviewed the proposed supplement and finds, having due regard to the adequacy of information disclosed and the public interest and protection of investors, that the proposed supplement may be furnished to customers as of the date of this order.

It is therefore ordered, pursuant to Rule 9b–1 under the Act,[9] that definitive copies of the proposed supplement to the ODD (SR–ODD–2007–01), reflecting disclosure regarding Non-Rate Modified FCOs and adding disclosure regarding Rate-Modified FCOs, may be furnished to customers as of the date of this order.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6709 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55569; File No. SR–Phlx–2007–031]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Remove References to Intermarket Trading System (''ITS'') Plan

April 2, 2007.

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 27, 2007, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared substantially by the Exchange.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is proposing to amend Phlx Rules 452 and 607 and the XLE Fee Schedule to remove references to the Intermarket Trading System (''ITS'') Plan and to delete Phlx Rules 2000–2002, which implemented the ITS Plan trading rules on the Exchange.

The text of the proposed rule change is available at Phlx, the Commission's Public Reference Room and *http://www.phlx.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 Phlx has prepared summaries, set forth in Sections A, B, and C below, of the

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[7] 17 CFR 200.30–3(a)(12).

[1] 17 CFR 240.9b–1.

[2] *See* letter from Jean M. Cawley, First Vice President and Deputy General Counsel, OCC, to Sharon Lawson, Senior Special Counsel, Division of Market Regulation (''Division''), Commission, dated March 5, 2007.

[3] *See* letter from Jean M. Cawley, First Vice President and Deputy General Counsel, OCC, to Sharon Lawson, Senior Special Counsel, Division, Commission, dated April 3, 2007.

[4] *See* Securities Exchange Act Release No. 55575 (April 3, 2007) (approving File No. SR–ISE–2006–59).

[5] *See* Securities Exchange Act Release No. 55035 (December 29, 2006), 72 FR 1358 (January 11, 2007) (SR–ODD–2006–01) (''January 2007 Supplement'').

[6] The Commission notes that the options markets must continue to ensure that the ODD is in compliance with the requirements of Rule 9b–1(b)(2)(i) under the Act, 17 CFR 240.9b–1(b)(2)(i), including when future changes are made regarding Non-Rate Modified FCOs and Rate-Modified FCOs. Any future changes to the rules of the options markets would need to be submitted to the Commission under Section 19(b) of the Act. 15 U.S.C. 78s(b).

[7] 17 CFR 240.9b–1(b)(2)(i).

[8] This provision permits the Commission to shorten or lengthen the period of time which must elapse before definitive copies may be furnished to customers.

[9] 17 CFR 240.9b–1.

[10] 17 CFR 200.30–3(a)(39).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to conform the Exchange's rules to the recent elimination of the ITS Plan.[3] Phlx Rules 2000–2002 were adopted to implement the ITS Plan on the Exchange. Those rules contain the trade-through and locked/crossed market rules that governed trading in certain securities pursuant to the ITS Plan. Those rules are now obsolete with the elimination of the ITS Plan. Trade-through and locked/crossed market rules are now mandated by Regulation NMS[4] and codified in Phlx Rules 185 and 186. In addition, references to the ITS Plan are being removed from Phlx Rules 452 and 607 and the XLE Fee Schedule.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx 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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] As required under Rule 19b–4(f)(6)(iii) under the Act,[9] the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of the filing of the proposed rule change.

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[10] However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Phlx has requested that the Commission waive the 30-day operative delay and render the proposed rule change operative immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission has eliminated the ITS Plan, which makes the various Phlx rules that refer to and implement the trading rules of the ITS Plan obsolete. For the reasons stated above, the Commission therefore designates the proposal to become operative upon filing with the Commission.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2007–31 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–Phlx–2007–31. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Phlx. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2007–31 and should be submitted on or before May 1, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–6670 Filed 4–9–07; 8:45 am]

BILLING CODE 8010–01–P

[3] *See* Securities Exchange Act Release No. 55397 (March 5, 2007), 72 FR 11066 (March 12, 2007)(File No. 4–208).

[4] 17 CFR 242.610–611.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii).

[10] *Id.*

[11] *Id.*

[12] For purposes of waiving the operative date of this proposal only, the Commission has considered the impact of the proposed rule on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Advisory Committee on Veterans Business Affairs; Public Meeting

The U.S. Small Business Administration (SBA), pursuant to the Veterans Entrepreneurship and Small Business Development Act of 1999 (Pub. L. 106–50), SBA Advisory Committee on Veterans Business Affairs will host a public federal meeting on Tuesday, April 24, 2007. The meeting will take place at the SBA, 409 3rd Street, SW., Washington, DC 20416, starting at 9 a.m. until 5 p.m. The meeting will be held in the Eisenhower Conference Room, Side B; located on the 2nd floor. The purpose of this meeting is to focus on SBA's services, programs and outreach for veterans and service-disabled veterans.

Anyone wishing to attend must contact Cheryl Clark, Program Liaison in the Office of Veterans Business Development at (202) 205–6773 or send an e-mail to *cheryl.clark@sba.gov*.

Matthew Teague,

Committee Management Officer.

[FR Doc. E7–6642 Filed 4–9–07; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages that will require clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. The information collection packages that may be included in this notice are for new information collections, approval of existing information collections, revisions to OMB-approved information collections, and extensions (no change) of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and on ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Written comments and recommendations regarding the information collection(s) should be submitted to the OMB Desk Officer and the SSA Reports Clearance Officer. The information can be mailed, faxed or e-mailed to the individuals at the addresses and fax numbers listed below:

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, E-mail address: *OIRA_Submission@omb.eop.gov*.

(SSA), Social Security Administration, DCBFM, Attn: Reports Clearance Officer, 1333 Annex Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–965–6400, E-mail address: *OPLM.RCO@ssa.gov*.

I. The information collections listed below are pending at SSA and will be submitted to OMB within 60 days from the date of this notice. Therefore, your comments should be submitted to SSA within 60 days from the date of this publication. You can obtain copies of the collection instruments by calling the SSA Reports Clearance Officer at 410–965–0454 or by writing to the address listed above.

1. *Request for Hearing by Administrative Law Judge—20 CFR 404.929, 404.933, 416.1429, 404.1433, 405.722, 418.1350—0960–0269.* The information collected on Form HA–501–U5 is used by SSA to document and initiate the Administrative Law Judge (ALJ) hearing process for determining eligibility or entitlement to Social Security benefits (Title II), Supplemental Security Income payments (Title XVI), Special Veterans Benefits (Title VIII), Medicare (Title XVIII). This information will also be used to request appeal of initial determinations regarding Medicare Part B income-related premium subsidy reductions. The methods for filing a request for an ALJ hearing are being expanded to include the Internet. If an individual receives a notice of denial of his/her disability claim and the notice provides rights to an ALJ hearing, he/she will have the option of filing for the ALJ hearing over the Internet. The individual will complete the appropriate appeal screens and submit the appeal to SSA for processing. The respondents are individuals requesting an ALJ hearing.

Type of Request: Revision of an OMB-approved information collection.

Number of Respondents: 669,469.

Estimated Annual Burden: 178,525 hours.

Collection method	Number of respondents	Frequency of response	Estimated completion time	Total burden hours
Paper & Modernized Claims System	334,735	1	10 minutes ..	55,789
i501	334,734	1	22 minutes ..	122,736
Totals:	669,469			178,525

2. *Request for Reconsideration—20 CFR 404.907–404.921, 416.1407–416.1421, 408.1009—0960–0622.* The information collected on Form SSA–561–U2 is used by SSA to document and initiate the reconsideration process for determining eligibility or entitlement to Social Security benefits (Title II), Supplemental Security Income payments (Title XVI), Special Veterans Benefits (Title VIII), Medicare (Title XVIII). This information will also be used to request appeal of initial determinations regarding Medicare Part B income-related premium subsidy reductions. The methods for filing a request for reconsideration are being expanded to include the Internet. If an individual receives a notice of denial of his/her disability claim and the notice provides the right to reconsideration, he/she will have the option of filing for the reconsideration over the Internet. The individual will complete the appropriate appeal screens and submit the appeal to SSA for processing. The respondents are individuals filing for reconsideration.

Type of Request: Revision of an OMB-approved information collection.

Number of Respondents: 1,461,700.

Estimated Annual Burden: 341,064 hours.

Collection method	Number of respondents	Frequency of response	Estimated completion time	Total burden hours
Paper & Modernized Claims System	730,850	1	8 min	97,447
i561	730,850	1	20 min	243,617
Totals:	1,461,700			341,064

Dated: April 5, 2007.

Elizabeth A. Davidson,

Reports Clearance Officer, Social Security Administration.

[FR Doc. E7–6754 Filed 4–9–07; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Urban Partnership-Related Federal Register Notices

AGENCY: Office of the Secretary of Transportation (''OST''), DOT.

ACTION: Notice of list of urban partnership-related **Federal Register** notices.

SUMMARY: The U.S. Department of Transportation (the ''Department'') is pleased to provide you the following list of solicitations issued by the Department in connection with its Urban Partnership Program announced in December 2006.

FOR FURTHER INFORMATION CONTACT: Please address questions regarding this notice to David B. Horner, Esq., Chief Counsel, Federal Transit Administration, U.S. Department of Transportation by e-mail at *David.Horner@dot.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of solicitations issued by the Department in connection with its Urban Partnership Program announced in December 2006.

The Urban Partnership Program reflects the Department's effort to develop, in the words of U.S. Transportation Secretary Mary Peters, ''21st Century Solutions to 21st Century Challenges'' facing the Nation's transportation network. One such challenge is the severe and worsening problem of metropolitan traffic congestion. Through the Urban Partnership Program, the Department is offering a combination of grants, technical expertise, regulatory relief and credit support to jurisdictions which are prepared to experiment with four strategies believed to be effective, on a combined basis, in reducing metropolitan traffic congestion: (i) Value pricing, (ii) bus transit, (iii) telecommuting and flextime, and (iv) intelligent transportation technology.

Representatives of metropolitan areas interested in becoming Urban Partners must submit an application to the Department that meets the requirements detailed in the Department's December 8, 2006, **Federal Register** Notice (''Applications for Urban Partnership Agreements (''UPAs'') as Part of Congestion Initiative''). Designation as an Urban Partner does not, by itself, qualify a party for any grant or funding amount. However, Urban Partners will receive priority consideration under the other departmental discretionary funding programs referenced below, to the extent that program terms provide or allow.

Applicants must apply separately to each of the programs from which they seek funding and must meet each program's specific statutory requirements. Applicants are encouraged to identify in each application those other Urban Partnership-related program solicitations, if any, to which they have applied. All application materials are due to the Department by April 30, 2007, apart from applications to the Federal Transit Administration's Alternatives Analysis and Bus & Bus Facilities Programs, which are due by May 22, 2007.

Date published	Citation	Title (description)	Link
12/08/2006	71 FR 71231	Applications for Urban Partnership Agreements (''UPAs'') as Part of Congestion Initiative (The purpose of this Notice is to solicit proposals by metropolitan areas to enter into UPAs with the Department in order to demonstrate strategies with a combined track record of effectiveness in reducing traffic congestion.).	*http://www.fightgridlocknow.gov/docs/upafrnotice20061208.pdf.*
12/18/2006	71 FR 77084	Applications for Funding Under Intelligent Transportation Systems Operational Testing to Mitigate Congestion Program (This notice invites State and local governments and other public authorities to apply to participate in a cooperative effort to deploy and evaluate the application of advanced technologies to reduce congestion in an urban area.).	*http://www.fightgridlocknow.gov/docs/itscongestionnotice20061218.pdf.*
12/22/2006	71 FR 77084	Value Pricing Pilot Program Participation, Fiscal Years 2007–2009 (This notice invites State and local governments and other public authorities to apply to participate in the Value Pricing Pilot (''VPP'') program and presents guidelines for program applications.).	*http://www.fightgridlocknow.gov/docs/vpppfrnotice20061222.pdf.*

Date published	Citation	Title (description)	Link
02/12/2007	72 FR 6663	Notice of Availability of Proposed Guidance on New and Small Starts Policies and Procedures (The purpose of this notice is to solicit comments on the policies and procedures for the New and Small Starts programs. The proposed improvements include the consideration of congestion management/pricing strategies and ''make-the-case'' documents as ''other factors'' for project justification. Approximately $266 million in discretionary funding is available for new fixed guideway capital projects, including up to $200 million for corridor-based bus projects, under the New Starts/Small Starts program in fiscal year 2007 (net of earmarks under SAFETEA–LU and recommendations in the President's Fiscal Year 2007 Budget)).	*http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/E7–2249.pdf.*
03/22/2007	72 FR 13552	Solicitation of Applications for Certain Federal-Aid Highway Funding Available in Fiscal Year 2007 under Federal Highway Discretionary Grant Programs (The purpose of this notice is to solicit applications for Federal grant funding and to issue supplemental notice and information to eligible grantees concerning discretionary grant funds available for obligation in Fiscal Year 2007 under eight discretionary grant programs administered by FHWA. It seeks applications to the programs that both meet the programs' respective statutory criteria and emphasize the proposed projects' highway safety and congestion reduction benefits.) This notice applies to the following programs:. • Ferry Boat Discretionary Program (23 U.S.C. 147); • Innovative Bridge Research and Deployment Program (23 U.S.C. 503(b)); • Interstate Maintenance Discretionary Program (23 U.S.C. 118(c)); • Public Lands Highway Discretionary Program (23 U.S.C. 202–204); • Highways for Life Pilot Program (§ 1502 of Pub. L. 109–59); • Transportation Community and System Preservation Program (§ 1117 of Pub. L. 109–59); • Truck Parking Facilities Pilot Program (§ 1305 Of Pub. L. 109–59); and • Delta Region Transportation Development Program (§ 1308 of Pub. L. 109–59).	*http://a257.g.akamaitech.net/7/257/2422/01jan20071800/ edocket.access.gpo.gov/2007/pdf/E7–5161.pdf.*
03/23/2007	72 FR 13973	Solicitation of Applications for Certain Funding Available in Fiscal Year 2007 Under the Federal Transit Administration's Section 5309 Bus and Bus-Related Facilities Discretionary Grant Program To Support Urban Partnerships (This notice solicits applications for a significant portion of funds not ''earmarked'' by law and otherwise available in Fiscal Year 2007 under the Section 5309 Bus and Bus-Related Facilities Discretionary Grant Program to support the objectives of the Congestion Initiative.).	*http://a257.g.akamaitech.net /7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/E7–4833.pdf.*

Date published	Citation	Title (description)	Link
03/23/2007	72 FR 13980	Alternatives Analysis Discretionary Program (This notice solicits proposals to compete for $12 million in Section 5339 funds to support technical work conducted within an alternatives analysis, in which one of the alternatives is a major transit capital investment. FTA will give priority to proposals to develop and apply methods to estimate the time savings experienced by highway users that result from transit investments.).	*http://a257.g.akamaitech.net/7/257/2422/ 01jan20071800/ edocket.access.gpo.gov/ 2007/pdf/E7–4830.pdf.*

Issued On: April 2, 2007.

Tyler Duvall,

Assistant Secretary for Transportation Policy.

[FR Doc. E7–6724 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice Before Waiver With Respect to Land at the Montgomery County Airpark, Gaithersburg, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent of waiver with respect to land.

SUMMARY: The FAA is publishing notice of proposed release of approximately one quarter (0.25) of an acre of land acquired with local funds at the Montgomery County Airpark to William C. Rickman Construction Company, Inc. The airport will receive 0.35 of an acre owned by Rickman located in the primary surface in exchange in addition to protective easements and other considerations that will complement anticipated airport development. There are no impacts to the Airport and the land is not needed for airport development as shown on the Airport Layout Plan.

DATES: Comments must be received on or before May 10, 2007.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Terry J. Page, Manager, FAA Washington Airports District Office, 23723 Air Freight Lane, Suite 210, Dulles, VA 20166.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Keith Miller, Executive Director, at the following address: Mr. Keith Miller, Executive Director, Montgomery County Revenue Authority, 101 Monroe Street, Suite 410, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Mr. Terry Page, Manager, Washington Airports District Office, 23723 Air Freight Lane, Suite 210, Dulles, VA 20166; telephone (703) 661–1354, fax (703) 661–1370, e-mail *Terry.Page@faa.gov*.

SUPPLEMENTARY INFORMATION: On April 5, 2000, new authorizing legislation became effective. That bill, the Wendell H. Ford Aviation investment and Reform Act for the 21st Century, Pub. L. 10–181 (Apr. 5, 2000; 114 Stat. 61) (AIR 21) requires that a 30-day public notice must be provided before the Secretary may waive any condition imposed on an interest in surplus property.

Dated: Issued in Chantilly, Virginia on March 30, 2007.

Terry J. Page,

Manager, Washington Airports District Office, Eastern Region.

[FR Doc. 07–1747 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership in the National Parks Overflights Advisory Group Aviation Rulemaking Committee

ACTION: Notice.

SUMMARY: By **Federal Register** notice (See 72 FR 2582; January 19, 2007) the National Park Service (NPS) and the Federal Aviation Administration (FAA) invited interested persons to apply to fill a vacant position on the National Parks Overflights Advisory Group (NPOAG) Aviation Rulemaking Committee (ARC). This notice invited interested persons to apply to fill the vacancy representing the commercial air tour operators' interests due to the incumbent member's completion of a three-year term appointment on May 19, 2007. This notice informs the public of the person selected to fill the vacancy on the NPOAG ARC.

FOR FURTHER INFORMATION CONTACT: Barry Brayer, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, P.O. Box 92007, Los Angeles, CA 90009–2007, telephone: (310) 725–3800, e-mail: *Barry.Brayer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181. The act required the establishment of the advisory group within 1 year after its enactment. The NPOAG was established in March 2001. The advisory group is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

In accordance with the Act, the advisory group provides ''advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands.''

Membership

The current NPOAG ARC is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members

representing Native American interests. Current members of the NPOAG ARC are as follows:

Heidi Williams representing general aviation; Alan Stephen, Elling Halvorson, and Matthew Zuccaro representing commercial air tour operations; Chip Dennerlein, Greg Miller, Mark Peterson, and Don Barger representing environmental interests; and Rory Majenty and Richard Deertrack representing Native American tribes.

Selection

Selected to fill this vacancy, for an additional term, is returning member Elling Halvorson. Mr. Halvorson's term begins on May 20, 2007. The term of service for NPOAG ARC members is 3 years.

Issued in Hawthorne, CA, on April 3, 2007.

Barry Brayer,

Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 07–1746 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2007–13]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before April 30, 2007.

ADDRESSES: You may submit comments [identified by DOT DMS Docket Number FAA–2004–19081] by any of the following methods:

- *Web site: http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tim Adams (202) 267–8033, Tyneka Thomas (202) 267–7626, or Frances Shaver (202) 267–9681, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on March 29, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petitions for Exemption

Docket No.: FAA–2004–19081.

Petitioner: United States Hang Gliding Association.

Section of 14 CFR Affected: 14 CFR 61.52(a)(3).

Description of Relief Sought: To allow the United States Hang Gliding Association (USHGA) approved tow pilots to apply their ultralight tow flight experience to the aeronautical experience requirements of the private pilot single engine airplane rating.

[FR Doc. E7–6647 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Research, Engineering and Development Advisory Committee

Pursuant to section 10(A)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App.2), notice is hereby given of a meeting of the FAA Research, Engineering and Development (R,E&D) Advisory Committee.

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of meeting.

Name: Research, Engineering and Development Advisory Committee.

Time and Date: May 2—9 9 a.m. to 5 p.m.

Place: Federal Aviation Administration, 800 Independence Avenue, SW.—Round Room (10th Floor), Washington, DC 20591.

Purpose: The meeting agenda will include receiving from the Committee guidance for FAA's research and development investments in the areas of air traffic services, airports, aircraft safety, human factors and environment and energy. Attendance is open to the interested public but seating is limited. Persons wishing to attend the meeting or obtain information should contact Gloria Dunderman at (202) 267–8937 or *gloria.dunderman@faa.gov.* Attendees will have to present picture ID at the security desk and escorted to the Round Room.

Members of the public may present a written statement to the Committee at any time.

Issued in Washington, DC, on April 4, 2007.

Barry Scott,

Acting Director, Research and Development Office.

[FR Doc. 07–1745 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Sunshine Act Meetings; Unified Carrier Registration Plan Board of Directors

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

Time and Date: April 24, 2007, 12 noon to 3 p.m., Eastern Daylight Time.

Place: This meeting will take place telephonically. Any interested person may call Mr. Avelino Gutierrez at (505) 827–4565 to receive the toll free number and pass code needed to participate in this meeting by telephone.

Status: Open to the public.

Matters To Be Considered: The Unified Carrier Registration Plan Board of Directors (the Board) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement and to that end, may consider matters properly before the Board.

FOR FURTHER INFORMATION CONTACT: Mr. Avelino Gutierrez, Chair, Unified Carrier Registration Board of Directors at (505) 827–4565.

Dated: April 6, 2007.

William Quade,

Acting, Associate Administrator, Enforcement and Program Delivery.

[FR Doc. 07–1807 Filed 4–6–07; 2:50 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2007–27774]

Notice of Receipt of Petition for Decision That Nonconforming 2007 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) Passenger Cars Manufactured Prior to September 1, 2006 Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 2007 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) passenger cars manufactured prior to September 1, 2006, are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 2007 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) passenger cars, manufactured prior to September 1, 2006, that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS) are eligible for importation into the United States because they have safety features that comply with, or are capable of being altered to comply with, all such standards.

DATES: The closing date for comments on the petition is May 10, 2007.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. [Docket hours are from 9 a.m. to 5 p.m.]. Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, Office of Vehicle Safety Compliance, NHTSA (202–366–3151).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS. When there is no substantially similar U.S.-certified counterpart, a nonconforming motor vehicle shall be refused admission into the United States unless NHTSA decides under 49 U.S.C. 30141(a)(1)(B), that the motor vehicle has safety features that comply with, or are capable of being altered to comply with, all applicable FMVSS based on destructive test data or such other evidence NHTSA decides to be adequate.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

G&K Automotive Conversion, Inc. of Santa Ana, California (''G&K'') (Registered Importer 90–007) has petitioned NHTSA to decide whether nonconforming 2007 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) passenger cars manufactured prior to September 1, 2006, are eligible for importation into the United States. In its petition, G&K noted that NHTSA has granted import eligibility to 2002–2006 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) passenger cars that G&K claims are identical to the 2007 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) passenger cars that are the subject of this petition. In its petitions for the 2002–2006 vehicles, the petitioner claimed that the vehicles were capable of being altered to comply with all applicable FMVSS (see NHTSA Docket Nos. NHTSA–2003–16401, NHTSA–2005–21334, NHTSA–2005–21912, NHTSA–2005–23391 & NHTSA–2006–25071). Because those vehicles were not manufactured for importation into, and sale in, the United States, and were not certified by their original manufacturer (DaimlerChrysler), as conforming to all applicable FMVSS, they cannot be categorized as ''substantially similar'' to the 2007 version for purposes of establishing import eligibility under 49 U.S.C. 30141(a)(1)(A). However, the petitioner seeks to rely on the data, views and arguments submitted as part of the 2002–2004 petition; proof of conformity information that the petitioner submitted for the first vehicle it conformed under the eligibility decision for the 2002–2004 vehicles; and upon the contention that the 2007 model vehicles differ from the 2002–2006 models only in that they were designated as 2007 model vehicles by their original manufacturer.

G&K contends that nonconforming 2007 Smart Car Passion, Pulse, and Pure (ForTwo Coupe and Cabriolet) passenger cars, manufactured prior to September 1, 2006, are eligible for importation under 49 U.S.C. 30141(a)(1)(B) because they have safety features that comply with, or are capable of being altered to comply with, all applicable FMVSS.

Specifically, the petitioner claims that 2007 Smart Car Passion, Pulse, and Pure (Coupe and Cabriolet) passenger cars have safety features that comply with Standard Nos. 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 116 *Brake Fluid*, 118 *Power Window Systems*, 124 *Accelerator Control Systems*, 135 *Passenger Car Brake Systems*, 202 *Head Restraints*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, and 219 *Windshield Zone Intrusion*.

Petitioner further contends that the vehicles are capable of being altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* (a) inscription of the word ''Brake'' and a seat belt warning symbol on the dash; and (b) modification of the speedometer to read in miles per hour.

Standard No. 102 *Transmission Shift Lever Sequence:* inscription of

shift sequence markings on the instrument cluster.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* (a) replacement or modification of the headlamps; (b) installation of side marker lamps; and (c) installation of turn signal lamps. The petition does not describe the headlamp modifications. G&K is claiming confidentiality with respect to some of these modifications.

Standard No. 110 *Tire Selection and Rims:* installation of a tire information placard.

Standard No. 111 *Rearview Mirror:* inscription of the required warning statement on the face of the passenger side rearview mirror.

Standard No. 114 *Theft Protection:* modification of the key locking system and installation of a supplemental key warning buzzer system to meet the requirements of this standard. The petition does not describe these modifications. G&K is claiming confidentiality with respect to these modifications.

Standard No. 201 *Occupant Protection in Interior Impact:* replacement of interior components with components fabricated by, and available only through, G&K. The petition does not describe these components or their manner of installation. G&K is claiming confidentiality with respect to these modifications.

Standard No. 208 *Occupant Crash Protection:* installation of supplemental wiring and replacement of the driver's seat belt buckle assembly to comply with the seat belt warning requirements of this standard.

Standard No. 209 *Seat Belt Assemblies:* replacement of the driver's seat belt buckle assembly with one that conforms to the requirements of Standards No. 208 and 209.

Standard No. 214 *Side Impact Protection:* modification of the vehicles through the installation of components available only from G&K. The petition does not describe these modifications. G&K is claiming confidentiality with respect to these modifications.

Standard No. 225 *Child Restraint Anchorage Systems:* installation of a tether anchorage behind the passenger seat on coupe models.

Standard No. 301 *Fuel System Integrity:* modification of the fuel system through the installation of three components and associated attachment hardware available only from G&K. The petition does not describe these modifications. G&K is claiming confidentiality with respect to these modifications.

Standard No. 302 *Flammability of Interior Materials:* treatment of interior materials and components covered by the standard. G&K is claiming confidentiality with respect to these modifications.

The petitioner states that a vehicle identification number plate must be affixed to the vehicles to meet the requirements of 49 CFR Part 565. The petitioner further states that a certification label must be affixed to the driver's doorjamb to meet the requirements of 49 CFR Part 567.

Additionally, petitioner states components available only from G&K will be installed on the vehicle to comply with the Bumper Standard found in 49 CFR Part 581. The petition does not describe these modifications. G&K is claiming confidentiality with respect to these modifications.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. [Docket hours are from 9 a.m. to 5 p.m.]. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(B) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 3, 2007.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. E7–6510 Filed 4–9–07; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–999X]

Caldwell County Railroad Company—-Discontinuance of Service Exemption—in Caldwell County, NC

On March 21, 2007, Caldwell County Railroad Company (CCRC) filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to discontinue service over a 5.2-mile segment of the rail line known as the HG Line, extending from milepost 107.5, near Lenoir, to the end of the line at milepost 112.7, near Valmead, in Caldwell County, NC.[1] The line traverses U.S. Postal Service Zip Code 28645, and does not include any current stations.

The line does not contain Federally granted rights-of-way. Any documentation in CCRC's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuing this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by July 9, 2007.

Any offer of financial assistance (OFA) to subsidize continued rail service under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,300 filing fee. *See* 49 CFR 1002.2(f)(25).[2]

All filings in response to this notice must refer to STB Docket No. AB–999X and must be sent to: (1) Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; and (2) Betty Jo Christian, Steptoe & Johnson, LLP, 1330 Connecticut Avenue, NW., Washington, DC 20036. Replies to the petition are due on or before April 30, 2007.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Services at (202) 245–0230 or refer to the full abandonment and discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: April 2, 2007.

[1] The line segment is leased by CCRC from the Caldwell County Economic Development Commission.

[2] Because this is a discontinuance of service proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Similarly, no environmental or historic documentation is required under 49 CFR 1105.6(c)(2) and 1105.8(e).

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–6482 Filed 4–9–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

April 2, 2007.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

Dates: Written comments should be received on or before May 10, 2007 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0990.

Type of Review: Revision.

Title: Form 8610, Annual Low-Income Housing Credit Agencies Report, Schedule A (Form 8610), Carryover Allocation of Low-Income Housing Credit.

Form: 8610.

Description: State housing agencies file Form 8610 to transmit copies of Form 8609, Schedule(s) A (Form 8610), and binding agreements and election statements to the IRS. The Agencies use Schedule A (Form 8610) to report certain information contained in carryover allocation documents to the IRS.

Respondents: State, local, or tribal governments.

Estimated Total Burden Hours: 5,599 hours.

OMB Number: 1545–1714.

Type of Review: Extension.

Title: Tip Reporting Alternative Commitment (TRAC) for most industries.

Description: Information is required by the Internal Revenue Service in its tax compliance efforts to assist employers and their employees in understanding and complying with section 6053(a), which requires employees to report all their tips monthly to their employers.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 4,877 hours.

OMB Number: 1545–0004.

Type of Review: Revision.

Title: Determination of Worker Status for Purposes of Federal Employment Taxes and Income Tax Withholding.

Form: 2587.

Description: Form SS–8 is used by employers and workers to furnish information to IRS in order to obtain a determination as to whether a worker is an employee for purposes of Federal employment taxes and income tax withholding. IRS uses this information to make the determination.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 101,464 hours.

OMB Number: 1545–1717.

Type of Review: Extension.

Title: Tip Rate Determination Agreement (TRDA) for Most Industries.

Description: Information is required by the Internal Revenue Service in its tax compliance efforts to assist employers and their employees in understanding and complying with section 6053(a), which requires employees to report all their tips monthly to their employers.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 1,897 hours.

OMB Number: 1545–1588.

Type of Review: Extension.

Title: REG–209682–94 (Final) Adjustments Following Sales of Partnership Interests.

Description: Partnerships, with a section 754 election in effect, are required to adjust the basis of partnership property following certain transfers of partnership interests. The regulations require the partnership to attach a statement to its partnership return indicating the adjustment and how it was allocated among the partnership property.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 904,000 hours.

OMB Number: 1545–1529.

Type of Review: Extension.

Title: Tip Reporting Alternative Commitment (Hairstyling Industry).

Description: Information is required by the Internal Revenue Service in its compliance efforts to assist employers and their employees in understanding and complying with section 6053(a), which requires employees to report all their tips monthly to their employers.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 43,073 hours.

OMB Number: 1545–0057.

Type of Review: Extension.

Title: Application for Recognition of Exemption Under Section 501(a).

Form: 1024.

Description: Organizations seeking exemption from Federal income tax under Internal Revenue Code section 501(a) as an organization described in most paragraphs of section 501(c) must use Form 1024 to apply for exemption. The information collected is used to determine whether the organization qualifies for tax-exempt status.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 291,542 hours.

OMB Number: 1545–1572.

Type of Review: Extension.

Title: REG–120200–97 (Final) Election Not to Apply Look-Back Methods in De Minimis Cases.

Description: The regulations provides rules for electing the benefits of section 460(b)(6) regarding not applying look-back methods to long-term contracts in *de minimis* cases.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 4,000 hours.

OMB Number: 1545–1870.

Type of Review: Extension.

Title: REG–125638–01 (Final) Guidance Regarding Deduction and Capitalization of Expenditures.

Description: The information required to be retained by taxpayers will constitute sufficient documentation for purposes of substantiating a deduction. The information will be used by the agency on audit to determine the taxpayer's entitlement to a deduction. The respondents include taxpayers who engage in certain transactions involving the acquisition of a trade or business or an ownership interest in a legal entity.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 3,000 hours.

OMB Number: 1545–2036.

Type of Review: Extension.

Title: Taxation and Reporting of REIT Excess Inclusion Income.

Description: The notice requires certain REITs, partnerships and other entities that have excess inclusion income to disclose the amount and character of such income allocable to their record interest owners. The record interest owners need the information to properly report and pay taxes on such income.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 100 hours.

OMB Number: 1545–0582.

Type of Review: Revision.

Title: Corporation Application for Tentative Refund.

Form: 1139.

Description: Form 1139 is filed by corporations that expect to have a net operating loss, net capital loss, or unused general business credits carried back to a prior tax year. IRS uses Form 1139 to determine if the amount of the loss or unused credits is proper.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 132,750 hours.

Clearance Officer: Glenn P. Kirkland, (202) 622–3428, Internal Revenue Service, Room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. E7–6744 Filed 4–9–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that the Research Advisory Committee on Gulf War Veterans' Illnesses will meet on April 24–25, 2007, in room 230 at the Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC. The meeting will be open to the public and it will start at 8 a.m. each day. The meeting will adjourn at 5 p.m. on April 24 and at 3 p.m. on April 25.

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Gulf War.

The Committee will review VA program activities relating to Gulf War veterans' illnesses and updates on relevant scientific research published since the last Committee meeting. Additionally, there will be presentations and discussion of background information on the Gulf War and Gulf War veterans' illnesses, mechanisms potentially underlying chronic symptoms affecting Gulf War veterans, and discussion of Committee business and activities. The Committee will also discuss the recommendations to be included in its 2007 report.

The meeting will include time reserved for public comments. A sign-up sheet for five-minute comments will be available at the meeting. Individuals who speak are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Dr. Lea Steele, RAC–Gulf War Veterans' Illnesses (T–GW), U.S. Department of Veterans Affairs, 2200 SW. Gage Blvd., Topeka, KS 66622.

Any member of the public seeking additional information should contact Dr. William Goldberg, Designated Federal Officer, at (202) 254–0294, or Dr. Steele, Scientific Director, at (785) 350–3111, ext. 54617.

Dated: April 3, 2007.

By Direction of the Secretary.

E. Philip Riggin,

Committee Management Officer.

[FR Doc. 07–1752 Filed 4–9–07; 8:45 am]

BILLING CODE 8320–01–M

Corrections

Federal Register

Vol. 72, No. 68

Tuesday, April, 10, 2007

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.

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 30

Foreign Futures and Options Transactions

Correction

In rule document 07–1521 beginning on page 14413 in the issue of Wednesday, March 28, 2007, make the following corrections:

1. On page 14414, in the first column, in the last paragraph, in the second to last line ''the'' should read ''and''.

2. On the same page, in the second column, in the first full paragraph, in the seventeenth line, ''that solicit and accept customer orders; '' should read ''who accept customer funds;''.

[FR Doc. C7–1521 Filed 4–9–07; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
April 10, 2007

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 414

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 414

[CMS–1270–F]

RIN 0938–AN14

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes competitive bidding programs for certain Medicare Part B covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act. These competitive bidding programs, which will be phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B.

DATES: *Effective Date:* This final rule is effective on June 11, 2007.

FOR FURTHER INFORMATION, CONTACT: Lorrie Ballantine, (410) 786–7543, Ralph Goldberg, (410) 786–4870, Karen Jacobs, (410) 786–2173, Michael Keane, (410) 786–4495, Alexis Meholic, (410) 786–5395, Linda Smith, (410) 786–5650.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents' home page address is *http://www.gpoaccess.gov/index.html*, by using local WAIS client software, or by telnet to *swais.access.gpo.gov*, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required).

Alphabetical Listing of Acronyms Appearing in This Final Rule

ABN Advance Beneficiary Notice
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BESS [Medicare] Part B Extract and Summary System
CBA Competitive bidding area
CBIC Competitive bidding implementation contractor
CBSA Core-based statistical area
CMS Centers for Medicare & Medicaid Services
CPI–U Consumer Price Index—All Urban Consumers
CPT [Physician] Current Procedural Terminology, Fourth Edition, 2007, copyrighted by the American Medical Association. CPT® is a trademark of the American Medical Association
CY Calendar year
DME Durable medical equipment
DME MAC Durable Medical Equipment Medicare Administrative Contractor
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DMERC Durable medical equipment regional carrier
DRA Deficit Reduction Act of 2005, Pub. L. 109–171
FAR Federal Acquisition Regulation
FEHB Federal Employees Health Benefits Program
FFS Fee-for-service
FTE Full-time equivalent
GAO Government Accountability Office
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
IIC Inflation indexed charge
IRF Inpatient rehabilitation facility
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MSA Metropolitan Statistical Area
NAICS North American Industry Classification System
NF Nursing facility
NPWT Negative pressure wound therapy
NSC National Supplier Clearinghouse
OBRA '87 Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203
OIG Office of the Inspector General, HHS
OTS Off-the-shelf
PAOC Program Advisory and Oversight Committee
PEN Parenteral and enteral nutrition
POV Power-operated vehicle
RFB Request for bids
SADMERC Statistical Analysis Durable Medical Equipment Regional Carrier
SBA Small Business Administration
SGD Speech generating device
SNF Skilled nursing facility
TENS Transcutaneous electrical nerve stimulator

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Regulation Text

I. Provisions of the May 1, 2006 Proposed Rule

A. Summary of the Proposed Rule

On May 1, 2006, we published in the **Federal Register** (71 FR 25654) a proposed rule to—

- Establish and implement competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under sections 1847(a) and (b) of the Social Security Act (the Act), as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173.
- Implement requirements for independent accreditation organizations that will be applying quality standards to all DMEPOS suppliers as required by section 1834(a)(20) of the Act. (We note that, as explained later under section VII. of this final rule, we have finalized certain provisions of the May 1, 2006 proposed rule relating to accreditation in the DMEPOS provisions of a final rule entitled ''Inpatient Rehabilitation Facility Prospective Payment System for Federal FY 2007; Provisions Concerning Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Accreditation of DMEPOS Suppliers,'' which appeared in the **Federal Register** on August 18, 2006 (71 FR 48354) and is referred to throughout this final rule as the ''FY 2007 IRF final rule.'')
- Establish a new fee schedule for home dialysis supplies and equipment that continue to be paid on a reasonable charge basis. (We note that we will respond to comments on this proposal in a future final rule.)
- Establish a revised methodology for calculating fee schedule amounts for new DMEPOS items. (We note that we will respond to comments on this proposal in a future final rule.)
- Codify in our regulations that the statutorily imposed eyeglass coverage exclusion under Medicare Part B encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision. (We note that we will respond to comments on this proposal in a future final rule.)
- Codify in regulations that the Medicare fee schedule amount for therapeutic shoes, inserts, and shoe modifications are established in accordance with the methodology specified in sections 1833(o) and 1834(h) of the Act. (We note that we will respond to comments on this proposal in a future final rule.)

B. Public Comments Received

We received approximately 2,129 timely pieces of correspondence in response to the May 1, 2006 proposed rule. Except where indicated in section II.B. of this final rule, this final rule discusses the provisions of the May 1, 2006 proposed rule, summarizes the public comments received on each subject area, sets out our responses to those comments, and sets forth our final rules.

II. Issuance of Final Rules

A. Issuance of the FY 2007 IRF Final Rule Which Finalized Certain Provisions Relating to Competitive Acquisition for DMEPOS and the Accreditation of DMEPOS Suppliers

To ensure timely implementation of the Medicare DMEPOS Competitive Bidding Program, we responded to comments submitted on certain provisions of the May 1, 2006 proposed rule and finalized our proposals concerning the designation of competitive bidding implementation contractors (CBICs), competitive bidding education and outreach, and the accreditation of DMEPOS suppliers in the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354). We also discussed in that final rule certain issues relating to the establishment of quality standards for DMEPOS suppliers that will be applied by independent accreditation organizations.

B. Future Issuance of a Final Rule on Certain Other Provisions Addressed in the May 1, 2006 Proposed Rule

We will respond to comments submitted on certain provisions of the May 1, 2006 proposed rule and finalize our proposals concerning the following provisions in a separate final rule that will be published at a later date in the **Federal Register:** (1) Establishment of a new fee schedule for home dialysis supplies and equipment that continue to be paid on a reasonable charge basis; (2) establishment of a revised methodology for calculating fee schedule amounts for new DMEPOS items; (3) codification in our regulations that the scope of the eyeglass coverage exclusion under Medicare Part B encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision; and (4) codification in our regulations that the Medicare fee schedule amounts for therapeutic shoes, inserts, and shoe modifications are established in accordance with the methodology specified in sections 1833(o) and 1834(h) of the Act.

III. Payment for DMEPOS Under Medicare Part B: Background

A. Payment for DMEPOS on the Basis of Reasonable Charges

Payment for most DMEPOS items, including supplies and equipment, furnished under Medicare Part B is made through contractors known as Durable Medical Equipment Medicare Administrative Contractors (DME MACs) (previously Durable Medical Equipment Regional Carriers (DMERCs), also known as Medicare carriers). Before January 1, 1989, payment for most of these items was made on a reasonable charge basis by Medicare carriers. Section 1842(b) of the Act sets forth the methodology for determining reasonable charges. Implementing regulations for section 1842(b) of the Act are located at 42 CFR Part 405, Subpart E.

Reasonable charge determinations are generally based on customary and prevailing charges derived from historic charge data, with the ''reasonable charge'' for an item being the lowest of the following factors:

- The supplier's actual charge for the item.
- The supplier's customary charge for the item.
- The prevailing charge in the locality for the item. The prevailing charge may not exceed the 75th percentile of the customary charges of suppliers in the locality.
- The inflation indexed charge (IIC). The IIC is defined in § 405.509(a) of the Medicare regulations as the lowest of the fee screens used to determine reasonable charges for services, including supplies, and equipment paid on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor. The inflation adjustment factor is based on the current change in the Consumer Price Index for All Urban Consumers (CPI–U), as compiled by the Bureau of Labor Statistics, for the 12-month period ending June 30 each year.

B. Payment for DMEPOS Under Fee Schedules

Section 1834 of the Act, as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, provides for implementation of a fee schedule payment methodology for most durable medical equipment (DME), prosthetic devices, and orthotic devices furnished after January 1, 1989. Specifically, sections 1834(a)(1)(A) and (B) and 1834(h)(1)(A) of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. We implemented this payment methodology at 42 CFR Part 414, Subpart D of our regulations. Sections 1834(a)(2) through (a)(5) and section 1834(a)(7) of the Act, and implementing regulations at § 414.200 through § 414.232 (with the exception of § 414.228), set forth separate payment categories of DME and describe how the fee schedule for each of the following categories is established:

- Inexpensive or other routinely purchased items (section 1834(a)(2) of the Act and § 414.220 of the regulations);
- Items requiring frequent and substantial servicing (section 1834(a)(3) of the Act and § 414.222 of the regulations);
- Customized items (section 1834(a)(4) of the Act and § 414.224 of the regulations);
- Oxygen and oxygen equipment (section 1834(a)(5) of the Act and § 414.226 of the regulations);
- Other items of DME (section 1834(a)(7) of the Act and § 414.229 of the regulations).

Each category has its own unique payment rules. With the exception of customized items, a fee schedule amount is calculated for each item or category of DME that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS). The HCPCS is discussed in section III.C. of this final rule. The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item. The fee schedule amounts for oxygen and oxygen equipment are monthly payment amounts. Payment under the DME benefit is made for supplies necessary for the effective use of DME (for example, lancets used with blood glucose monitors). These supplies are paid for using the same methodology that we use to pay for the purchase of inexpensive or routinely purchased items.

The fee schedule amounts for DME are generally adjusted annually by the change in the CPI–U for the 12-month period ending June 30 of the preceding year. The fee schedule amounts are also generally limited by a ceiling (upper limit) and floor (lower limit) equal to 100 percent and 85 percent, respectively, of the median of the Statewide fee schedule amounts.

Since 1994, Medicare has paid for most surgical dressings in accordance with section 1834(i) of the Act and § 414.220(g) of the regulations, using the same methodology as is used for payment of purchased inexpensive or routinely purchased DME.

Under section 1834(h) of the Act and § 414.228 of the regulations, payment for prosthetic and orthotic devices is made on a lump sum basis and is equal to the lower of the fee schedule amount calculated for the item or the actual charge for the item, less any unmet deductible amount. The fee schedule amounts are calculated using a weighted average of Medicare payments made in the States in each of 10 CMS regions from July 1, 1986, through June 30,

1987, adjusted annually by the change in the CPI–U for the 12-month period ending June 30 of the preceding year. The regional fee schedule amounts are limited by a ceiling (upper limit) and floor (lower limit) equal to 120 percent and 90 percent, respectively, of the average of the regional fee schedule amounts for each State.

As authorized under section 1842(s) of the Act and 42 CFR Part 414, Subpart C of our regulations, Medicare pays for parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies on the basis of 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item (§ 414.102(a)). The fee schedule amounts for PEN items are calculated on a nationwide basis and are the lesser of the reasonable charges for CY 1995 or the reasonable charges that would have been used in determining payment for these items in CY 2002 under the former reasonable charge payment methodology (§ 414.104(b)). The fee schedule amounts are generally adjusted annually by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding year (§ 414.102(c)). Under § 414.104(a), payment for PEN nutrients and supplies is made on a purchase basis, and payment for PEN equipment that is rented is made on a monthly basis. (We note that we proposed to revise § 414.1 in the May 1, 2006 proposed rule to specify that fee schedules were established for PEN items in accordance with our authority under section 1842(s) of Act. We will address this proposal in a final rule that will be published later in the **Federal Register**.)

Section 1833(o)(2) of the Act, as amended by section 627 of the MMA, requires implementation of fee schedule amounts, effective January 1, 2005, for the purpose of determining payment for custom molded shoes, extra-depth shoes, and inserts (collectively, ''therapeutic shoes''). We stated in the May 1, 2006 proposed rule that we believe this section of the MMA is largely self-implementing because it mandates use of the methodology set forth in section 1834(h) of the Act for prosthetic and orthotic devices in determining the fee schedule amounts for therapeutic shoes. We implemented the methodology for payment for prosthetic and orthotic devices in regulations at 42 CFR Part 414, Subpart D, and section 627 of the MMA provides that the same methodology shall apply to therapeutic shoes. We implemented section 627 of the MMA through program instructions, and on January 1, 2005, Medicare began paying for therapeutic shoes based on fee schedule amounts determined in accordance with section 1834(h) of the Act and Part 414, Subpart D of our regulations.

Section 5101(a) of the Deficit Reduction Act of 2005 (DRA), Public Law 109–171, amended section 1834(a)(7)(A) of the Act to change the way Medicare pays for capped rental items. As a result, section 1834(a)(7)(A)(i)(I) of the Act now states that payment for a capped rental item may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months, and section 1834(a)(7)(A)(i)(II) of the Act sets forth how the 13 monthly rental payment amounts are to be determined. In addition, section 1834(a)(7)(A)(ii) of the Act now provides that on the first day that begins after the 13th continuous month during which payment is made for a capped rental item, the supplier of the capped rental item must transfer title to the item to the Medicare beneficiary. Once the title has transferred, or once a purchase agreement for a power wheelchair has been entered into in accordance with section 1834(a)(7)(A)(iii) of the Act as amended, section 1834(a)(7)(A)(iv) of the Act provides that reasonable and necessary maintenance and servicing payments (for parts and labor not covered by the supplier's or the manufacturer's warranty, as determined by the Secretary to be appropriate for the particular item) will be made. These statutory changes apply only to capped rental items whose first rental month occurs on or after January 1, 2006. We implemented section 5101(a) of the DRA in a final rule, CMS–1304–F: Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005; Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment, that was published in the **Federal Register** on November 9, 2006 (71 FR 65884).

Section 5101(b) of the DRA amended section 1834(a)(5) of the Act to limit monthly rental payments for oxygen equipment to a 36-month period of continuous use (as determined by the Secretary). On the first day that begins after the 36th continuous month during which payment is made for the oxygen equipment, new section 1834(a)(5)(F)(ii)(I) of the Act provides that the supplier must transfer title to the equipment to the Medicare beneficiary. Section 1834(a)(5)(F)(ii)(II)(aa) of the Act provides that Medicare will continue to make monthly payments for oxygen contents for beneficiary-owned oxygen equipment in the amounts recognized under section 1834(a)(9) of the Act for the period of medical need. However, under section 1834(a)(5)(F)(ii)(II)(bb) of the Act, maintenance and servicing payments for beneficiary-owned oxygen equipment (for parts and labor not covered by the supplier's or manufacturer's warranty) will be made only if they are reasonable and necessary. These statutory changes went into effect on January 1, 2006. For beneficiaries receiving Medicare-covered oxygen equipment as of December 31, 2005, the 36-month rental period began on January 1, 2006. We implemented section 5101(b) of the DRA in a final rule, entitled CMS–1304–F Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005; Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment, that was published in the **Federal Register** on November 9, 2006 (71 FR 65884).

C. Use of the Healthcare Common Procedure Coding System (HCPCS)

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs by providers, physicians, and other suppliers. The HCPCS code set is divided into the following two principal subsystems, referred to as Level I and Level II of the HCPCS:

- Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes, which are copyrighted by the American Medical Association. CPT codes are a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals which are billed to public or private health insurance programs. CPT codes are developed, published, and maintained by the American Medical Association. CPT codes do not include codes needed to separately report medical items that are regularly billed by suppliers other than physicians.
- Level II of the HCPCS codes is a standardized coding system used primarily to identify products and supplies that are not included in the CPT codes, such as DMEPOS when used outside a physician's office.
- HCPCS Level II codes classify like items by category for the purpose of efficient claims processing. Assignment of a HCPCS code is not a coverage determination, and does not imply that any payer will cover the items in the code category. For some DMEPOS items,

such as wheelchairs and wheelchair cushions, minimum performance standards must be met before an item can be classified under a HCPCS code. In October 2003, the Secretary delegated authority under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to CMS to maintain and distribute the HCPCS Level II codes. In the May 1, 2006 proposed rule, we proposed that the HCPCS Level II codes would be used to describe the DME, orthotic, and enteral nutrients, equipment, and supplies furnished under the Medicare DMEPOS Competitive Bidding Program, both for the purpose of requesting bids and for establishing payment amounts.

IV. Medicare Competitive Bidding Demonstrations

Prior to enactment of the MMA, section 4319 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–33, authorized implementation of up to five demonstration projects of competitive bidding for Medicare Part B items, except physician services. In accordance with section 4319 of the BBA, we planned and implemented the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for DMEPOS. The demonstration was implemented at two sites: Polk County, Florida, and in the San Antonio, Texas, Metropolitan Statistical Area (MSA). The competitive bidding demonstrations, authorized under the BBA, were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program, and offered beneficiaries sufficient access and quality products.

At the first site, Polk County, Florida, we conducted the first of two rounds of bidding in 1999. Five categories of DMEPOS were put up for bidding: oxygen equipment and supplies (required by statute); hospital beds and accessories; enteral nutrition formulas and equipment; urological supplies; and surgical dressings. A total of 16 contract suppliers began providing demonstration products in Polk County on October 1, 1999, and continued for 2 years. The second and final round of bidding in Polk County was conducted in 2001 for the same product categories minus enteral nutrition. (Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes.) The second set of competitively bid payment amounts took effect in October 2001. As in round one, 16 suppliers were selected, of whom half had participated as winners previously. The new fee schedules developed from the bids in each round replaced the Statewide Medicare DMEPOS fees. The second round of the demonstration in Polk County ended in September 2002.

Texas was the second site for the demonstration. In Bexar, Comal, and Guadalupe counties in the San Antonio MSA, we conducted bidding in 2000 for five kinds of DMEPOS: oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; general orthotics; and nebulizer drugs. Fifty-one suppliers were selected and began serving Medicare beneficiaries under the new fees in February 2001. The San Antonio site ended operations in December 2002, the statutorily required termination date in the BBA.

In each area of evaluation, the data indicated mostly favorable results for the Medicare program. The demonstration led to lower Medicare fees for almost every item in almost every product category in each round of bidding. Fee reductions varied by product category and item, resulting in a nearly 20 percent overall savings at each site. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged.

The DMEPOS Competitive Bidding Demonstration offered valuable information for understanding the impacts of competitive bidding for Medicare services. This information is especially important now because section 302(b) of the MMA mandates a larger role for competitive bidding within the Medicare program by requiring the Secretary to implement competitive bidding programs for the furnishing of certain DME and associated supplies, enteral nutrition and associated supplies, and off-the-shelf (OTS) orthotics. In addition, section 303(d) of the MMA required the Secretary to implement a competitive bidding program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis, and section 302(b) of the MMA requires that competitive bidding demonstration projects be implemented for clinical laboratory services and managed care.

V. Discussion of the Provisions of This Final Rule

In this final rule we are adding new sections to 42 CFR Part 414, Subpart F that implement rules relating to the Medicare DMEPOS Competitive Bidding Program. A discussion of the specific provisions of the proposed rule, a summary of the public comments we received and our responses to those comments are presented in sections VI. through XVII. of this final rule. We present a regulatory impact analysis of the provisions of this final rule in section XVIII. of this final rule. The regulation text appears at the end of this final rule.

VI. Medicare DMEPOS Competitive Bidding Program

A. Legislative Authority and Program Advisory and Oversight Committee

1. Legislative Authority

Section 302(b)(1) of the MMA (Pub. L. 108–173) amended section 1847 of the Act to require the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items for which payment is made under Medicare Part B (the ''Medicare DMEPOS Competitive Bidding Program''). Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are certain durable medical equipment (DME) and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act, including items used in infusion and drugs, (other than inhalation drugs) and supplies used in conjunction with DME, but excluding class III devices under the Federal Food, Drug and Cosmetic Act; enteral nutrients, equipment and supplies (as described in section 1842(s)(2)(D) of the Act); and OTS orthotics (as described in section 1861(s)(9) of the Act) for which payment would otherwise be made under section 1834(h) of the Act and which require minimal self-adjustment. In addition, sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS Competitive Bidding Program.

Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost to the program. In our view, the Medicare DMEPOS Competitive Bidding Program has five main objectives:

- To implement competitive bidding programs for certain DMEPOS items.
- To assure beneficiary access to quality DMEPOS as a result of the program.
- To reduce the amount Medicare pays for DMEPOS and create a payment structure under competitive bidding that is more reflective of a competitive market.

• To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program.

• To contract with suppliers that conduct business in a manner that is beneficial for the program and for Medicare beneficiaries.

As discussed in section IV. of this final rule, the Medicare DMEPOS competitive bidding demonstration projects that were conducted prior to the enactment of the MMA offered valuable information for understanding the impacts of competitive bidding for Medicare services. This information, in part, led to the adoption of section 302(b) of the MMA, which requires that the Secretary implement competitive bidding programs for the furnishing of certain DMEPOS under the Medicare program.

2. Program Advisory and Oversight Committee

Section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, required the Secretary to establish a Program Advisory and Oversight Committee (PAOC) to provide advice to the Secretary with respect to the following functions:

• The implementation of the Medicare DMEPOS Competitive Bidding Program.

• The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS Competitive Bidding Program, taking into account the needs of small providers.

• The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS Competitive Bidding Program.

• The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.

• The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

In addition, section 1847(c)(3)(B) of the Act authorizes the PAOC to perform such additional functions to assist the Secretary in carrying out the Medicare DMEPOS Competitive Bidding Program as the Secretary may specify.

As authorized under section 1847(c)(2) of the Act, the PAOC members were appointed by the Secretary and represent a broad mix of relevant industry, consumer, and government parties. Specifically, the membership roster includes two beneficiary/consumer representatives, four manufacturer representatives, five supplier representatives, three certification/standards representatives, six Federal and State program representatives, one physician, and one pharmacist. The representatives have expertise in a variety of subject matter areas, including DMEPOS, competitive bidding methodologies and processes, and rural and urban marketplace dynamics.

We held the first PAOC meeting, which was announced in a **Federal Register** notice (69 FR 31125), at the CMS Headquarters on October 6, 2004. We held the second meeting on December 6 and 7, 2004. We have held two additional PAOC meetings in 2005 and 2006 during which we, along with our contractor, RTI International, presented material to both the PAOC and the public relating to the provisions that are outlined in the proposed rule and in this final rule. The topics that we presented included—

• Medicare's timeline for implementation of the Medicare DMEPOS Competitive Bidding Program;

• Results of the Medicare competitive bidding demonstration projects authorized by section 4319 of the BBA;

• Structure of the Medicare DMEPOS Competitive Bidding Program;

• Existing non-Medicare competitive bidding programs for DMEPOS;

• Program design options for the Medicare DMEPOS Competitive Bidding Program;

• Criteria for selecting Metropolitan Statistical Areas (MSAs) in which competition under the Medicare DMEPOS Competitive Bidding Program will occur in both CYs 2007 and 2009;

• Criteria for selecting items for competitive bidding;

• Bidding process overview;

• Methodology for setting single payment amounts for competitively bid items;

• Capacity of DMEPOS suppliers and beneficiary utilization of DMEPOS;

• Financial capabilities of bidding suppliers;

• Exception authority under section 1847(a)(3) of the Act for rural areas and areas with low population density within urban areas that are not competitive; and

• Quality standards and accreditation procedures applicable to DMEPOS suppliers.

In addition to the PAOC meetings, we have designed and implemented a CMS Web site at *http://cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp* specifically for the public to have access to all PAOC presentations, minutes, and updates for the Medicare DMEPOS Competitive Bidding Program. In accordance with section 1847(c)(5) of the Act, the PAOC will continue to operate until December 31, 2009. Future PAOC meeting dates, as well as other information pertinent to the Medicare DMEPOS Competitive Bidding Program, can be found on the CMS Web site.

B. Purpose and Definitions (§§ 414.400 and 414.402)

In the May 1, 2006 proposed rule, we proposed in § 414.400 to state that the purpose of 42 CFR Part 414, Subpart F would be to implement the Medicare DMEPOS Competitive Bidding Program for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

As set forth in proposed § 414.402, we proposed to define certain frequently occurring terms that would be used in competitive bidding. Specifically, we proposed to define the following terms:

Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart [42 CFR Part 414, Subpart F]. (We note that the definition language included in the preamble of the proposed rule was inconsistent with the definition language in the proposed regulation text, which was correct.)

Composite bid means the sum of a bidding supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers.

Competitive bidding program means a program established under this subpart [42 CFR Part 414, Subpart F]. (We note that the definition language included in the preamble of the proposed rule was inconsistent with the definition language in the proposed regulation text, which was correct.)

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

Grandfathered item means any one of the following items for which payment is made on a rental basis prior to the implementation of a competitive bidding program under this subpart [42 CFR Part 414, Subpart F]:

(1) An inexpensive or routinely purchased item described in § 414.220.

(2) An item requiring frequent and substantial servicing as described in § 414.222.

(3) Oxygen and oxygen equipment described in § 414.226.

(4) A capped rental item described in § 414.229.

Grandfathered supplier means a noncontract supplier that furnishes a grandfathered item.

Item means one of the following products identified by a HCPCS code, other than class III devices under the Federal Food, Drug and Cosmetic Act and inhalation drugs, and includes the services directly related to the furnishing of that product to the beneficiary:

(1) Durable medical equipment (DME), as defined in § 414.202 and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a);

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a);

(iii) Oxygen and oxygen equipment, as specified in § 414.226(b).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate in a competitive bidding area when compared to other items in the same product category.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Nationwide competitive bidding area means a competitive bidding area that includes the United States and its territories.

Noncontract supplier means a supplier that is located in a competitive bidding area or that furnishes items through the mail to beneficiaries in a competitive bidding area but that is not awarded a contract by CMS to furnish items included in a competitive bidding program for that area.

Physician has the same meaning as in section 1861(r)(1) of the Act.

Pivotal bid means the highest composite bid based on bids submitted by a suppliers for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Product category means a grouping of related items that are included in a competitive bidding program.

Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

Comment: Several commenters supported the definitions of ''bid'' and ''item'' because these definitions acknowledge that services are involved in the delivery of products to Medicare beneficiaries. One commenter suggested that Medicare competitively bid class III devices, which appear to be excluded under the proposed definition of ''item.''

Response: We appreciate the commenters' support. Section 1847(a)(2)(A) of the Act specifically excludes class III devices under the Federal Food, Drug, and Cosmetic Act from the Medicare DMEPOS Competitive Bidding Program. Therefore, we do not have the authority to conduct competitive bidding for these items. We are clarifying in the definition of ''item'' that the DME excludes class III devices under the Federal Food, Drug and Cosmetic Act as defined in § 414.402 and that inhalation drugs are not included in the term ''supplies necessary for the effective use of DME.'' We are also revising the regulatory cross-reference for ''oxygen and oxygen equipment.''

We agree with the commenters that the definition of an item should acknowledge what is included in an item for which bids are being submitted. Therefore, in this final rule, we are revising the definition of ''item'' to indicate that although we will always identify the product by its HCPCS code, we may combine several codes to form one competitively bid item or specify a particular method by which the item is furnished. For example, if we were to include diabetic test strips in a mail-order competitive bidding program, we would identify the item by its HCPCS code and indicate that the product is to be furnished only by mail. We are making this change because we need to be able to modify HCPCS codes or combine HCPCS codes to identify the items for which we will be conducting competitive bidding because HCPCS codes, by themselves, do not always fully define the items for which we wish to solicit competitive bids. We further discuss this revision in section VI.B. of this final rule. Therefore, in this final rule, we have revised the definition of ''item'' to specify that an item for purposes of competitive bidding may be comprised of two or more products identified by different HCPCS codes and/or modifiers and that these codes may be defined based on how a product is furnished (for example, by mail).

Comment: One commenter stated that the definitions for the ''composite bid'' and the ''single payment amount'' for the individual items should include all the costs associated with training the beneficiary and properly putting equipment in place to ensure the safe administration of a piece of DMEPOS in a beneficiary's home.

Response: We are not changing the definitions of ''composite bid'' and ''single payment amount'' because these definitions are based upon the bids, which, by definition, include any services that are directly related to the furnishing of the item to the beneficiary. In addition, to the extent that the service component is included in the definitions of ''bid'' and ''item,'' the ''composite bid'' and the ''single payment amount'' calculated for each item would reflect the costs of services associated with furnishing that item to a beneficiary.

Comment: Several commenters suggested that the proposed definition of ''noncontract supplier'' does not address suppliers that are physically located outside of a CBA, yet provide services to beneficiaries whose permanent address is inside a CBA. One commenter suggested that the definition read: ''A supplier that furnishes items to beneficiaries in a competitive bidding area, but that is not awarded a contract by Medicare to furnish items included in the competitive bidding program for that area.''

Response: Our proposed definition of the term ''noncontract supplier'' only included suppliers located in a CBA or that mailed items to beneficiaries in a CBA. However, we recognize the commenter's concerns that this definition would not capture suppliers that are located outside the CBA but that furnish items to beneficiaries who maintain a permanent residence in a CBA. Therefore, we are revising the definition of the term ''noncontract supplier'' in this final rule to mean: ''a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.''

Comment: Many commenters suggested that the definition of ''physician'' be expanded to allow podiatrists, optometrists and dentists to prescribe a particular brand or mode of

delivery of DMEPOS, along with physician assistants, nurse practitioners, and clinical nurse specialists. The commenters asserted that this expansion would allow a variety of qualified practitioners, in addition to physicians, to prescribe particular brands or modes of delivery where appropriate. The commenters requested that the definition of physician be changed from that specified in section 1861(r)(1) of the Act to that specified in section 1861(r) of the Act.

Response: We agree with the commenters and are revising the definition of ''physician'' applicable in this final rule to have the same meaning as in section 1861(r) of the Act. We believe that this revision is consistent with the intent of the 1847(a)(5)(A) as it reflects which professionals would be ordering Medicare-covered items under the Medicare DMEPOS Competitive Bidding Program. In addition, we are finalizing the definition that we had proposed that a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as defined in section 1861(aa)(5) of the Act. In ordering DMEPOS under the Medicare program, these treating practitioners can specify a particular brand or mode of delivery for an item, which would be paid at the single payment amount.

After consideration of the public comments received, we are finalizing proposed § 414.400 with only a technical change to the heading of the section (changing the heading from ''Basis'' to ''Purpose and Basis''). In addition, we are revising the definitions of ''item,'' ''noncontract supplier,'' and ''physician'' in § 414.402 as discussed above. We are also revising the definitions of several other terms in § 414.402, as well as adding new definitions. Below we state the revised and new definitions and indicate where a full discussion of each change can be found in this final rule:

- Revising the regulatory reference to the oxygen payment classes in the definition of ''item'' so that the definition now references § 414.226(c)(1) instead of § 414.225(b). We discuss this revision in section VI.G.6 of this final rule.
- Revising the definition of ''item weight'' by removing the phrase ''in a competitive bidding area'' and adding the phrase ''using national data'' in referencing the beneficiary utilization rate. We discuss this revision in section VI.D.2. (Evaluation of Bids) of this final rule.
- Adding a definition of ''mail order contract supplier'' to mean a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.'' This new definition is discussed in section V.I.E.5. of this final rule.
- Adding a definition of ''minimal self-adjustment'' to mean ''an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training. This new definition is discussed in section VI.F. of this final rule.
- Adding a definition of ''nationwide mail order contract supplier'' to mean a mail order contract supplier that furnishes items in a nationwide competitive bidding area, and a definition of ''regional mail order contract supplier'' to mean a mail order contract supplier that furnishes items to any Medicare beneficiary residing within a certain region(s) that are designated as CBAs and are located within the United States, its Territories, or the District of Columbia, as discussed in section VI.E.5. of this final rule.
- Adding a definition of ''network'' to mean a group of small suppliers that form a legal entity that submits a bid to furnish competitively bid items in a CBA, and that meets additional requirements. This change is discussed in section XII. of this final rule.
- Revising the definition of ''pivotal bid'' to mean the ''lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.'' We consider this revision to be a clarification that the pivotal bid is the lowest composite bid in terms of the bid amounts submitted by the suppliers rather than the highest composite bid that includes sufficient number of suppliers to meet demand, as discussed in section VII.D.3. of this final rule.
- Revising the definition of ''product category'' to mean ''a grouping of related items that are used to treat a similar medical condition'', as discussed in section VI.G.5. of this final rule.
- Adding a definition of ''regional competitive bidding area ''to mean'' a CBA that consists of a region of the United States, its Territories, and/or the District of Columbia''as discussed in section VI.E.5. of this final rule.
- Adding a definition of ''small supplier'' to mean the ''a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue,'' as discussed in section XII. of this final rule.

We are also making the following technical changes to proposed § 414.402:

- Revising the definition of ''competitive bidding program'' to clarify that such a program established under 42 CFR Part 414, Subpart F occurs ''within a designated CBA.''
- Clarifying the introductory language of the definition of ''grandfathered item'' to read: ''any one of the following items for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish items in accordance with § 414.408(j).''
- Revising the definition of ''grandfathered supplier'' to mean a noncontract supplier ''that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.''
- Revising the definition of a ''nationwide competitive bidding area'' to mean a CBA that includes the United States, its Territories, and the District of Columbia.''

We are finalizing all of the other definitions in proposed § 414.402 without modification.

C. Competitive Bidding Implementation Contractors (CBICs) (§§ 414.406(a) and (e))

Section 1847(b)(9) of the Act provides that the Secretary may contract with appropriate entities to implement the Medicare DMEPOS Competitive Bidding Program. Section 1847(a)(1)(C) of the Act also authorizes the Secretary to waive such provisions of the Federal Acquisition Regulation (FAR) as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

In the May 1, 2006 proposed rule (71 FR 25661), we proposed to designate one or more competitive bidding implementation contractors (CBICs) for the purpose of implementing the Medicare DMEPOS Competitive Bidding Program (proposed § 414.406(a)). We also stated that we envisioned the program would have six primary functions, including overall oversight and decision making, operation design functions (including the design of both bidding and outreach material templates, as well as program processes), bidding and evaluation,

access and quality monitoring, outreach and education, and claims processing.

As we stated earlier, under the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354), we addressed the public comments we received on the proposed provisions relating to implementation contractors under the Medicare DMEPOS Competitive Bidding Program and finalized regulations at § 414.406(a), which allows us to designate one or more CBICs for the purpose of implementing the program, and at § 414.406(e), which codifies our proposal to have the regional carrier (now referred to as a Durable Medical Equipment Medicare Administrative Contractor, or DME MAC) that would otherwise be processing claims for a particular geographic region also process claims for items furnished under a competitive bidding program in the same geographic region. In the same final rule, we also finalized our policy regarding the elements of performance that will be included in a contract we enter into with a CBIC.

D. Payment under the Medicare DMEPOS Competitive Bidding Program

1. Payment Basis (§§ 414.408(a), (c), and (d))

Section 1847(b)(5) of the Act mandates that a single payment amount be established for each item in each CBA based on the bids submitted and accepted for that item. Medicare payment for the item is then made on an assignment-related basis equal to 80 percent of the applicable single payment amount, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(a)(6) of the Act requires that this payment basis be substituted for the payment basis otherwise applied under section 1834(a) of the Act for DME, section 1834(h) of the Act for OTS orthotics, or section 1842(s) of the Act for enteral nutrients, equipment, and supplies, as appropriate.

As discussed in detail in section II.C. of the May 1, 2006 proposed rule (71 FR 25662), we proposed that payment to the contract supplier would be based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence (proposed § 414.408(a)(1)). If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item would be 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item (proposed § 414.408(a)(2)). We also proposed that implementation of a competitive bidding program would not preclude the use of an advanced beneficiary notice (ABN) to allow beneficiaries to make informed consumer choices regarding whether to obtain items for which Medicare might not make payment (proposed § 414.408(d)). Finally, as required under section 1847(b)(5)(C) of the Act, we proposed in § 414.408(c) that payment for an item furnished under a competitive bidding program would be made on an assignment-related basis.

Comment: Several commenters stated that basing payment amounts on the CBA where the beneficiary maintains a permanent residence, and not on the location where the item is furnished, may cause suppliers to be paid less than the single payment amount in their area. They recommended that CMS allow payment to be made at the payment amount for the area where the item is furnished. The commenters pointed out that it will also be difficult for contract suppliers to determine what the single payment amount is for beneficiaries who reside outside their CBA.

Response: Medicare currently pays for all DMEPOS items based on the payment amount applicable for the primary residence of the beneficiary, regardless of where the item is furnished. The Medicare payment system is set up to base payment amounts on the beneficiary's primary residence. We proposed to adopt this longstanding rule for the Medicare DMEPOS Competitive Bidding Program because it is an effective way to ensure that suppliers do not organize their businesses to obtain higher payment amounts that apply to certain geographic areas of the country. We do not believe it will be difficult for contract suppliers to determine how much they will be paid for an item furnished to a beneficiary who does not reside in the contract supplier's CBA because we will make the single payment amounts for each item in each CBA, along with the fee schedule amounts that will continue to be paid in areas that are not CBAs, publicly available to all suppliers.

Comment: Several commenters suggested that CMS not conduct competitive bidding, but simply lower the payment amounts for DMEPOS until the only suppliers left to provide these items are the minimum number necessary to furnish items needed by Medicare beneficiaries.

Response: Section 302(b) of the MMA mandated that the Secretary establish and implement competitive bidding programs for certain items of DMEPOS, and we have a legal obligation to comply with this legislative mandate.

After consideration of the public comments we received, we are finalizing, without substantive revisions, proposed § 414.408(a) that governs the payment basis under the Medicare DMEPOS Competitive Bidding Program. We did not receive comments on proposed §§ 414.408(c) and (d) and are finalizing those sections. We have made an editorial revision to § 414.408, using the acronym CBA instead of the terms ''area'' or ''competitive bidding area.''

2. General Payment Rules

Section 1834(a) of the Act and implementing regulations at 42 CFR § 414.200 through § 414.232 (with the exception of § 414.228) set forth the Medicare Part B payment methodology we currently use to pay for the rental or purchase of new and used DME. Each item of DME that is paid for under these sections is classified into a payment category, and each category has its own unique payment rules. Section 1842(s) of the Act provides authority for establishing a statewide or areawide fee schedule to be used for the payment of items described in section 1842(s)(2) of the Act. Under this authority, we implemented fee schedules for payment for the purchase and rental of enteral nutrients, equipment, and supplies (§ 414.100 through § 414.104). Section 1834(h) of the Act and § 414.228 of our regulations set forth the Medicare Part B payment methodology we currently use to pay for orthotics and prosthetics.

Other than the rules governing calculation of the single payment amount and other modifications to existing rules that are addressed in this final rule, we proposed that the current requirements regarding the rental or purchase of DMEPOS items would continue to apply under the Medicare DMEPOS Competitive Bidding Program. While we believe that we have discretion under section 1847(a)(6) of the Act to adopt new rules that would govern these requirements, we proposed only to change the payment basis for these items and to make a few modifications to existing rules.

3. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers) (§ 414.408(j))

a. Process for Grandfathering Suppliers

Section 1847(a)(4) of the Act requires that in the case of covered DME items for which payment is made on a rental basis under section 1834(a) of the Act, and in the case of oxygen for which

payment is made under section 1834(a)(5) of the Act, the Secretary shall establish a ''grandfathering'' process by which rental agreements for those covered items and supply arrangements with oxygen suppliers entered into before the start of a competitive bidding program may be continued. DME paid on a rental basis under section 1834(a) of the Act includes inexpensive or routinely purchased items furnished on a rental basis (as described in § 414.220 of the regulations), items requiring frequent and substantial servicing (as described in § 414.222 of the regulations), and capped rental items (as described in § 414.229 of the regulations). Section 1834(a)(5) of the Act and § 414.226 of our regulations provide that payment be made on the basis of monthly payment amounts for oxygen and oxygen equipment (other than portable oxygen equipment) with separate add-on payments for portable oxygen equipment. In cases where the beneficiary owns stationary and/or portable gaseous or liquid oxygen equipment, payment is made on the basis of monthly payment amounts for oxygen contents.

In the May 1, 2006 proposed rule (71 FR 25662), in proposed § 414.408(k) (redesignated as § 414.408(j) in this final rule), we proposed to establish the grandfathering process described below for rented DME and oxygen and oxygen equipment when these items are included under the Medicare DMEPOS Competitive Bidding Program. We proposed that this process would apply only to suppliers that began furnishing the items described above to Medicare beneficiaries who maintain a permanent residence in an area prior to the implementation of the competitive bidding program in that area that includes the same items.

In the case of the specific items identified in this section, we proposed in § 414.408(k)(4) to give Medicare beneficiaries the choice of deciding whether they would like to continue receiving the item from the grandfathered supplier or a contract supplier, unless the grandfathered supplier is not willing to continue furnishing the item under the terms we have specified below. If the grandfathered supplier is not willing to continue furnishing the item under these terms, a contract supplier would assume responsibility for continuing to furnish the item and be paid based on the single payment amount determined for that item under the Medicare DMEPOS Competitive Bidding Program. In addition, the beneficiary could elect, at any time, to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer. Suppliers that agree to be grandfathered suppliers for a specific item must agree to be a grandfathered supplier for all beneficiaries who request to continue to use their service for that item.

Comment: One commenter supported our grandfathering proposal. The commenter stated that our proposal would allow some beneficiaries to maintain an established relationship with a current supplier and that this was important to minimize disruption for beneficiaries.

Response: We appreciate the comment and agree that minimizing disruption of service for beneficiaries is an important principle that underlies our grandfathering rules.

b. Payment Amounts to Grandfathered Suppliers

(1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in a CBA

For items requiring frequent and substantial servicing, as well as oxygen and oxygen equipment, we proposed that a grandfathered supplier may continue furnishing these items to beneficiaries in accordance with existing rental agreements or supply arrangements. However, we proposed that, as long as the items remain medically necessary, the grandfathered supplier would be paid the single payment amounts determined for those items under the competitive bidding program because beneficiaries rent these items for extended time periods (proposed §§ 414.408(k)(2)(iii) and (iv)); redesignated as §§ 414.408(j)(2)(iii) and (iv) in this final rule). We believe that this payment proposal is consistent with section 1847(a)(4) of the Act, which requires us to establish a ''process'' under which rental agreements and supply arrangements ''may be continued,'' but is silent regarding the terms of that process. Because the rental payments for these items are not calculated based on, or limited to, the purchase fee for that item as is the case for other rented DME items, we do not believe that it is reasonable to continue paying the fee schedule amounts for these items and believe that payment at the competitively determined rates (that is, the single payment amounts) will comport with an overarching goal of competitive bidding to achieve savings for the Medicare program.

Unlike other items requiring frequent and substantial servicing, the duration of the rental payments for capped rental items and inexpensive or routinely purchased items is limited. In addition, unlike oxygen equipment, the payment amounts made for capped rental items and inexpensive or routinely purchased items are limited to the approximate purchase fee for the item.

Therefore, for items that are furnished on a rental basis under § 414.220 or § 414.229, we proposed in §§ 414.408(k)(2)(i) and (k)(2)(ii) (redesignated as §§ 414.408(j)(2)(i) and (ii) in this final rule) that the grandfathered supplier could continue furnishing the items in accordance with existing rental agreements and continue to be paid in accordance with section 1834(a) of the Act. We believe that continuing to pay for these grandfathered items at the fee schedule rates is authorized under section 1862(a)(17) of the Act, which allows the Secretary to specify ''other circumstances'' in which Medicare will make payment where the expenses for a competitively bid item furnished in a CBA were incurred by a supplier other than a contract supplier. In our view, the limited duration of the rental agreements for capped rental items and inexpensive or routinely purchased items furnished on a rental basis, in addition to the fact that payments for these items are based on or limited to the purchase fees for the items, constitute appropriate circumstances under which we would allow these rental agreements, including their payment terms, to continue until their conclusion. The rental fee schedule amounts that we would pay for grandfathered items in the capped rental or inexpensive or routinely purchased categories would be those fee schedule amounts established for the State in which the beneficiary maintains a permanent residence.

Comment: Some commenters stated that the grandfathering and transition policies are both unworkable and unfair to contract suppliers that will be required to continue to furnish capped rental or oxygen equipment to beneficiaries in the CBA regardless of the number of rental payments that have already been made to other suppliers for the equipment. They added that a contract supplier could inherit an unknown number of beneficiaries who have been renting oxygen equipment for 20 to 30 months of continuous use. In these cases, the contract supplier would receive a minimal number of rental payments that would be insufficient to cover the cost of oxygen equipment for which title will transfer to the beneficiary after 36 months of continuous use. The commenters stated that if a contract supplier has to supply a capped rental item for the last 6 months of the rental cycle, the supplier

would only receive 45 percent of the single payment amount, which is not enough to cover costs. They recommended that Medicare initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

One commenter suggested that CMS establish a defined timeframe within which a beneficiary can transfer to a new contract supplier. The commenter also suggested that CMS not require contract suppliers to accept, as customers, beneficiaries who are already currently using capped rental equipment furnished by another supplier. Another commenter stated that CMS should mandate grandfathering by requiring the supplier that furnished oxygen or a capped rental item to a beneficiary before the implementation of a competitive bidding program to continue to furnish that item to the beneficiary for the remainder of the rental period. Some commenters also questioned how section 5101 of the DRA, which imposes new requirements regarding the rental of oxygen, oxygen equipment, and capped rental items, will affect competitive bidding. Several commenters suggested that the information in the proposed rule is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the DRA will have on competitive bidding. Several commenters noted that until CMS establishes the scope of the DRA provisions and how they dovetail with competitive bidding, they cannot provide meaningful comments or make recommendations. For example, the commenters questioned how CMS intended to apply the DRA oxygen provisions to grandfathered suppliers and beneficiaries and whether the grandfathered relationship would terminate at the conclusion of 36 months.

Response: Section 5101 of the DRA (discussed in detail in section III.B. of this final rule) caps the number of rental payments that may be made for oxygen equipment and capped rental DME items and requires that title to these items transfer to the beneficiary at the conclusion of the rental period. We proposed in the May 1, 2006 proposed rule (71 FR 25662) that current requirements regarding the rental or purchase of DMEPOS items would continue to apply under the Medicare DMEPOS Competitive Bidding Program. These requirements include the changes we recently made to 42 CFR Part 414, Subpart D of our regulations that implemented section 5101 of the DRA, new supplier requirements that protect beneficiary access to oxygen, oxygen equipment and capped rental items, and new payment classes for oxygen and oxygen equipment (see 71 FR 65884 for a full discussion of these provisions). We recognize that the title transfer provisions that are part of these new requirements, when read together with proposed § 414.408(k)(1) (allowing a supplier to elect to be a grandfathered supplier) and proposed § 414.408(k)(4) (allowing a beneficiary the choice of receiving a grandfathered item from a grandfathered supplier or a contract supplier), might place a contract supplier in the position of being required to furnish oxygen equipment or a capped rental item to a beneficiary who previously rented the item from another supplier (either a supplier that does not elect to become a grandfathered supplier or a grandfathered supplier) and then transfer title to that item without being paid a sufficient amount to cover its costs. We also recognize that contract suppliers will not be able to predict how many beneficiaries will obtain capped rental items or oxygen equipment from them, rather than from a supplier that does not elect to become a grandfathered supplier.

In response to the commenters' concerns, we are implementing two new payment rules to ensure that contract suppliers that must begin furnishing oxygen equipment and/or capped rental items to which the grandfathering process would otherwise apply receive a sufficient number of monthly rental payments to recover their costs. We believe that these changes are consistent with our statutory mandate under sections 1847(a) and (b) of the Act, which give us broad authority regarding how to structure the Medicare DMEPOS Competitive Bidding Program, and more specifically with section 1847(b)(3)(A) of the Act, which allows us to specify the terms and conditions of contracts we enter into with contract suppliers.

Capped Rental: For capped rental items furnished on a rental basis, we are providing in a new § 414.408(h)(2) that a contract supplier that must begin furnishing a capped rental item during the rental period to a beneficiary who is no longer renting the item from his or her previous supplier (because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers) will receive 13 monthly rental payments for the item, regardless of how many monthly rental payments Medicare previously made to the prior supplier, assuming the item remains medically necessary. This will ensure that the contract supplier can recover its costs because, as discussed in section VI.G.5. of this final rule, the 13 monthly rental payments for the capped rental item will be based on a single payment amount that reflects the purchase price for that item. At the end of this new 13 month rental period, the contract supplier will transfer title to the capped rental item to the beneficiary. This rule does not apply when a beneficiary who is renting a capped rental item from a contract supplier elects to obtain the same item from another contract supplier, because the grandfathering provisions, as described in section 1847(a)(4) of the Act, only apply to those situations in which a beneficiary had been previously receiving the item from a noncontract supplier. In this case, the new contract supplier would be paid the single payment amount for the duration of the rental period.

Oxygen Equipment: For oxygen equipment, we provide in a new § 414.408(i)(2) that a contract supplier that must begin furnishing oxygen equipment after the rental period has already begun to a beneficiary who is no longer renting the item from his or her previous supplier (because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers) will receive at least 10 rental payments for furnishing the equipment. For example, if a contract supplier begins furnishing oxygen equipment to a beneficiary in months 2 through 26, we would make payment for the remaining number of rental months in the 36-month rental period, because the number of payments to the contract supplier would be at least 10 payments. In other words, a contract supplier that begins furnishing oxygen equipment beginning with the 20th month of rental will receive 17 payments (17 for the remaining number of rental months in the 36 month rental period). However, if a contract supplier begins furnishing oxygen equipment to a beneficiary in month 27 or later, we would make 10 rental payments assuming the equipment remains medically necessary. We believe this is a reasonable solution because our data from the GAO and the OIG and data available through the Internet show that most oxygen equipment can be purchased for $1,000 or less, and data from the competitive bidding demonstrations indicate that suppliers received more than $1,000 over 10 months for furnishing oxygen equipment. Based on these data, we believe that 10 months is sufficient to cover the contract supplier's cost to furnish the equipment, irrespective of

the modality that is used to administer the oxygen. This rule regarding the minimum number of rental payments does not apply when a beneficiary switches from a contract supplier to another contract supplier to receive his or her oxygen equipment. In this case, the new contract supplier would be paid the single payment amount for the remaining number of months in the rental period.

We note that the DRA does not apply to inexpensive or routinely purchased items when they are furnished on a rental basis. Therefore, we do not see a need to make these special payment provisions applicable to those items.

Comment: Several commenters suggested that CMS establish a transition period that would allow beneficiaries who reside in a CBA to continue to receive items from a noncontract supplier. They indicated that suppliers should be paid the current fee schedule amounts for these items during this transition period. They further suggested that CMS could use this period of time to educate beneficiaries and suppliers about the Medicare DMEPOS Competitive Bidding Program. Other commenters stated that the payment amount to grandfathered suppliers should always be the fee schedule amount (not just during a transition period) and never be the single payment amount.

Response: We proposed to establish a grandfathering process that would allow existing rental agreements for certain rented items to continue because we want to minimize the potential that these arrangements will be disruptive to the beneficiary due to the implementation of competitive bidding. We do not believe it is necessary to establish a transition process, however, as discussed in the proposed rule, we are requiring that a supplier that elects to be a grandfathered supplier for a specific item must serve as a grandfathered supplier to all beneficiaries who elect to receive that item from them. We plan to start educating suppliers, beneficiaries, and referral agents about competitive bidding as soon as this final rule is published and expect that these efforts will make the transition to this new program go as smoothly as possible. We do not, however, have authority to establish a grandfathering process that would allow beneficiaries to continue receiving from their current supplier items other than those specified in section 1847(a)(4) of the Act.

We proposed to pay grandfathered suppliers the single payment amount for items requiring frequent and substantial servicing and oxygen and oxygen equipment because the rental payments for these items are not calculated based on, or limited to, the purchase fees for these items. Therefore, we believe that it is reasonable to require suppliers that want to continue furnishing these items as grandfathered suppliers to accept the same payment that will be made for these items to contract suppliers. This achieves the goal of the program to achieve savings for the Medicare program.

However, the payment amounts made to grandfathered suppliers for furnishing capped rental and inexpensive or routinely purchased items will continue to be based on the fee schedule amounts that are paid for these items. Unlike items requiring frequent and substantial servicing and oxygen and oxygen equipment, the monthly rental payments for these items are made for a more limited period of time. In addition, the payment amounts for these items are based on the purchase fees for these items. Therefore, we believe that it is reasonable to continue paying for these items in accordance with existing rental agreements.

(2) Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

There may be instances when a supplier that was awarded a contract to furnish rental items or oxygen and oxygen equipment under a competitive bidding program is not awarded a contract to furnish the same items under a subsequent competitive bidding program in the same area. We are concerned that if this occurs, beneficiaries will need to switch suppliers in the middle of the rental period and could experience a disruption of service as a result. In order to minimize this possibility, we proposed to apply section 1847(a)(4) of the Act not only in a CBA where we implement a competitive bidding program for the first time, but also in the same area when we implement a subsequent competitive bidding program (proposed § 414.408(k)(3); redesignated § 414.408(j)(3) in this final rule). We believe our proposal is consistent with section 1847(a)(4) of the Act, which we interpret as applying to each competitive bidding ''program'' that we implement in an area because each program will be unique in terms of bidders, contract suppliers, items included in the program, and prices. Under the proposed rule, Medicare beneficiaries would be allowed to continue renting medically necessary items from their existing supplier, even if that supplier has lost its contract status under a subsequent competitive bidding program.

However, where a supplier that is no longer a contract supplier continues to furnish a rental item or oxygen and oxygen equipment on a grandfathered basis, we proposed that Medicare make payment for the item in the amount established for that item under the new competitive bidding program for that area. We believe that section 1847(a)(4) of the Act gives us this discretion, since that section only requires us to establish a ''process'' under which these rental agreements or supply arrangements ''may continue'' but does not specify a payment methodology that must be used under that process. In addition, we do not believe that the alternative, which would be to make payment for the item under the fee schedule, is reasonable since the rental agreement or supply arrangement began under a competitive bidding program.

All rules that applied to grandfathered suppliers will apply in this situation when a supplier is a contact supplier in under one competitive bidding program *e.g.* in round one but is not a contract supplier in a subsequent competitive bidding program in the same CBA, *e.g.* in round two. However, the payment amounts will not revert back to the current fee schedule but rather the payment amounts will be the new competitive bid single payment amounts as determined under § 414.416.

We did not receive any specific comments on these proposals. Therefore, in this final rule, we are redesignating proposed § 414.408(k)(3) as § 414.408(j)(3), making editorial revisions, and finalizing that section.

c. Payment for Accessories for Items Subject to Grandfathering (§ 414.408(j)(5))

We proposed that accessories and supplies used in conjunction with an item which is furnished under a grandfathering process described above may also be furnished by the grandfathered supplier. Payment would be based on the single payment amount established for the accessories and supplies if the item is oxygen or oxygen equipment or one that requires frequent and substantial servicing. For accessories and supplies used in conjunction with capped rental and inexpensive or routinely purchased items, we proposed that the payment amounts would be based on the fee schedule amounts for the accessories and supplies furnished prior to the implementation of the first competitive bidding program in an area, or on the newly established competitively bid single payment amounts if the items are

furnished by a grandfathered supplier that was a contract supplier for a competitive bidding program, but is no longer a contract supplier for a subsequent competitive bidding program in the same area.

Our proposal is similar to the grandfathering approach that was used in the DMEPOS competitive bidding demonstrations under which we paid grandfathered suppliers the competitively bid amount for certain items and the fee schedule amounts for other items. We specifically solicited comments on our grandfathering proposals.

Comment: Several commenters supported our proposal to require that accessories and supplies used in conjunction with an item furnished under the grandfathering process be furnished by a grandfathered supplier.

Response: We appreciate the commenters' support and continue to believe that this approach is reasonable. To clarify the situations in which this may occur, we are revising proposed § 414.408(k) (redesignated § 414.408(j) in this final rule) by adding a new paragraph (j)(5) to specify that accessories and supplies that are necessary for the effective use of DME may also be furnished by the same grandfathered supplier that furnishes the grandfathered item. This approach will provide the beneficiary with continuity of service by requiring one supplier to provide all related items the beneficiary may need for the proper use of their equipment. This rule will not apply to accessories that are not an integral part of the base equipment. For example, a standard mattress is an essential accessory for a hospital bed and may be furnished by a grandfathered supplier of a hospital bed, if the supplier has elected to be a grandfathered supplier for the hospital bed. However, a special, powered alternating pressure mattress furnished to prevent decubitus ulcers is not an essential part of the base equipment and is furnished in addition to the general service of furnishing the hospital bed.

Assuming the grandfathered supplier for the base equipment is willing to also furnish accessories or supplies for the base equipment, beneficiaries will be able to choose to obtain any competitively bid accessories or supplies from either the grandfathered supplier or a contract supplier. We believe that the amount to be paid under the Medicare DMEPOS Competitive Bidding Program should be the single payment amount, regardless of which supplier furnishes the accessories or supplies. Payment for most accessories or supplies for DME is made on a purchase basis, and in those cases where a single payment amount has been established for the accessories or supplies, we believe it is reasonable to pay the single payment amount for the accessories or supplies to the grandfathered supplier for the base equipment. We believe this is reasonable, regardless of what payment category the base equipment falls under because the single payment amount reflects a reasonable payment amount determined by a competitive market. If the grandfathered supplier chooses not to furnish the accessories or supplies for the grandfathered base equipment, a contract supplier would be responsible for furnishing the accessories or supplies.

Comment: One commenter suggested that CMS needs to establish a transition plan for Medicare Advantage beneficiaries who disenroll from their MA plan and enroll in traditional fee-for-service Medicare Part B. The commenter pointed out that these beneficiaries may currently be using a noncontract supplier and should be given the option to remain with their existing supplier under the grandfathering provisions.

Response: All beneficiaries to whom the grandfathering process applies can elect to continue receiving certain rented items from a supplier that elects to become a grandfathered supplier. Therefore, if a supplier from whom a Medicare Advantage beneficiary previously rented one of these items is eligible, and elects, to become a grandfathered supplier, then the beneficiary could continue to receive the item from that supplier.

Comment: One commenter stated that the rule should apply grandfathering provisions to enteral equipment, nutrition, and supplies. The commenter stated that beneficiaries on enteral nutrition develop an ongoing relationship with their suppliers. The commenter pointed out that suppliers that furnish enteral equipment, nutrition, and supplies frequently service and maintain the enteral pumps. The commenter added that, under the proposed rule, contract suppliers would be responsible for servicing and maintaining enteral pumps that they did not provide to beneficiaries. The commenter recommended that the previous enteral supplier be able to continue to provide enteral equipment, nutrition, and supplies to the beneficiary until the 15-month rental period ends.

Another commenter stated that our grandfathering proposal did not include a process for grandfathering glucose testing supplies. The commenter indicated that competitive bidding could force many beneficiaries to switch their glucose monitoring system if the contract supplier does not offer the testing supplies for the monitor they currently use.

Another commenter suggested that Medicare allow grandfathering for all DMEPOS items. Another commenter suggested that Medicare only allow grandfathering for oxygen equipment because otherwise, competitive bidding for capped rental items, oxygen, and oxygen equipment will only affect beneficiaries who need to obtain these items after a competitive bidding program has been implemented in their area, which undermines a program goal to harness market place dynamics.

Response: Section 1847(a)(4) of the Act requires that we establish a process by which rental agreements for DME and supply arrangements for suppliers of oxygen and oxygen equipment entered into before the implementation of a competitive bidding program may be continued. We do not believe we have authority to allow grandfathering for other DMEPOS, such as glucose testing supplies and enteral nutrition, equipment, and supplies.

After consideration of the public comments received, we are redesignating proposed § 414.408 (k) as § 414.408 (j) and finalizing this section as discussed above and with additional technical modifications. We are also adding new § 414.408(h)(2) and § 414.408(i)(2), which provide for special payments to certain contract suppliers that furnish certain rented items.

4. Payment Adjustments

a. Adjustment to Account for Inflation (§ 414.408(b))

The fee schedule payment amounts for DMEPOS items are updated by annual update factors described in 42 CFR Part 414, Subparts C and D. In general, the update factors are established based on the percentage change in the CPI–U for the 12-month period ending June 30 of each year and preceding the calendar year to which the update applies. In accordance with section 1847(b)(3)(B) of the Act, the term of a competitive bidding contract may not exceed 3 years.

In the May 1, 2006 proposed rule (71 FR 25663), we proposed to apply an annual inflation update to the single payment amounts established for a competitive bidding program (proposed § 414.408(b)). Specifically, beginning with the second year of a contract entered into under a competitive bidding program, we proposed to

update the single payment amounts by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding calendar year. We stated that using the CPI–U index would be consistent with Medicare using this index to update the DME fee schedule. This would account for inflation in the cost of business for suppliers submitting bids for furnishing items under a multi-year contract.

Comment: One commenter suggested that CMS not finalize its proposal to make an annual inflation update to the single payment amounts. The commenter believed that this payment adjustment may make it possible for single payment amounts to rise faster than current fee schedule payment amounts, particularly in the event of a payment freeze or a payment reduction. The commenter recommended that CMS determine a single payment amount that will apply for the full term of the contract or allow each bidder to specify an annual adjustment in its bid.

Response: We agree with the commenter and will not finalize our proposal to make an annual inflation update to the single payment amounts. The single payment amounts will remain in effect for the duration of the contract. We believe it is more appropriate for suppliers to address the possible effects of inflation or price increases when they formulate their bids because automatic payment adjustments to competitively bid items may result in higher payment amounts than would occurred under the DMEPOS fee schedule payment amounts if these amounts are subject to Congressional freezes or payment reductions.

Comment: Several commenters stated that the proposal did not address situations where the manufacturers or distributors raise their prices, thereby requiring suppliers to pay more money to purchase their products. They believe that suppliers may be required to continue to furnish these items at the single payment amounts notwithstanding the fact that their costs have increased.

Response: While we recognize that increases in suppliers' costs for equipment and other costs can occur at any time, suppliers should be generally aware of how often these changes occur and how these changes affect their businesses. We expect suppliers to consider this factor when developing their bids, which represent bids for furnishing items during the entire period that the contract will be in effect.

Comment: Several commenters recommended that CMS continue to use the CPI–U to adjust fee schedule amounts for class III devices. The commenters indicated that the March 2006 GAO report was flawed because it did not provide a full assessment of changes over time in the costs of producing, supplying and servicing class III devices. The commenters also noted that the report does not specify a specific percentage update for CY 2007 or CY 2008. Another commenter stated that the GAO report examines class III devices in relation to only a very limited number of higher-technology class III items that may not be reflective of the general class III items. One commenter unfavorably compared the GAO report to the Medicare Payment Advisory Commission (MedPAC) reports which assess the adequacy of Medicare payments for hospital inpatient and outpatient services, physician services, outpatient dialysis services, skilled nursing facility services, home health services, long-term care hospital services and inpatient rehabilitation facility services. (Following each detailed assessment, MedPAC then recommends an update policy for each provider category for the coming year.) The commenter noted that the GAO report does not justify its alternative assessment methodology or its failure to take into account changes over time in manufacturer costs for class III devices. Another commenter recommended that the class III proposal be included in a separate rulemaking procedure because it is not related to competitive bidding.

Response: Pursuant to section 1834(a)(14)(H)(i) of the Act, in determining the appropriate fee schedule update percentages for class III medical devices prescribed in section 513(a)(1)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(c)(1)(C)) for CY 2007, we must take into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the MMA. We have not yet made a determination regarding the appropriate percentage change for CY 2007 in the fee schedule amounts for class III DME and, therefore, are not making that determination as part of this final rule. We will address this issue in a future rulemaking.

After consideration of the public comments received, in this final rule, we are revising proposed § 414.408(b) to specify that the single payment amount for each item that is determined under each competition will be in effect for the duration of the contract and will not be adjusted by an annual inflation update.

b. Adjustments to Single Payment Amounts to Reflect Changes in the HCPCS (§ 414.426)

We proposed under § 414.426 that revisions to HCPCS codes for items under a competitive bidding program that occur in the middle of a bidding cycle would be handled as follows:

- If a single HCPCS code for an item is divided into multiple codes for the components of that item, the sum of payments for these new codes would be equal to the payment for the original item. Suppliers selected through competitive bidding to provide the item would also provide the components of the item. During the subsequent competitive bidding cycle, suppliers would bid on each new code for the components of the item, and we would determine new single payment amounts for these components.
- If a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes would continue to be the same payment amount applied to the single code until the next competitive bidding cycle. During the next cycle, suppliers would bid on the new separate and distinct codes.
- If the HCPCS codes for several components of one item are merged into one new code for the single item, the payment amount of the new code would be equal to the total of the separate payment amounts for the components. Suppliers that were selected through competitive bidding to supply the various components of the item would continue to supply the item using the new code. During the subsequent bidding cycle, suppliers would bid on the new code for the single item to determine a new single payment amount for this new code.
- If multiple codes for different, but related or similar items are placed into a single code, the payment amount for the new single code would be the average (arithmetic mean) weighted by frequency of payments for the formerly separate codes. Suppliers would also provide the item under the new single code. During the subsequent bidding cycle, suppliers would bid on the new single code and determine a new single payment amount for this code.

Comment: Several commenters stated that when multiple codes for similar items are merged to a new code, CMS should continue to use the former codes and single payment amounts for the remainder of the contract period. One commenter stated that the proposal that the payment amounts for new HCPCS codes continue to be the same payment

amounts until the next competitive bidding cycle is not an equitable proposal and a more appropriate procedure must be developed. Another commenter stated that CMS' only authority to adjust payment amounts for an item is through the inherent reasonableness authority under the Medicare statute. The commenter disagreed with the proposal for paying for new HCPCS codes that are established during a competitive bidding cycle. The commenter stated that CMS should rebid these items, assuming they are appropriate for inclusion in the program.

Response: After further consideration, we are clarifying that when multiple codes for different items are discontinued and the items are placed into a new single code, the payment for the new code will be based on the fee schedule methodology, even if we had previously established a single payment through competitive bidding for the items included in the new code. The old codes will be considered invalid and therefore will no longer be included in the competitive bidding program for the remainder of the contract term. During a subsequent competitive bidding program, suppliers would bid on the new single code and we will determine a new single payment amounts for this code based on the bids submitted and accepted. We are not finalizing this part of the proposed methodology because we do not believe the single payment amount in this case would be reflective of the bids submitted and accepted for these multiple items. However, unlike this proposal, our other three proposals will be finalized because they are reflective of the bids submitted and accepted for the items described by the new codes.

We note that we do not believe we have authority to use the inherent reasonableness authority to adjust the single payment amounts set through competitive bidding. We believe that the prices set by competitive bidding will be reasonable because they will be reflective of the market. When we split or merge HCPCS codes, we will ensure that the new payment amounts are reflective of the previously established payment amounts, and this does not require the use of the inherent reasonableness authority or the need to rebid the items.

After consideration of the public comments we received, we are finalizing §§ 414.426(a) through (c) and revising § 414.426(d) as discussed above and with additional technical changes.

5. Authority to Adjust Payments in Other Areas

Section 1834(a)(1)(F)(ii) of the Act provides authority, effective for covered items furnished on or after January 1, 2009, that are included in a competitive bidding program, for us to use the payment information determined under that competitive bidding program to adjust the payment amounts otherwise recognized under section 1834(a)(1)(B)(ii) of the Act for the same DME items in areas not included in a competitive bidding program. Sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act provide the same authority for orthotic and prosthetic devices, and enteral nutrition, respectively.

In the May 1, 2006 proposed rule (71 FR 25664), we proposed to use this authority but stated that we had not yet developed a detailed methodology for doing so. Therefore, we specifically invited comments and recommendations on this issue. We stated that we believed that our methodology would be influenced by our experience and information gained from the competitive bidding programs in CYs 2007 and 2009. When submitting recommendations on a methodology for using this authority, we asked commenters to keep in mind the following factors that are likely to be incorporated in the methodology:

- The threshold or amount or level of savings that the Medicare program must realize for an item or group of items before we would use payment information from a competitive bidding program to adjust payment amounts for those items in other areas.
- Whether adjustments of payment amounts in other areas would be on a local, regional, or national basis, depending on the extent to which the single payment amounts and price indexes (for example, local prices used in calculating the CPI–U) for an item or group of items varied across different areas of the country.
- Whether adjustments of payment amounts in other areas would be based on a certain percentage of the single payment amount(s) from the CBA(s).

Comment: Some commenters stated that CMS must issue a final rule to spell out a detailed plan for using the authority provided by sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act before it can implement these provisions.

Response: We agree with the commenters that a more detailed plan must be developed for using the authorities provided by sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act, and we plan to conduct subsequent rulemaking prior to implementing these provisions. Subsequent rulemaking would provide a more detailed plan for using these authorities. Therefore, we are not finalizing proposed § 414.408(e) until the subsequent rulemaking is completed.

6. Requirement to Obtain Competitively Bid Items From a Contract Supplier (§§ 411.15(s), 414.408(e))

Beneficiaries often travel, for example, to visit family members or to reside in a State with a warmer climate during the winter months. To prevent these beneficiaries from having to return home to obtain needed DMEPOS, in proposed § 414.408(f)(2)(ii) (redesignated § 414.408(e)(2)(iii) in this final rule), we proposed to allow beneficiaries who are traveling outside the CBA where they permanently reside to obtain items that they would ordinarily be required to obtain from a contract supplier for their CBA from a supplier that has not been awarded a contract to furnish items for that area. If the area that the beneficiary is visiting is also a CBA and the item is subject to the competitive bidding program in that area, the beneficiary would be required to obtain the item from a contract supplier for that area. If the area that the beneficiary is visiting is not a CBA, or if the area is a CBA but the item needed by the beneficiary is not included in the competitive bidding program for that area, the beneficiary would be required to obtain the item from a supplier that has a valid Medicare supplier number. In either case, payment to the supplier would be made based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence.

In the May 1, 2006 proposed rule, we proposed that if a beneficiary is not visiting another area, but is merely receiving competitively bid items from a supplier located outside but near the boundary of the CBA, the proposed exemption to the general rule that beneficiaries who reside in a CBA must obtain DMEPOS covered by competitive bidding from contract suppliers in that area would not apply. We stated that we plan to monitor the programs closely to ensure that this type of abuse or circumvention of the competitive bidding process and requirements to obtain items from a contract supplier does not occur.

We also proposed to base claims jurisdiction and the payment amount on the beneficiary's permanent residence as we have done since the early 1990s with the current DMEPOS program under § 421.210(e). Under this proposal, the

DME MAC responsible for the area where the beneficiary maintains a permanent residence would process all claims submitted for items furnished to that beneficiary, whether or not the beneficiary obtained the item in that area. If the beneficiary maintained a permanent residence in a CBA and obtained an item included in the competitive bidding program for that area, Medicare would pay the supplier the single payment amount for the item determined under the competitive bidding program for that area. If the beneficiary did not maintain a permanent residence in a CBA, Medicare would pay the supplier the fee schedule amount for the area in which the beneficiary maintains a permanent residence. We believe that this proposal is consistent with our current policy, under which suppliers across the country are paid the same amount for similar products obtained by beneficiaries who maintain their permanent residence within the same geographic area.

We proposed that Medicare beneficiaries who maintain their permanent residence in a CBA be required to obtain competitively bid items from a contract supplier for that area with the following two exceptions:

- A beneficiary may obtain an item from a supplier or a noncontract supplier in accordance with the competitive bidding program grandfathering provisions described in section VI.C.3. of this final rule.
- A beneficiary who is outside of the CBA where he or she maintains a permanent residence may obtain an item from a contract supplier, if he or she is in another CBA and the same item is included under a competitive bidding program for that area, or from a supplier with a valid Medicare supplier number, if he or she is either in another CBA that does not include the item in its program or is in an area that is not a CBA.

We proposed that unless one of the exceptions discussed above applies, Medicare would not pay for the item. We also proposed to add a new § 411.15(s) that would prohibit Medicare from making payment for an item that is included in a competitive bidding program if that item is furnished by a supplier other than a contract supplier, unless an exception applies.

Comment: Several commenters suggested that CMS exclude from competitive bidding beneficiaries who have Medicare as their secondary insurance. The commenters stated that claims for beneficiaries with Medicare as a secondary payer should be processed and paid under the standard fee schedule.

Response: We believe that the commenters' intent was to request that Medicare pay for an item that was furnished by a supplier that the beneficiary is required to use under his or her primary insurance policy even if that item is furnished by a supplier that is not a contract supplier. We agree with the commenters that an exception under the Medicare DMEPOS Competitive Bidding Program needs to be made for beneficiaries with Medicare as their secondary insurance. Section 1862(a)(17) of the Act allows the Secretary to specify circumstances under which it would be appropriate to pay for an item that is furnished by an entity other than a contract supplier. To address secondary payer concerns, we are adding an exception at § 414.408(e)(2)(ii) of the list of circumstances when Medicare will make payment where the expenses for a competitively bid DMEPOS item furnished in a CBA were incurred by a supplier other than a contract supplier. Under this exception Medicare may make a secondary payment for a DMEPOS item that is furnished by a noncontract supplier if the beneficiary, in order to comply with his or her primary insurance plan, does not have the option to use a contract supplier. In addition, Medicare will only make a secondary payment to a supplier that the beneficiary is required to use under his or her insurance plan if the supplier is eligible to submit claims to Medicare. These suppliers will need to have a valid Medicare billing number to be eligible to submit claims to Medicare. This regulation does not supersede the established Medicare secondary payer statutory and regulatory requirements, including the Medicare secondary payment rules found at 42 CFR 411.32 and 411.33, and payment will be calculated in accordance with those rules.

Comment: One commenter stated that the requirement to obtain competitively bid items from a contract supplier will be extremely confusing to the traveling beneficiary and will limit beneficiary access to DMEPOS while the beneficiary is away from his or her permanent residence. The commenter also proposed that the supplier outside of the beneficiary's CBA be reimbursed either (a) the regular fee schedule amount for the product if the area traveled to is not a CBA or (b) the higher single payment amount for the two CBAs, if the area where the beneficiary has traveled is in a CBA.

Some commenters were concerned that the difference between the fee schedule amount and the single payment amount may be substantial, thereby hindering beneficiary access to needed equipment. They recommended that CMS continue to pay for an item based on the fee schedule amount that corresponds with the beneficiary's permanent residence if the beneficiary obtains the item while visiting another area. The commenters were concerned about the impact that the requirement to obtain competitively bid items from a contract supplier would have on both suppliers and beneficiaries who travel to ''snowbird'' areas.

Response: The approach set out in the proposed rule is consistent with our long-standing rule under which Medicare payment for DMEPOS is based on the beneficiary's primary residence. If a beneficiary maintains a permanent residence in a CBA, payment for an item that the beneficiary obtains while visiting another area will be based on the payment amount for the item in the beneficiary's CBA. We note that, under our current rule, there are instances when a supplier is paid more or less than the fee schedule amount that the supplier would otherwise receive for an item because the payment amount has been determined based on where the beneficiary resides. The same will be true under the Medicare DMEPOS Competitive Bidding Program. For example, when a beneficiary who resides in an area that is not a CBA travels into a CBA and needs to obtain an item, the supplier that furnishes the item will be paid the current fee schedule amount for the item based on the beneficiary's residence, even if the fee schedule amount is greater than the single payment amount that the supplier would otherwise receive for furnishing the item. We believe that it is appropriate to adopt our current claims jurisdiction policy for the Medicare DMEPOS Competitive Bidding Program because it minimizes the possibility that suppliers will set up locations in certain geographic areas for the purpose of obtaining higher payment amounts.

We plan to conduct an extensive education campaign to minimize confusion on the part of both beneficiaries and suppliers regarding this provision and all other provisions of the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters stated that suppliers need access to a beneficiary database that identifies the county in which a beneficiary resides at the zip code level, so they can determine if the beneficiary resides in a CBA.

Response: We do not believe that this is necessary for suppliers. Currently,

payment is based on beneficiary residence, and suppliers do not have access to beneficiary zip code information to bill for items. We will post all counties and zip codes where competitive bidding is conducted on our Web site. The Medicare claims form requires a beneficiary address. Therefore, the supplier will be able to ascertain if the beneficiary resides in a CBA. We currently post fee schedules on our Web site and the single payment amounts for each item in each CBA will also be posted. Therefore, suppliers can look to the postings to determine payment amounts in other areas. In addition, our claims processing systems are equipped to identify the appropriate payment amount so no calculations are necessary to determine the payment amount for an item.

Comment: Several commenters stated that beneficiaries will not have access to newer technology for competitively bid products.

Response: One of the main objectives of the Medicare DMEPOS Competitive Bidding Program is to ensure that beneficiaries have access to quality DMEPOS. Therefore, we have built safeguards into the competitive bidding program to ensure there is continued access to quality medical equipment and supplies, as well as to services necessary to maintain the equipment. As we discuss more fully in response to comments in section XV. Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids of this final rule (§ 414.422(c)), we have proposed to include a nondiscrimination clause in each contract awarded under this program. We believe that the inclusion of this contract provision will ensure that beneficiaries who obtain items under a competitive bidding program have access to the same products as other Medicare customers and private pay individuals. In addition, we are taking other steps to ensure that high quality items are furnished to beneficiaries under this program. We plan to implement a complaint system so that beneficiaries, referral agents, providers, and suppliers can report problems and difficulties they encounter with the ordering and furnishing of DMEPOS in CBAs. In addition, we will not award a contract to a supplier unless that supplier meets our eligibility standards, is accredited, and meets our financial standards.

In addition, items that represent new technology and that receive a new HCPCS code to separately designate them, rather than updates to current technology will not be added to a contract supplier's contract. Instead, beneficiaries will be able to obtain these items from any supplier for the remainder of the contract period, and the supplier will be paid the fee schedule amount for those items.

Comment: One commenter stated that competitive bidding will limit full-time access to supplies that are crucial to beneficiaries with diabetes. The commenter stated that beneficiaries may find that they can no longer purchase their supplies from their current supplier and may be inconvenienced. The commenter recommended that CMS implement an aggressive education outreach program.

Response: We do not believe that competitive bidding will limit beneficiary access to any competitively bid items, including diabetic supplies. Although it is true that some beneficiaries will have to find a contract supplier to purchase their supplies, we do not believe this will result in an inconvenience to beneficiaries, because there will be a sufficient number of contract suppliers that furnish these items for each CBA. The process we have proposed for awarding contracts under the Medicare DMEPOS Competitive Bidding Program will ensure that there are a sufficient number of contract suppliers to furnish items to all beneficiaries located in a CBA. We plan to conduct an aggressive outreach program for all beneficiaries, suppliers, and referral agents. (We refer readers to the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354) for a complete discussion of our planned education and outreach policy.)

Comment: One commenter expressed concern that in a State with multiple MSAs, there could be a different payment rate for the same item in each MSA. The commenter believed this would add confusion and would increase billing time and expenses, which will, in turn, increase the price of products.

Response: We agree that if we conducted competitive bidding in multiple CBAs within a State, there could be different prices in each CBA for the same item. However, we do not believe that this would be a problem for contract suppliers. Under the current program, suppliers may have a customer base that comes from areas with different fee schedule amounts because the fee schedules vary by State. Therefore, we believe that many suppliers are already equipped to handle price variations for an item. In addition, the fee schedule for each item in each State is published on our Web site, and we plan to also publish the single payment amounts for each item in each CBA on our Web site.

After consideration of the public comments we received, we are redesignating proposed § 414.408(f) as § 414.408(e) and adding a new § 414.408(e)(2)(ii) that specifies that Medicare may make a secondary payment for a DMEPOS item that is furnished by a supplier that is not awarded a contract under a competitive bidding program. We are also finalizing the remainder of proposed §§ 414.408(f)(1) and (f)(2)(i) and (f)(2)(ii) (redesignated as §§ 414.408(e)(2)(i) and (e)(2)(iii)) with only technical modifications. We are also finalizing § 411.15(s).

7. Limitation on Medicare Payment and Beneficiary Liability for Items Furnished by Noncontract Suppliers (§§ 414.408(e)(3) and (e)(4)

In the May 1, 2006 proposed rule (71 FR 25664), we proposed that if a noncontract supplier located in a CBA furnishes an item included in the competitive bidding program for that area to a beneficiary who maintains a permanent residence in that area, the beneficiary would have no financial liability to the noncontract supplier unless the grandfathering exception discussed in section VI.D.3. of this final rule applies (proposed § 414.408(f)(2)(iii); redesignated § 414.408(e)(3) in this final rule).

We proposed that this rule would not apply if the noncontract supplier furnished items that are not included in the competitive bidding program for the area. We proposed to specially designate the supplier numbers of all noncontract suppliers so that we will easily be able to identify whether a noncontract supplier has furnished a competitively bid item to a beneficiary who maintains a permanent residence in a CBA (proposed § 414.408(f)(3)) (redesignated in this final rule as § 414.408(e)(4)).

Comment: Several commenters suggested that proposed § 414.408(f)(2)(ii) be clarified to include a limitation on beneficiary liability unless the noncontract supplier has obtained a signed ABN, which indicates that the beneficiary was informed prior to receiving service that there would be no coverage due to the supplier's noncontract status and that the beneficiary still desired to receive the service from the noncontract supplier.

Response: We are revising the regulation to add § 414.408(e)(3)(ii) and § 414.408(c) to reflect that there is a limitation on beneficiary liability unless the noncontract supplier has obtained a signed ABN because, if the beneficiary desires to receive this item from a

supplier that is not a contract supplier, the ABN indicates the beneficiary's knowledge and understanding that Medicare will not pay for that item. In this circumstance, a noncontract supplier cannot bill the Medicare program and receive payment for a competitively bid item provided to a beneficiary whose primary residence is in a CBA unless an exception discussed in this rule applies.

We are also revising proposed § 414.408(f)(2)(iii) (redesignated in this final rule as § 414.408(e)(3)(ii) to delete the phrase ''who maintains a permanent residence in a CBA.'' We believe this change clarifies our final policy that beneficiaries will not be financially responsible for making payment to a noncontract supplier that furnishes a competitively bid item in violation of the Medicare DMEPOS competitive bidding program.

After consideration of the public comments we received, we are redesignating proposed §§ 414.408(f)(2)(iii) and (f)(3) as final §§ 414.408(e)(3)(ii) and (e)(4), respectively, and finalizing these sections as discussed above and with additional technical changes.

8. Payment for Repair and Replacement of Beneficiary-Owned Items (§ 414.408(k))

In the proposed rule (71 FR 25681), we proposed that repair or replacement of beneficiary-owned DME, enteral nutrition equipment, or OTS orthotics that are subject to the Medicare DMEPOS Competitive Bidding Program must be furnished by a contract supplier because only winning suppliers can provide these items in a CBA (proposed § 414.422(c)). The contract supplier could not refuse to repair or replace beneficiary-owned items subject to competitive bidding. We indicated that this proposed provision would help ensure that the beneficiaries will get the items from qualified suppliers, and is consistent with the competitive bidding program in that it directs business to contract suppliers.

Therefore, we proposed that repair or replacement of beneficiary-owned items subject to a competitive bidding program must be furnished by a contract supplier. We indicated that this proposed requirement would not apply to Medicare beneficiaries who are outside of a CBA.

Comment: Some commenters objected to the requirements that repair of beneficiary-owned equipment that is subject to a competitive bidding program must be furnished by a contract supplier and that a contract supplier must agree to service all items included in its contract. The commenters remarked that a limited number of suppliers have repair facilities. In addition, the commenters noted that contract suppliers may not have access to the parts necessary to repair equipment sold by another contract supplier, and this provision would allow manufacturers to inflate the price for parts that must be obtained by contract suppliers that do not regularly furnish their products. The commenters also suggested that, in cases where the manufacturer is the sole distributor of an item, the repair parts and accessories for the item might not be interchangeable and the use of parts that are not provided by the manufacturer may void the manufacturer's warranty. The commenters also suggested that if there are warranties that must be honored on previously rented or purchased equipment, the cost of service should be borne by the contract supplier that received reimbursement for the malfunctioning item. Several commenters expressed concern about assuming the liability for modifying a splint if they were not the contract supplier that originally furnished it. In addition, the commenters suggested that this proposal could restrict Medicare beneficiary access to a choice of suppliers that can repair their equipment. Several commenters noted that contract suppliers may not have the training and expertise required for repairs. One commenter asked how the repair proposal might be affected by the DRA provisions that impose new requirements regarding capped rental items, oxygen, and oxygen equipment.

Another commenter recommended that repairs should be treated as a separate bid on the RFB, rather than as a cost of furnishing an item in an overall product category.

Response: After consideration of the commenters' concerns, we are revising our proposal on payment for repairs and replacement of beneficiary-owned items. We will not require that repairs of beneficiary-owned competitively bid items be performed by contract suppliers because we recognize that contract suppliers may not have the training and expertise to repair every make and model of equipment that could be provided to a Medicare beneficiary. This policy will also apply to maintenance services required by the DRA. We will pay for maintenance and servicing of competitively bid items, including replacement parts that may be needed, that are performed by any supplier as long as those repairs are made by suppliers that have a valid Medicare billing number that enables them to receive payment for covered Medicare services (§ 414.408(k)). Payment will generally be made for parts and labor consistent with the methodology we currently use to make these payments, which can be found in 42 CFR 414.210(e)(1) of our regulations for durable medical equipment, and prosthetic and orthotic devices. However, if the part needed to repair the item is itself a competitively bid item for the CBA in which the beneficiary maintains a permanent residence, we will pay the supplier the single payment amount for the part because we do not believe that the payment amount for the part should be different from what it would otherwise be in the CBA solely because the part is furnished by a supplier that is not a contract supplier. For example, if a beneficiary needs to obtain a new battery for his or her wheelchair, and the battery is itself a competitively bid item for the applicable CBA, we will pay the supplier that performs the repair the reasonable and necessary charges for the labor needed to service the wheelchair and the single payment amount for the battery. We believe that allowing any supplier to furnish a part when performing a repair, even though the part is itself a competitively bid item, is a reasonable accommodation that will enable the supplier to complete the repair properly, and an appropriate circumstance under which we can make payment to the supplier under our authority in section 1862(a)(17) of the Act.

In addition, under final § 414.408(k)(2) to be consistent with our current maintenance and servicing rules for oxygen equipment, we will make general maintenance and servicing payments to suppliers that service oxygen equipment (other than liquid and gaseous equipment) in accordance with § 414.210(e)(2) and an additional payment to a supplier that picks up and stores or disposes of beneficiary-owned oxygen tanks or cylinders that are no longer medically necessary, as provided under § 414.210(e)(3).

We note that we do not have authority under § 1847(a)(2) to include splints in the Medicare DMEPOS Competitive Bidding Program.

Comment: Numerous commenters raised concerns regarding the requirement that replacement of beneficiary-owned equipment that is subject to the Medicare DMEPOS Competitive Bidding Program must be furnished by a contract supplier. The commenters suggested that CMS allow contract suppliers to replace items even if they do not ordinarily furnish these items. The commenters believed that implementing the replacement

provision may be difficult as a replacement may relate to a warranty claim or require that the same product be furnished to ensure continuity of care. The commenters also noted that, under the proposed provision, contract suppliers would be required to replace products that have been damaged despite the fact that they did not sell the item initially. The commenters asserted that if a beneficiary purchased a product from a noncontract supplier prior to competitive bidding, the noncontract supplier should be responsible for repairs or replacement and be paid accordingly. The commenters also stressed that payment rates should be generous enough to ensure that beneficiaries receive an appropriate level of response or service, and contract suppliers should be reimbursed for the service and replacement items they provide. The commenters remarked that the proposed rule assumes that replacement equipment will be provided and paid for in an amount equal to the single payment amount. Several commenters suggested that CMS eliminate the requirement that beneficiary-owned equipment subject to competitive bidding must be replaced by a contract supplier. Other commenters requested that CMS revise proposed § 414.422(c) to limit the scope of this requirement so that contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the CBA are exempt and would only be required to replace their own products. One commenter asked how the replacement proposal might be affected by DRA provisions that imposed new requirements regarding capped rental items, oxygen, and oxygen equipment.

Response: As we stated above, we have decided to modify our proposal regarding the maintenance and servicing of beneficiary-owned items to allow any supplier to perform this service, provided that the supplier has a valid Medicare billing number. However, we do not believe that this modification should extend to situations where an item must be replaced in its entirety because the concern expressed by the commenters, namely that suppliers cannot be expected to have the expertise to repair every make and model of equipment, would not be a factor in the event that an item must be replaced. Accordingly, we continue to believe that beneficiaries should be required to obtain a replacement of an entire item, as apposed to replacement of a part for repair purposes, from a contract supplier. As we stated in the May 1, 2006 proposed rule (71 FR 25681), this rule will help ensure that beneficiaries obtain replacement items from qualified suppliers, and it is consistent with one of the competitive bidding program's goals, that is, to direct business to contract suppliers that conduct business in a manner that is beneficial for the Medicare program and for beneficiaries. Therefore, in final § 414.408(k)(3) we have retained this requirement.

Medicare regulations at 42 CFR 414.210(f) provide that if an item of DME or a prosthetic or orthotic device paid for by Medicare has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment. If these requirements are met, the Medicare beneficiary would be required to go to a contract supplier to obtain a complete replacement of beneficiary-owned equipment. However, as we stated above, if a beneficiary needs to obtain a replacement part for his or her beneficiary-owned equipment, or needs to obtain maintenance or servicing of the equipment, the beneficiary may obtain the part or service from any supplier that has a valid Medicare billing number. If the replacement part is itself a competitively bid item in the CBA where the beneficiary maintains a permanent residence, the supplier that performs the repair would generally be paid for the labor associated with the repair in accordance with the methodology described in § 414.210(e)(1), and the single payment amount for the part.

We do not agree with the commenters that our replacement rules would generally require a contract supplier replace an entire competitively bid item with the same make or model to ensure continuity of care. Rather, as we discuss in § 414.420 of this final rule, this would only be required if a physician or treating practitioner prescribed a particular brand or mode of delivery for an item. If a beneficiary needs a replacement item, a manufacturer that only furnishes its own brand would generally be able to furnish that brand to the beneficiary. In addition, we expect that a manufacturer's warranty would be honored by the manufacturer, regardless of which supplier from which the Medicare beneficiary obtains the replacement.

In summary, after consideration of the public comments we received, in this final rule, we are redesignating proposed § 414.422(c) as new § 414.408(k) and revising this section as discussed above.

E. Competitive Bidding Areas (§§ 414.402, 414.406(b)–(c), 414.410, 414.412(f) and (g)

1. Background

Section 1847(a)(1)(A) of the Act requires that competitive bidding programs be established and implemented in areas throughout the United States. We are interpreting the term ''United States'' to include all States, Territories, and, as discussed in section VI.B. of this final rule, the District of Columbia. Section 1847(a)(1)(B) of the Act provides us with the authority to phase in competitive bidding programs so that the competition under the programs occurs in—

- 10 of the largest MSAs in CY 2007;
- 80 of the largest MSAs in CY 2009; and
- Additional areas after CY 2009.

We proposed to implement this statutory provision in § 414.406(b)–(c), and in § 414.410.

Section 1847(a)(1)(B) of the Act also authorizes us to phase in competitive bidding programs first among the highest cost and volume items or those items that we determine have the largest savings potential. As we proposed, we describe our methodologies for selecting the MSAs for CYs 2007 and 2009 below. Once the MSAs have been selected for CYs 2007 and 2009, we proposed to define the CBAs for CYs 2007 and 2009. The process we proposed for establishing CBAs in future years, which we are finalizing in this final rule, is also discussed below.

2. Methodology for MSA Selection for CYs 2007 and 2009 Competitive Bidding Programs (§§ 414.410(a) and (b))

Based on sections 1847(a)(1)(B)(i)(I) and (II) of the Act, we have the authority to select from among the largest MSAs during the first two implementation phases in order to phase in the programs in the most successful way, thereby achieving the greatest savings while maintaining quality and beneficiary access to care. In phasing in the competitive bidding programs, we proposed to adopt a definition of the term ''Metropolitan Statistical Area'' (MSA) consistent with that issued by the Office of Management and Budget (OMB) and applicable for CYs 2007 and 2009 (§ 414.402). OMB is the Federal agency responsible for establishing the standards for defining MSAs for the purpose of providing nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas. OMB most recently revised its standards for defining MSAs in CY 2000 (65 FR

82228 through 82238). Under these standards, an MSA is defined as a core-based statistical area (CBSA) (a statistical geographic area consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration as measured through commuting ties with the counties containing the core) associated with at least one urbanized area that has a population of at least 50,000, and is comprised of the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting. OMB issues periodic updates of the MSAs between decennial censuses based on United States Census Bureau estimates, but other than identifying certain MSAs having a population core of at least 2.5 million, does not rank MSAs based on population size. However, the U.S. Census Bureau periodically publishes a Statistical Abstract of the United States, which contains a table listing large MSAs, or MSAs having a population of 250,000 and over. For the purpose of this rule, we proposed to use these data to identify the largest MSAs.

In the May 1, 2006 proposed rule (71 FR 25665), we proposed a formula driven methodology for selecting the MSAs for competitive bidding in CYs 2007 and 2009. After we select the MSAs, we would define the CBAs. For the purpose of our proposal, DMEPOS allowed charges would be the Medicare fee-for-service (FFS) allowed charge data for DMEPOS items that we have authority to include in a competitive bidding program. These data do not include Medicare expenditures for DMEPOS items under the Medicare Advantage Program.

a. MSAs for CY 2007

We proposed to use a multiple step process in selecting the MSAs for CY 2007. First, we proposed to identify the 50 largest MSAs in terms of total population in CY 2005 using population estimates published by the U.S. Census Bureau in its table of large MSAs from the Statistical Abstract of the United States. Second, 25 MSAs out of the 50 MSAs identified in step one would be eliminated from consideration based on our determination that they have the lowest totals of DMEPOS allowed charges for items furnished in CY 2004. This step would allow us to focus on the 25 MSAs that have the highest totals of DMEPOS allowed charges which, we believe, would produce a greater chance of savings as a result of competitive bidding than MSAs with lower total DMEPOS allowed charges. Table 1 of the proposed rule (71 FR 25665 and 25666), which is republished below, illustrated the DMEPOS allowed charge data for items furnished in CY 2003 and Census Bureau population estimates as of July 1, 2003.

TABLE 1.—TOP 25 MSAS BASED ON TOTAL DMEPOS MEDICARE ALLOWED CHARGES FOR CY 2003

MSA	Allowed charges
New York-Northern New Jersey-Long Island, NY-NJ-PA (New York)	$312,124,291
Los Angeles-Long Beach-Santa Ana, CA (Los Angeles)	253,382,483
Miami-Fort Lauderdale-Miami Beach, FL (Miami)	221,660,443
Chicago-Naperville-Joliet, IL-IN-WI (Chicago)	173,922,952
Houston-Baytown-Sugar Land, TX (Houston)	149,060,607
Dallas-Fort Worth-Arlington, TX (Dallas)	139,910,862
Detroit-Warren-Livonia, MI (Detroit)	121,444,298
San Juan, PR	108,478,208
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD (Philadelphia)	97,487,063
Atlanta-Sandy Springs-Marietta, GA (Atlanta)	75,860,276
Tampa-St. Petersburg-Clearwater, FL (Tampa)	71,309,635
Boston-Cambridge-Quincy, MA-NH (Boston)	62,467,094
Washington-Arlington-Alexandria, DC-VA-MD-WV (DC)	61,416,109
Baltimore-Towson, MD (Baltimore)	59,714,310
Pittsburgh, PA	56,612,095
St. Louis, MO-IL	55,931,373
Riverside-San Bernardino-Ontario, CA (Riverside)	52,910,209
Cleveland-Elyria-Mentor, OH (Cleveland)	52,237,312
Orlando, FL	51,982,164
San Francisco-Oakland-Fremont, CA (San Francisco)	45,565,320
San Antonio, TX	44,113,886
Cincinnati-Middletown, OH-KY-IN (Cincinnati)	41,582,961
Kansas City, MO-KS	41,310,326
Virginia Beach-Norfolk-Newport News, VA-NC (Virginia Beach)	41,016,726
Charlotte-Gastonia-Concord, NC-SC (Charlotte)	37,874,144

Table 1 showed the 25 MSAs that would be left for consideration after step two is completed. However, we proposed to select the actual MSAs for CY 2007 using U.S. Census Bureau population data published as of July 1, 2005, and DMEPOS allowed charge data for items furnished in CY 2004. We proposed using population data for CY 2005 and DMEPOS allowed charge data for CY 2004 because we believed these data would be the most recently available data at the time that the MSAs are selected for CY 2007 implementation. We now have more current utilization data (that is, from CY 2005); we will use these data in selecting the MSAs for the first round of competitive bidding.

Third, we proposed to score the MSAs based on combined rankings of DMEPOS allowed charges per FFS beneficiary (charges per beneficiary) and the number of DMEPOS suppliers per number of beneficiaries receiving DMEPOS items (suppliers per beneficiary) in CY 2004, with equal weight (50 percent) being given to each factor. The MSAs would be ranked from 1 to 25 in terms of DMEPOS allowed charges per FFS beneficiary (for example, the MSA with the highest DMEPOS allowed charges per FFS beneficiary would be ranked number 1). Similarly, areas having more suppliers per beneficiary are more likely to be

competitive and would be ranked higher than MSAs having fewer suppliers per beneficiary. Based on our experience from the DMEPOS competitive bidding demonstrations, the number of suppliers would be based on suppliers with at least $10,000 in allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2004. The number of beneficiaries would be based on the number of beneficiaries receiving DMEPOS items in the MSA in CY 2004. If more than one MSA receives the same score, we proposed to use total DMEPOS allowed charges for items that we have authority to include in a competitive bidding program in each MSA as the tiebreaker because this would be an indicator of where more program funds would be spent on DMEPOS items subject to competitive bidding. Table 2 in the proposed rule (71 FR 25666), which is republished below, illustrated how the 25 MSAs from Table 1 in the proposed rule would be scored, based on data for CY 2003.

TABLE 2.—SCORING OF TOP 25 MSAS BASED ON DATA FOR CY 2003

[Scoring based on combined rank from columns 3 and 4]

MSA	Score	Charges per beneficiary	Suppliers per beneficiary	Allowed charges
Miami	3	$428.44 (1)	0.01121 (2)	$221,660,443
Houston	6	348.83 (2)	0.00864 (4)	149,060,607
Dallas	8	297.33 (3)	0.00749 (5)	139,910,862
Riverside	9	220.93 (8)	0.01144 (1)	52,910,209
San Antonio	9	243.03 (6)	0.00897 (3)	44,113,886
Los Angeles	11	277.16 (5)	0.00692 (6)	253,382,483
Charlotte	14	226.09 (7)	0.00661 (7)	37,874,144
Orlando	18	212.57 (9)	0.00569 (9)	51,982,164
San Juan	25	291.97 (4)	0.00388 (21)	108,478,208
Atlanta	25	185.80 (15)	0.00569 (10)	75,860,276
Tampa	25	190.30 (13)	0.00529 (12)	71,309,635
Kansas City	25	186.39 (14)	0.00555 (11)	41,310,326
Pittsburgh	26	197.95 (11)	0.00484 (15)	56,612,095
Virginia Beach	26	207.28 (10)	0.00477 (16)	41,016,726
St. Louis	32	169.81 (18)	0.00488 (14)	55,931,373
San Francisco	32	127.56 (24)	0.00632 (8)	45,565,320
Cincinnati	32	167.06 (19)	0.00528 (13)	41,582,961
Cleveland	33	182.01 (16)	0.00470 (17)	52,237,312
Detroit	37	195.99 (12)	0.00290 (25)	121,444,298
Baltimore	37	174.38 (17)	0.00396 (20)	59,714,310
Philadelphia	40	152.38 (21)	0.00443 (19)	97,487,063
DC	41	128.97 (23)	0.00449 (18)	61,416,109
Chicago	44	160.26 (20)	0.00327 (24)	173,922,952
New York	45	139.81 (22)	0.00342 (23)	312,124,291
Boston	47	113.99 (25)	0.00371 (22)	62,467,094

We proposed that the final scoring be based on utilization data for CY 2004 and population data for CY 2005 because we believed these data would be the most recently available data at the time that the MSAs are selected for CY 2007 implementation. However, we will use utilization data for CY 2005 when we perform the final scoring for the third step because this is the most current utilization data that we have.

For purposes of phasing in the programs, we proposed to exclude from consideration for competitive bidding until CY 2009 the three largest MSAs in terms of population, as well as any MSA that is geographically located in an area served by two DME MACs. The three largest MSAs based on total population (based on CY 2003 data) are New York, Los Angeles, and Chicago. We believe that these MSAs should not be phased in until CY 2009 because of the logistics associated with the start-up of this new and complex program. As of 2000, each of these three MSAs had a total population of over 9 million. By comparison, the largest area in which the demonstrations were conducted was San Antonio (total population of 1.7 million in 2000). We want to gain experience with the competitive bidding process in MSAs larger than San Antonio before moving onto the three largest MSAs. After we have gained experience operating competitive bidding programs in CBAs that encompass smaller MSAs in CYs 2007 and 2008, we plan to implement programs that include New York, Los Angeles, and Chicago in CY 2009.

In the May 1, 2006 proposed rule, we indicated that we were considering an alternative under which we would establish CBAs that include portions of one or more of these MSAs (for example, by county). We believe that this alternative is authorized by section 1847(a)(1)(B)(II) of the Act, which states that competition under the programs shall occur in 80 of the largest MSAs in CY 2009 but does not require the competition to occur in the entire MSA. In addition, section 1847 of the Act does not prohibit us from implementing a competitive bidding program in an area that is larger than a MSA. In the proposed rule, we solicited specific comments on these alternatives.

Comment: Several commenters stated that CMS does not have the authority to extend or decrease the size of the MSA boundaries and that this proposal is inconsistent with the statute. They noted that section 1847(a)(1)(B) of the Act requires that competitive acquisition occur in MSAs in CY 2007 and CY 2009, and only authorizes competitive acquisition in ''other areas'' after CY 2009.

Response: Section 1847(a)(1)(B) of the Act requires that competition under the programs occur in CY 2007 and CY 2009 in a minimum number of MSAs. We did not propose to extend or decrease any MSA boundaries. Rather, we stated that section 1847(a)(1)(B) of the Act does not require us to define the boundaries of a CBA congruently with the boundaries of an MSA, as long as 10 MSAs are involved in CY 2007 and 80 MSAs are involved in CY 2009. We also proposed to consider an area for inclusion in a CBA in CY 2007 or CY 2009, or both,

if (1) The area is not part of the MSA but adjoins an MSA in which a competitive bidding program will be operating; (2) the area is competitive (meaning that it has high DMEPOS utilization, significant expenditures, and/or a large number of suppliers that furnish items that will be included in the competitive bidding program for the adjoining MSA); and (3) the area is part of the normal service area or market for suppliers that also serve the MSA market or areas within the boundaries for an MSA in which a competitive bidding program will be operating. We continue to believe this approach is reasonable because if an area meets these criteria, we believe that we could properly characterize the area as being integrated with the MSA in terms of the DMEPOS market.

Comment: One commenter recommended that, when picking the first 10 MSAs, CMS should pick the smallest of the 10 largest MSAs.

Response: Section 1847(a)(1)(B) of the Act requires us to phase-in the competitive bidding programs so that the competition occurs in 10 of the largest MSAs in 2007. The process that we proposed and are finalizing in this final rule is a formula driven approach that bases the decision on the total population of an MSA, the Medicare allowed charges for DMEPOS items per FFS beneficiary in an MSA, the total number of DMEPOS suppliers per FFS beneficiary who received DMEPOS items in an MSA, and the MSA's geographic location, for example, in the first round, to ensure that there is at least one CBA in each DME MAC region. We believe that this approach will result in the selection of MSAs that have more potential to produce savings for the Medicare program than we might otherwise achieve if we selected MSAs based on their size alone. However, we also recognize that implementing the Medicare DMEPOS Competitive Bidding Program will involve many challenges, and we want to gain sufficient experience in administering the program before we implement competitive bidding programs in the three largest MSAs in terms of population size. Therefore, we proposed to exclude the MSAs that include New York City, Los Angeles, and Chicago from the competition that will occur in CY 2007.

Comment: One commenter recommended excluding Miami from the first round of bidding. The commenter noted that Miami has the largest MSA market based charges per beneficiary, suppliers per beneficiary, and total DMEPOS allowed charges. The commenter stated that there is a big difference between the Medicare DMEPOS market in an MSA and the total population of an MSA. The commenter also recommended that CMS exclude, until CY 2009, or once further experience has been accumulated and cultural competency has been accounted for, culturally diverse MSAs such as Miami and those located in Puerto Rico from competitive bidding. A number of other commenters also recommended excluding MSAs located in Puerto Rico.

Response: We believe our methodology results in the selection of top priority areas in terms of potential savings for the program. Cultural diversity is not one of the factors we considered when developing a formula driven approach because our goal in implementing the program is to select areas that provide the greatest opportunity for savings.

We proposed not to include CBAs that cross DME MAC regions because this could complicate implementation by having two DME MACs processing claims from one CBA.

The next step that we proposed entails ensuring that there is at least one CBA in each DME MAC region by first selecting the highest scoring MSA in each DME MAC region (other than New York, Los Angeles, Chicago, or MSAs that cross DME MAC boundaries). This would ensure that each DME MAC gains some experience with competitive bidding prior to CY 2009, when competitive bidding would be implemented in CBAs that include 80 MSAs.

Comment: One commenter recommended that one MSA be selected from each DME MAC region for CY 2007.

Response: Section 1847(a)(1)(B) requires us to implement competitive bidding in 10 of the largest MSAs in CY 2007. We are adopting as final the approach outlined in our proposed rule (71 FR 25667) which ensures that there is a least one CBA in each DME MAC region. This would ensure that each DME MAC region gains experience with the competitive bidding program prior to CY 2009 when we phase in 70 additional CBAs.

We also proposed to select no more than two MSAs per State among the initial CBAs selected for CY 2007 in order to learn how competitive bidding works in more States and regions of the country. In summary, we proposed to select the 10 MSAs in which competition under the programs would occur in CY 2007 using the following steps:

- Identify the top 50 MSAs in terms of general population.
- Focus on the 25 MSAs from step one with the greatest total of DMEPOS allowed charges.
- Score the MSAs from step two based on combined rankings of DMEPOS allowed charges per beneficiary and suppliers per beneficiary, with lower scores indicating a greater potential for savings if programs are implemented in those areas.
- Exclude the three largest MSAs in terms of population (New York, Los Angeles, Chicago) and any MSA that crosses DME MAC boundaries.
- Select the lowest scoring MSA from each DME MAC region.
- Select the next six lowest scoring MSAs regardless of DME MAC region, but not more than two MSAs from one State.
- Break ties in scores using DMEPOS allowed charges, selecting MSAs with higher total DMEPOS allowed charges.

In the proposed rule, we indicated that we considered a number of alternative methods for selecting the MSAs for CY 2007. We indicated that the MSAs could be selected based on a combination of one or more variables or measures including, but not limited to—

- General population;
- Medicare FFS beneficiary population;
- Number of beneficiaries receiving DMEPOS items that we have authority to include in a competitive bidding program;
- Total Medicare allowed charges for DMEPOS items subject to competitive bidding; and
- Number of suppliers of DMEPOS items that we have authority to include in a competitive bidding program.

In evaluating these alternatives, we defined the general population as all individuals residing in an MSA, whether or not they were enrolled in Medicare. One advantage of this variable would have been that total population is a widely accepted measure of gauging MSA size and the data are readily accessible to the general public through the U.S. Census Bureau Web site. Another advantage of using this variable would be that total population takes into account the demand for DMEPOS items and other supplies from population groups other than the Medicare population. DMEPOS demand from non-Medicare individuals might make it less likely that a supplier not selected as a contract supplier would exit the market. This could help increase the likelihood of competition in future rounds of competitive bidding within that MSA. However, we recognize that the MSAs with the largest total populations might not have the

most Medicare beneficiaries or the greatest potential for savings. One reason is that the age distribution is not uniform across MSAs. MSAs located in States that have either large immigrant populations or have experienced rapid recent growth often have younger than average age profiles. Another reason is that DMEPOS utilization and potential profits are not uniform across MSAs. It is quite possible that some of the smaller population MSAs may have a greater potential for savings than MSAs with much larger populations. We believe that the disadvantages of selecting MSAs based on general population are greater than the advantages of using this method and, therefore, did not propose using general population as the sole variable in selecting the MSAs for CY 2007.

An advantage of selecting MSAs based on the Medicare FFS population would have been that this population represents the number of individuals who could potentially be affected by competitive bidding. A disadvantage of selecting MSAs based solely on this variable is that it does not reflect actual DMEPOS utilization. Therefore, we did not propose using the FFS population as the sole variable in selecting the MSAs for CY 2007. Per capita DMEPOS utilization rates vary across MSAs. As a result, MSAs with fewer Medicare beneficiaries could have a greater potential for savings from competitive bidding. The advantage of using the number of Medicare beneficiaries receiving DMEPOS items to select the MSAs is that MSAs would be selected based on the number of individual beneficiaries who are most likely to be directly affected by competitive bidding because they already have a need for these items. A disadvantage of this variable is that the number of specific beneficiaries receiving DMEPOS items is only a static measure. The number of beneficiaries who would be receiving DMEPOS products in the future could be substantially different from the current number. Treatment patterns within the MSA could change or the number of beneficiaries receiving DMEPOS items could fluctuate if beneficiaries switch from FFS benefits to a Medicare Advantage plan. For these reasons, we did not propose using the number of beneficiaries receiving DMEPOS items as the sole variable in selecting the MSAs for CY 2007.

Selecting the MSAs using the steps we proposed utilizes a variety of variables that we believe would help us predict which MSAs will offer the largest savings potential under a competitive bidding program. In step 2 above, we would focus on a subset of large MSAs with higher allowed charges for DMEPOS items, which is consistent with section 1847(a)(1)(B)(ii) of the Act and which would allow us to phase in the Medicare DMEPOS Competitive Bidding Program first for those items that have the highest cost and highest volume, or those items that have the largest savings potential. This step would directly address the question of which MSAs have the highest costs. In step 3 above, we proposed to use allowed DMEPOS charges per beneficiary and the number of suppliers per beneficiary to further measure the savings potential for each MSA. Allowed DMEPOS charges per beneficiary is a measure of per capita DMEPOS utilization in terms of the overall DMEPOS cost per beneficiary. We believe that areas with higher utilization rates and costs would have a greater potential for savings under the programs, which will rely on competition among suppliers to lower costs in the area. Competition among suppliers is necessary for competitive bidding to be successful. Without sufficient competition among suppliers, suppliers have little incentive to submit low bids in response to the RFBs for DMEPOS products. In addition, we believe that competition for market share among winning suppliers will act as a market force to maintain a high level of quality products. The number of suppliers per beneficiary is a direct measure of how many suppliers are competing for each beneficiary's business. We expect that the higher the number of suppliers per beneficiary, the higher the degree of competition will be.

In the proposed rule, we invited specific comments about the selection method for the original 10 MSAs in CY 2007. We welcomed recommendations of other options and criteria for consideration. We indicated that, after further consideration of comments received, in the final rule, we may adopt other criteria regarding issues described above or other criteria and options brought to our attention through the comment process.

Comment: Several commenters recommended that CMS identify the initial 10 MSAs in the final regulation.

Response: We plan to announce the first 10 MSAs, which will be based on 10 of the largest MSAs, at the same time we publish this final rule.

Comment: Several commenters recommended that CMS stagger the implementation of the initial 10 MSAs to identify and correct problems encountered early in the implementation process.

Response: Section 1847(a)(1)(B)(i)(I) of the Act requires that the competition take place in 10 of the largest MSAs in CY 2007. In implementing competitive bidding programs in 10 CBAs that include these MSAs, we do not believe it is necessary or practical to use the staggered approach recommended by the commenters, as we believe that this would likely result in confusion for beneficiaries and suppliers and make the phase-in process too administratively complicated.

Comment: Several commenters suggested that CMS use an area selection methodology that initially results in a limited number of small CBAs. The commenters also stated that this is an experimental program. They noted that there is little geographic diversity in the CBAs identified in Table 2 of the proposed rule (republished as Table 2 in this final rule), and that based on this table, the CBAs would be disproportionately concentrated in DME MAC Region C. The commenters suggested that the geographic diversity should be expanded to provide more useful information that CMS can consider when implementing the program in more areas in the future.

Response: We believe that our proposed methodology for selecting MSAs will result in the selection of the most appropriate MSAs (and therefore CBAs) in terms of achieving one of the most critical goals of the program to reduce Medicare expenditures for DMEPOS. As we explained above, several aspects of our methodology, including in the first round of competitive bidding selecting at least one MSA in each DME MAC region, and selecting not more than two MSAs per State, allow for geographic diversity.

b. MSAs for CY 2009

In selecting the 70 additional MSAs in which competition will occur in CY 2009, we proposed using generally the same criteria used to select the MSAs for CY 2007 (proposed § 414.410(b)). Because the number of MSAs in which competition must occur in CY 2009 is much higher than the number for CY 2007, we proposed that the steps in the selection process would change as follows:

- We would score all of the MSAs included in the table of large MSAs in the most recent publication of the U.S. Census Bureau's Statistical Abstract of the United States.
- We would use the same criteria to score the MSAs as we would use in selecting the MSAs for CY 2007, but use data from CY 2006.

In the proposed rule, we indicated that one option we were considering and on which we requested comments is whether we should modify the

ranking of MSAs based on allowed DMEPOS charges per beneficiary so that it focuses on charges in each MSA for the items that experienced the largest payment reductions or savings under the initial round of competitive bidding in CY 2007.

In selecting the MSAs for CY 2009, we did not propose excluding the 3 largest MSAs in terms of population size or MSAs that cross DME MAC boundaries from the 80 largest MSAs to be included in the CBAs. In addition, we did not propose limiting the number of MSAs that could be selected from any one State.

Comment: One commenter suggested that New York, Los Angeles, and Chicago be top priorities in the CY 2009 phase of implementation due to the potential for significant cost savings to the Medicare program.

Response: These MSAs are only being excluded from consideration during the first phase of competitive bidding and will be included in the selection methodology for the second phase.

After consideration of the public comments we received, we are finalizing our rules under proposed §§ 414.410(a) and (b) regarding the methodology for MSA selection with only technical changes.

3. Establishing Competitive Bidding Areas and Exemption of Rural Areas and Areas With Low Population Density Within Urban Areas (§ 414.410(c))

Section 1847(a)(1) of the Act requires that we phase in competitive bidding programs and establish CBAs throughout the United States over several years beginning in CY 2007. Section 1847(a)(3)(A) of the Act gives us the authority to exempt ''rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service.''

In the May 1, 2006 proposed rule, we proposed to use the authority in section 1847(a)(3) of the Act to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on one or more of the following indicators:

- Low utilization of items in terms of the number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas.
- Low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas.
- Low number of Medicare beneficiaries receiving FFS benefits in the area relative to other similar geographic areas.

We proposed to make decisions regarding what constitutes low (noncompetitive) levels of utilization, suppliers, and beneficiaries on the basis of our analysis of the data for allowed charges, allowed services for items that may be subject to competitive bidding, and the number of Medicare beneficiaries receiving FFS benefits and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, we proposed to use the definitions currently in § 412.64(b)(1)(ii) of our regulations. We proposed to incorporate these provisions in proposed § 414.410(c).

We invited comments on the methodologies we proposed for determining whether an area within an urban area that has a low population density is not competitive. We indicated that we would be reviewing the total allowed charges, the number of beneficiaries, and the number of suppliers to determine whether a rural area should be exempted from competitive bidding. In addition, we invited comments on standards for exempting particular rural areas from competitive bidding.

Comment: Several commenters believed that competitive bidding should not be implemented in MSAs with less than 500,000 people. They indicated that this will help keep small business owners in rural communities open and, therefore, beneficiary access in these areas will not be compromised.

Response: Section 1847(a)(1) of the Act requires that we establish competitive bidding programs throughout the United States. We have the authority under section 1847(a)(3) of the Act to exempt rural areas and areas with low population density within urban areas that are not competitive unless there is a significant mail order market for a particular item. When we implement the program, we will only include areas in CBAs that are competitive and that we believe will produce savings for the program. In addition, we have revised our rules regarding small suppliers in response to public comments and believe that the revised rules will help to ensure that small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program. A full discussion of these modifications can be found in section XI. of this final rule.

After consideration of the public comments we received, we are finalizing, with only technical changes, proposed § 414.410(c) regarding the exclusion of rural areas or areas with low population density from a CBA.

4. Establishing Competitive Bidding Areas for CYs 2007 and 2009 (§§ 414.406(b) and (c))

Section 1847(a)(1)(B) of the Act requires that the competition ''occurs in'' 10 of the largest MSAs in CY 2007, and in 80 of the largest MSAs in CY 2009, but does not require us to define the competition boundaries concurrently with the MSA boundaries, as long as 10 MSAs are involved in CY 2007 and 80 MSAs are involved in CY 2009. Therefore, we do not believe that section 1847(a)(1)(B) of the Act prohibits us from extending individual competition areas beyond the MSA boundaries in CYs 2007 or 2009.

In the May 1, 2006 proposed rule, we proposed in § 414.406(b) to designate through program instructions each CBA in which a competitive bidding program will take place, and we proposed in § 414.406(c) that we could revise the CBAs if necessary. We also proposed (71 FR 25668) that an area (for example, a county, parish, or zip code) outside the boundaries of an MSA be considered for inclusion in a CBA for CY 2007 or CY 2009, or both if all of the following apply:

- The area adjoins an MSA in which a competitive bidding program will be operating in CY 2007 or CY 2009.
- The area is not part of an MSA in which a competitive bidding program will be operating in CY 2007 or CY 2009.
- The area is competitive, as explained below.
- The area is part of the normal service area or market for suppliers that also serve the MSA market or areas within the boundaries of an MSA in which a competitive bidding program will be operating in CY 2007 or CY 2009.

As explained in section VI.E.2. of this final rule, we proposed to define an MSA as a Core Based Statistical Area associated with at least one urbanized area that has a population of at least 50,000, and comprised of the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting. However, when using this definition to establish the boundaries of an MSA, OMB would not consider whether an area or areas adjoining an MSA are served by the same DMEPOS suppliers that furnish items to beneficiaries residing in the MSA. If an area has a high level of utilization, significant expenditures, and/or a large number of suppliers of DMEPOS items included in the competitive bidding program for the

adjoining MSA, we stated that we believe that it would be practical and beneficial to include this area in the CBA. The savings to the program associated with adding the area to the CBA would likely offset any incremental administrative costs incurred by the CBIC associated with including the area in the competitive bidding program for the MSA.

Finally, we did not propose to consider counties that do not adjoin an MSA for inclusion in a CBA for CY 2007 or CY 2009 because we believe that these outlying counties are too far removed from the areas that OMB has determined to be economically integrated. We stated that we have the discretion to define a CBA to be either concurrent with an MSA, larger than an MSA, or smaller than an MSA. We also stated that we would detail in the RFBs the exact boundaries of each CBA. We invited comments on the criteria to be used in considering whether to include counties outside MSAs in a CBA in CY 2007 or CY 2009.

Comment: Several commenters recommended that the maximum number of CBAs in a State should be one instead of two. They stated that the methodology should be changed to distribute the CBAs so that there are three areas in each of two of the DME MAC regions, and two in each of the remaining two DME MAC regions to ensure geographic distribution.

Response: We believe that our proposed methodology for selecting MSAs and designating CBAs will not only produce large savings for the Medicare program, but that it will also ensure that the work involved with administering the program and processing claims is evenly distributed among our contractors. We also note that one of the factors we proposed to consider when selecting MSAs is their geographic location.

Comment: Several commenters urged CMS to adopt CBAs that are somewhat smaller than the MSAs to help minimize the risk of a CBA crossing a state line or areas shared by more than one DMERC and to ensure adequate geographic distribution of suppliers within a CBA in order to maintain beneficiary access to competitively bid items.

Response: We proposed to designate CBAs whose boundaries are concurrent with, larger than, or smaller than the associated MSA because we believe that it is practical and beneficial to implement competitive bidding programs in areas that are integrated in terms of DMEPOS utilization, expenditures, and suppliers. We believe that these factors, as well as the other factors that we proposed to consider when designating CBAs, will help ensure that the CBAs are geographically distributed in a way that does not limit beneficiary access to competitively bid items. We also note that, as specified in § 414.412 of this final rule, each contract supplier will be required to furnish items to every beneficiary who maintains a permanent residence in the contract supplier's CBA. We believe that this requirement will further ensure that beneficiary access to competitively bid items is maintained.

Comment: Several commenters suggested that CMS not rely heavily on DMEPOS allowed charges per beneficiary and suppliers per beneficiary.

Response: We disagree. We believe that our methodology properly identifies large MSAs with a significant savings potential by considering DMEPOS allowed charges per FFS beneficiary and suppliers per FFS beneficiary, as these data would indicate that these MSAs have the largest number of suppliers available for competition and the most expenditures/utilization per Medicare beneficiary.

Comment: One commenter suggested that CMS divide the MSAs by some easily recognized boundaries as proposed as an alternative proposal in the proposed rule.

Response: We will establish the CBAs based on the most current data and use our authority to adjust the areas to exclude rural areas and areas with low population density within urban areas that are not competitive. We will set easily recognizable boundaries by using county lines and zip codes to identify the CBAs we select.

Comment: One commenter supported the criteria for MSA selection that would consider MSAs based on their total population, total DMEPOS charges, charges per beneficiary, and the number of DMEPOS suppliers per DMEPOS users. The commenter also suggested considering the numbers of suppliers of constituent categories of DMEPOS, for example, oxygen and supplies or hospital beds. The commenter believed that, if there are enough suppliers to conduct a competition for each of the constituent categories within a CBA, the constituent categories should be included in the competitive bidding program.

Response: We believe our methodology, which concentrates on allowed charges per beneficiary and suppliers per beneficiary, will result in the selection of areas with the most potential for savings under the programs. This methodology relies on average expenditures per beneficiary and the availability of competing suppliers. We believe that the criteria that we will be using are sufficiently representative to select the appropriate MSAs for competitive bidding because they will identify those MSAs that have high beneficiary allowed charges and a high number of DMEPOS suppliers per DMEPOS users. We acknowledge the value of more specific item data for the purposes of selecting items for competitive bidding. Therefore, we will be looking at utilization of items when we select the items for competitive bidding.

Comment: One commenter suggested that we identify the top 80 MSAs for competitive bidding using the methodology as proposed. However, for the initial competitive bidding program, the commenter proposed that the agency use only the allowed DMEPOS charges per beneficiary metric when selecting the 10 MSAs from the set of 80. The commenter believed that this selection methodology will provide us with a range of valuable data regarding areas that have many suppliers per beneficiary and areas that have fewer suppliers per beneficiary.

Response: We believe that selecting the initial 10 MSAs based on combined rankings of both DMEPOS allowed charges per FFS beneficiary and the number of DMEPOS suppliers per number of beneficiaries receiving DMEPOS items, as well as based on the MSA's total population and geographic area, is important and necessary for designating CBAs that will produce savings for the Medicare program. In addition, we believe that these factors are appropriate indicators of how robust competition is likely to be in an area which will ultimately result in lower prices and increased savings for the program.

Comment: One commenter questioned CMS' decision to exclude the top three MSAs from consideration for competition prior to CY 2009. The commenter stated that the decision was arbitrary and discriminatory.

Response: As stated in the proposed rule, because of the logistics associated with the startup of this new and complex program, we would like to gain experience in the first phase of competitive bidding prior to implementing programs in CBAs that include the three largest MSAs (New York, Los Angeles, and Chicago). However, we will include these MSAs when we consider which MSAs to select for the CY 2009 competition.

Comment: One commenter requested that implementation of competitive bidding be delayed indefinitely to

permit thoughtful review and revisions to the program.

Response: Section 1847(a)(1) of the Act requires that competition under the competitive bidding program occurs in 10 of the largest MSAs in CY 2007. Therefore, the Act does not permit us to delay indefinitely implementation of the program.

Comment: One commenter recommended that CMS count all suppliers that have submitted Medicare DMEPOS claims in the past year in determining the number of suppliers per beneficiary. The commenter asked if CMS will only calculate suppliers with physical locations inside of the CBA or if it will base its number of suppliers on those that have submitted Medicare claims for DMEPOS for a specific time period. Another commenter believed that the proposed dollar amount, $10,000, for suppliers with allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2004 is too low. In addition, the commenter added that the $10,000 threshold may be too small for some items of DME. The commenter further stated that for higher cost items, $10,000 in allowed charges would not indicate that the supplier has an adequate level of experience with a product to appropriately meet the needs of Medicare beneficiaries. The commenter suggested that CMS look at total allowed charges and allowed charges for the items being bid. In addition, the commenter recommended that the supplier set an appropriate dollar threshold for each product category that would demonstrate that the supplier has adequate experience with the product category before counting that supplier for MSA selection purposes.

Response: We believe that the $10,000 threshold will give us an assurance that there will be a sufficient number of suppliers that have the capability to serve the area regardless of the experience with the particular product category. For suppliers with less than $10,000 in allowed charges, we do not have the assurance that the majority of them because of the cost of participating in the competitive bidding program and accreditation will be interested in participating in the competitive bidding program. By including in our calculations only those suppliers with allowed charges of at least $10,000, we are ensuring that we select MSAs that have a large number of suppliers that are interested and able to participate in the competitive bidding program considering those suppliers.

Comment: One commenter recommended that CMS adjust data on DMEPOS allowed charges and on the number of beneficiaries and suppliers in ''snowbird'' locations before selecting CBAs.

Response: We believe that our methodology provides us with the most appropriate CBA selection and greatest savings for the program. As part of our evaluation of Medicare allowed charges for items per fee-for-service beneficiary and the total number of suppliers per fee-for-service beneficiary, we will consider how these data might be affected in areas where beneficiaries reside for only part of the year.

Comment: One commenter recommended that CMS exclude areas that have a high probability of experiencing a natural disaster until CY 2009 and consult with both the Federal Emergency Management Agency (FEMA) and the Department of Homeland Security before implementing competitive bidding in these areas.

Response: The statute provides us with a geographic exception authority only for rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant nationwide market through mail order for a particular item or service. We do not have authority to exclude areas that might experience a natural disaster.

Comment: One commenter recommended that CMS initially implement competitive bidding programs in three CBAs in October 2007; in three CBAs in February 2008, and in four CBAs in June 2008. The commenter also recommended excluding St. Louis, Kansas City, Baltimore, and Washington, D.C. from the MSA selection process because these MSAs overlap with multiple DME MAC regions or recent transition to a new DME MAC. In addition, the commenter recommended excluding Orlando and San Antonio from the MSA selection process because these areas were part of the demonstration projects.

Response: We believe that our approach to conduct the competition in all 10 CBAs at once is appropriate and will ensure that the CBAs are geographically dispersed. In addition, as stated above, we believe that this approach will alleviate the confusion that could otherwise result if we conducted the competition in the manner suggested by the commenter. The statute provides us with a geographic exception authority only for rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant nationwide market through mail order for a particular item or service.

Comment: One commenter recommended initially implementing competitive bidding programs in 3 MSAs, Miami, Houston, and Dallas, then 120 days later, implementing programs in the next 3 MSAs in February, and finally implementing programs in the last 4 MSAs. The commenter indicated that this will allow CMS to monitor and proactively make changes before it fully implements programs in the 10 MSAs.

Response: The statute requires that the competition occur in 10 of the largest MSAs in CY 2007. As we explained above, we believe that our methodology provides us with the most appropriate CBA selection methodology and greatest savings potential for the program and that initially implementing programs in all 10 CBAs at once will reduce the potential for confusion that could otherwise result if we conducted the competition in the sequence suggested by the commenter.

Comment: One commenter requested that CMS define ''combined rankings.'' The commenter asked whether this term means the allowed charges that suppliers have submitted to Medicare or the allowed payments.

Response: ''Combined rankings'' means a combined score for the DMEPOS allowed charges per beneficiary in an MSA and the number of DMEPOS suppliers per beneficiary in the same MSA with equal weight given to each. The term ''allowed charges'' includes both Medicare's approved payment amount and the beneficiary's coinsurance amount.

Comment: One commenter recommended that, in the situation where more than one MSA receives the same score, instead of using the total DMEPOS allowed charges for items that CMS has the authority to include in competitive bidding in each MSA as the tiebreaker, CMS use the FFS charges for the items proposed for bidding in each MSA and the total number of accredited suppliers in each MSA to break ties.

Response: We chose to use the total DMEPOS allowed charges because this number indicates the size of the overall business that is conducted in an MSA for items subjected to the competitive bidding program. We believe that using total DMEPOS allowed charges is a better indication of savings than the total number of suppliers in an area for the purpose of having a tie breaker because this measure indicates how many items are actually being furnished in an area.

Comment: One commenter agreed with our proposal to exclude the three largest MSAs from inclusion in competitive bidding until CY 2009.

Response: The three largest MSAs will be included in the list of potential MSA candidates for the CY 2009 competitive bidding program.

5. Nationwide or Regional Mail Order Competitive Bidding Program (§§ 414.410(d)(2) and 414.412(f) and (g))

Our data show that a significant percentage of certain items such as diabetic testing supplies (blood glucose test strips and lancets) are furnished to beneficiaries by nationwide mail order suppliers. Therefore, in the May 1, 2006 proposed rule (71 FR 25669), we proposed in § 414.410(d)(2) and §§ 414.412(f) and (g) to establish a nationwide or regional competitive bidding program, effective for items furnished on or after January 1, 2010, for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail. We proposed that the national or regional CBAs under the Medicare DMEPOS Competitive Bidding Program would be phased in after CY 2009, and payment would be based on the bids submitted and accepted for the furnishing of items through mail order throughout the nation or region. Suppliers that furnish these items through mail order on either a national or regional basis would be required to submit bids to participate in any competitive bidding program implemented for the furnishing of mail order items.

We proposed that, prior to the establishment of a nationwide or regional competitive bidding program in CY 2010, mail order suppliers would be eligible to submit bids for furnishing items in one or more of the CBAs we establish for purposes of the CYs 2007 and 2009 implementation phases. In addition, beginning with programs implemented in CY 2010, we proposed that mail order suppliers would be eligible to submit bids in one or more CBAs to furnish items that are not included in a nationwide or regional competitive bidding program. Nationwide or regional mail order suppliers would be required to submit bids and be selected as contract suppliers for each CBA in which they seek to furnish these items. However, we proposed that they would have the choice of either submitting the same bid amounts for each CBA or submitting separate bids.

For items that are subject to a nationwide or regional mail order competitive bidding program, we proposed that suppliers that furnish these same items in the local market and do not furnish them via mail order would not be required to participate in the nationwide or regional mail order competitive bidding program. However, we would only allow these suppliers to continue furnishing the items in CBAs if they were selected as contract suppliers.

We proposed to allow these nonmail order suppliers to continue furnishing these items in areas subject to a competitive bidding program if the supplier has been selected as a contract supplier. When furnishing items to beneficiaries who do not maintain a permanent residence in a CBA, nonmail order suppliers would be paid based on the payment amount applicable to the area where the beneficiary maintains his or her permanent residence.

In a September 2004 report (GAO–04–765), GAO recommended that we consider using mail delivery for items that can be provided directly to beneficiaries in the home as a way to implement a DMEPOS competitive bidding strategy. In the proposed rule, we solicited comments on our proposal to implement this recommendation and on the types of items that would be suitable for a mail order competitive bidding program.

In addition, we requested public comment on an alternative that would require that replacement of all supplies such as test strips and lancets for Medicare beneficiaries be furnished by mail order suppliers under a nationwide or regional mail order program. For example, there are services paid under the Medicare Physician Fee Schedule (MPFS) that are associated with the furnishing of blood glucose testing equipment (for example, home blood glucose monitors) such as training, education, assistance with product selection, maintenance, and servicing, that do not relate to the furnishing of replacement supplies used with the equipment. Once the brand of monitor has been selected by the beneficiary, the services associated with furnishing the supplies must be provided on a timely basis and the beneficiary must receive the brand of test strips needed for his or her monitor. We invited public comment on whether the service of furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by nationwide mail order suppliers.

Comment: Several commenters suggested that a separate program for mail order is unnecessary for CY 2010. They also noted that mail order supplies are not excluded for CYs 2007 and 2009.

Response: Our data indicate that over 60 percent of Medicare expenditures for diabetic supplies are for items furnished by nationwide mail order suppliers. We believe that the implementation of a separate mail order competitive bidding program would result in significant savings because it would focus on suppliers that can obtain discounts from manufacturers because they furnish a large volume of items to beneficiaries through the mail. Therefore, we envision that large savings for the Medicare program would result from the implementation of a separate mail order program.

Comment: Several commenters noted that there is no definition of a ''mail order supplier'' or description of a nationwide or regional mail order company in the proposed rule.

Response: In the proposed rule, we provided a definition of a ''supplier'' that includes an entity that furnishes items through the mail. However, to further prevent confusion, as discussed in section VI.A. we have added definitions of ''mail order contract suppler,'' ''nationwide mail order contract supplier,'' ''regional competitive bidding area,'' and ''regional mail order contract supplier'' in § 414.402. For purposes of competitive bidding a ''mail order contract supplier'' will be a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Comment: One commenter asked whether a supplier would qualify to participate in a mail order competitive bidding program if the supplier furnishes items both through the mail and through a storefront location to beneficiaries.

Response: Any national or regional mail order competitive bidding program that we might choose to implement starting in CY 2010 would be limited to the furnishing of items through the mail. Therefore, if a supplier wants to participate in a mail order program, it will have to submit a separate mail order program bid. Only a designated mail order contract supplier may furnish items under a mail order competitive bidding program. To participate in a program for providing items from a local storefront, a separate bid would have to be submitted.

Comment: One commenter noted that mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies (test strips and lancets). Several commenters opposed the requirement for beneficiaries to use the mail order suppliers and suggested that the mail order program be voluntary for beneficiaries. Several commenters noted that beneficiaries

must have the option to get the supplies from their local suppliers.

Response: We continue to believe that a national or regional mail order program will be cost effective for the Medicare program, and did not propose that it would be mandatory for beneficiaries. Such a mail order program will be voluntary and beneficiaries will have the option to receive their items through the mail or from a local contract supplier.

Comment: One commenter suggested that CMS specifically ensure that all suppliers in a mail order competitive bidding program are in compliance with the DMEPOS quality standard that requires that ''mail services are not used for the initial delivery, set-up, and beneficiary education/training'' for DME equipment and supplies.

Response: The DMEPOS quality standard that the commenter is referring to was included in the draft quality standards that were released for public comments on September 25, 2005. Although the final quality standards do not preclude suppliers from furnishing certain DMEPOS through the mail, they also require suppliers to verify that a beneficiary has received an item and to provide clear instructions to the beneficiary related to the use, maintenance, and potential hazards of the item. A supplier cannot be accredited unless a CMS-approved accreditation organization has determined that the supplier is complying with the quality standards, and accreditation is a prerequisite to a supplier being eligible to participate in the Medicare DMEPOS Competitive Bidding Program. Therefore, our goal is to award contracts only to suppliers that conduct business in a manner that is beneficial to beneficiaries under the program. The final Quality Standards document can be found under the basic standards and the consumer services section at the Medicare DMEPOS Competitive Bidding Program Web site: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp#TopofPage.*

Comment: One commenter suggested that CMS not implement a mail order competitive bidding program for diabetes testing supplies until the effects of such a program on beneficiaries with diabetes have been carefully studied, perhaps through a pilot program.

Response: We do not believe a pilot program is necessary. Our data show that 60 percent of beneficiaries currently receive supplies from mail order suppliers. Under the competitive bidding programs, beneficiaries will continue to have the option of receiving their supplies through the mail or from a local supplier.

Comment: One commenter suggested that CMS create a national supplier designation for which suppliers, mail-order or retail, can apply.

Response: As we discussed above, we will separately designate the supplier numbers of all noncontract suppliers to monitor whether they are complying with the rules regarding the limited circumstances under which they can furnish a competitively bid item. To address the commenter's concern, in addition to differentiating between contract suppliers and noncontract suppliers, we will also differentiate between mail order contract suppliers and mail order noncontract suppliers. We will be making those designations with the award of contracts.

Comment: One commenter recommended that, if CMS decides to create a nationwide or regional mail order competitive bidding program, CMS include a program oversight provision related to refilling of supplies. The commenter suggested that CMS prohibit contract suppliers from automatically refilling and sending replacement supplies without receiving a refill request from the beneficiary.

Response: Section 200, Chapter 20 of the Medicare Claims Processing Manual (Publication 100–4), prohibits suppliers/manufacturers from automatically delivering replacement supplies to beneficiaries unless the beneficiary, or their caregiver has requested them. The reason for this prohibition is to ensure that the beneficiary actually needs the replacement supplies. This requirement will apply to the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter opposed mail order/drop shipping for oxygen and related equipment because this might actually encourage contract suppliers to ship oxygen cylinders or other similar devices than deliver directly to the beneficiary.

Response: Pursuant to our DMEPOS supplier standards at 42 CFR 424.57(c), a supplier must operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements. Therefore, suppliers are required to furnish oxygen cylinders and other similar devices in accordance with these requirements.

6. Additional Competitive Bidding Areas After CY 2009 (§ 414.410(d)(1))

Section 1847(a)(1)(B)(III) of the Act requires that competition under the Medicare DMEPOS Competitive Bidding Program occur in additional areas after CY 2009. Beginning in CY 2010, we proposed in § 414.410(d)(1) to designate through program instructions additional CBAs based on our determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

We did not receive any comments on this specific.

Therefore, after considering the comments we received on Section II. D. of the proposed rule, we are finalizing §§ 414.406(b)–(c) and § 414.410 as discussed above and with additional technical changes, which include specifying in § 414.406(b) that we may designate CBAs through program instructions or by other means. We are also adding a several definitions, including a of ''mail order contract supplier'' under § 414.402. Finally, we are finalizing §§ 414.412(f) and (g) as discussed above and with technical changes.

F. Criteria for Item Selection (§§ 414.402 and 414.406(d))

Section 1847(a)(2) of the Act describes the DMEPOS items that are subject to competitive bidding. They include:

- Durable medical equipment and medical supplies: Covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.
- Other equipment and supplies (enteral nutrition, equipment, and supplies)—Items described in section 1842(s)(2)(D) of the Act, other than parenteral nutrients, equipment, and supplies.
- OTS orthotics: Orthotics described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h) of the Act, which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual.

In the May 1, 2006 proposed rule, we proposed in § 414.406(d) to designate the items that would be included in each competitive bidding program through program instructions. We also proposed (71 FR 25669) to define ''minimal self-adjustment'' to mean an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist (that is, an individual certified by either the American Board for Certification in

Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification). We also proposed to consider any adjustments that can only be made by a certified orthotist to be adjustments that require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. We proposed to consult with a variety of individuals, including experts in orthotics, to determine which items and/or HCPCS codes would be classified as OTS orthotics. We invited comments on a process for identifying OTS orthotics subject to competitive bidding.

Section 1847(a)(1)(B)(ii) of the Act gives us the authority to phase in competitive bidding ''first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential.'' In addition, section 1847(a)(3)(B) of the Act grants us the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings. In exercising this authority, we proposed to exempt items outright or on an area-by-area basis using area-specific utilization data. For example, if we found that utilization (that is, allowed services or allowed charges) for commode chairs was low (or the number of commode chair suppliers was low) in a given area compared to other areas, we might choose to exempt commode chairs from the competitive bidding programs in the CBA where significant savings would not be likely while including commode chairs in the competitive bidding programs for other CBAs. This decision would be based on area-specific utilization data.

We proposed to use the authority provided by section 1847(a)(1)(B)(ii) of the Act to phase in only those items that we determine are among the highest cost and highest volume items during each phase of the Medicare DMEPOS Competitive Bidding Programs. In section II.F. of the proposed rule, we proposed to conduct competitive bidding for product categories that would be described in each RFB. Suppliers would submit a separate bid for each item under a defined product category, unless specifically excluded in the RFB. We proposed to include a ''core'' set of product categories in each CBA. We indicated that we might elect to phase in some individual product categories in a limited number of CBAs in order to test and learn about their suitability for competitive bidding.

Because we had not yet identified the product categories for competitive bidding at the time we issued the proposed rule, we used policy groups developed by the statistical analysis durable medical equipment regional carrier (SADMERC) for purposes of illustration. The SADMERC has defined a set of 64 DMERC [DME MAC] policy groups for analytical purposes in its role as the statistical analysis contractor for DMEPOS. A policy group is a set of HCPCS codes that describe related items that are addressed in a DME MAC medical review policy. For example, the policy group ''oxygen and supplies'' consists of approximately 20 HCPCS codes. Although the product categories subject to competitive bidding will not necessarily correspond to these policy groups, we presented data for these policy groups and items contained in these policy groups for the purpose of identifying the highest cost and highest volume DMEPOS items that may be subject to competitive bidding. In other words, we proposed using SADMERC data for ''policy groups'' to identify groups of items we will consider phasing in first under the competitive bidding programs, but the actual ''product categories'' for which we would request bids could be a subset of items from a ''policy group'' or a combination of items from different ''policy groups.'' The highest volume items (HCPCS codes) fall into a relatively small number of policy groups as illustrated in Table 3.

TABLE 3.—CY 2003 HIGH VOLUME ITEMS (HCPCS CODES)

HCPCS code	Allowed charges	Product description	Policy group
E1390	$2,033,123,147	Oxygen concentrator	Oxygen.
K0011*	1,176,277,899	Power wheelchair with programmable features	Wheelchairs.
A4253	779,756,243	Blood glucose/reagent strips, box of 50	Diabetic Supplies & Equipment.
E0260	331,457,962	Semi-electric hospital bed	Hospital Beds/Accessories.
E0431	228,066,037	Portable gaseous oxygen equipment	Oxygen.
B4150*	206,396,813	Enteral formula, category I	Enteral Nutrition.
B4035	197,057,150	Enteral feeding supply kit, pump fed, per day	Enteral Nutrition.
E0277	156,762,241	Powered air mattress	Support Surfaces.
E0439	141,268,474	Stationary liquid oxygen	Oxygen.
E0601	123,865,463	Continuous positive airway pressure device (CPAP)	CPAP Devices.
K0001	103,217,209	Standard manual wheelchair	Wheelchairs.
K0004	87,208,486	High strength lightweight manual wheelchair	Wheelchairs.
A4259	79,575,166	Lancets, box of 100	Diabetic Supplies & Equipment.
E0570	76,588,088	Nebulizer with compressor	Nebulizers.
B4154*	76,326,903	Enteral formula, category IV	Enteral Nutrition.
E0143	75,950,410	Folding wheeled walker w/o seat	Walkers.
K0533*	75,136,517	Respiratory assist device with backup rate feature	Respiratory Assist Devices.
K0538*	65,603,531	Negative pressure wound therapy electrical pump	Negative Pressure Wound Therapy (NPWT) Devices.
K0532*	56,046,930	Respiratory assist device without backup rate feature	Respiratory Assist Devices.
K0003	55,318,959	Lightweight manual wheelchair	Wheelchairs.
K0108	52,139,979	Miscellaneous wheelchair accessory	Wheelchairs.
E0192*	48,413,938	Wheelchair cushion	Support Surfaces.
E0163	48,216,855	Stationary commode chair with fixed arms	Commodes.
B4034	42,277,968	Enteral feeding supply kit syringe, per day	Enteral Nutrition.

*Due to HCPCS coding changes made since 1993, the descriptions or code numbers for these codes have been modified. The power wheelchair codes became effective November 15, 2006 and will be billed under several new HCPCS codes.

Because we proposed that we would conduct competitive bidding for items grouped into product categories, we indicated that we would consider DMEPOS allowed charges and volume at the product category level for the

purpose of selecting which items to phase in first under the competitive bidding programs. The table below provides data for the top 20 policy groups based on Medicare allowed charges for the items within each policy group that we may choose to include in the competitive bidding programs. Data from the SADMERC for claims received in CY 2003 are used for all policy groups except those for nebulizers and OTS orthotics. For the nebulizer and OTS orthotics groups, data are included from the CMS BESS (Part B Extract and Summary System) database for items furnished in CY 2003. The percentage of total allowed Medicare charges for DMEPOS that each policy group makes up is included in Table 4.

TABLE 4.—CY 2003 DMEPOS ALLOWED CHARGES BY POLICY GROUP

Rank	Policy group	CY 2003	Percent of DMEPOS
1	Oxygen Supplies/Equipment	$2,433,713,269	21.3
2	Wheelchairs/Power Operated Vehicle (POVs)**	1,926,210,675	16.9
3	Diabetic Supplies & Equipment	1,110,934,736	9.7
4	Enteral Nutrition	676,122,703	5.9
5	Hospital Beds/Accessories	373,973,207	3.3
6	CPAP Devices	204,774,837	1.8
7	Support Surfaces	193,659,248	1.7
8	Infusion Pumps & Related Drugs	149,208,088	1.3
9	Respiratory Assist Devices	133,645,918	1.2
10	Lower Limb Orthoses*	122,813,555	1.1
11	Nebulizers*	98,951,212	0.9
12	Walkers	96,654,035	0.8
13	Negative Pressure wound therapy (NPWT) Devices	88,530,828	0.8
14	Commodes/Bed Pans/Urinals	51,372,352	0.5
15	Ventilators	42,890,761	0.4
16	Spinal Orthoses*	40,731,646	0.4
17	Upper Limb Orthoses*	29,069,027	0.3
18	Patient Lifts	26,551,310	0.2
19	Seat Lift Mechanisms	15,318,552	0.1
20	TENS Devices**	15,258,579	0.1
Total for 20 Groups		7,830,384,538	68.6
Total for DMEPOS		11,410,019,351	

*Data are from the CMS BESS (Date of Service). Data for orthoses policy groups exclude data for custom fabricated orthotics, but may include data for other items that will not be considered OTS orthotics.

**POVs are power-operated vehicles (scooters), and TENS devices are transcutaneous electrical nerve stimulation devices.

Section 1847(a)(1)(B)(ii) of the Act provides that the items we phase in first under competitive bidding may include products having the greatest potential for savings. In the May 1, 2006 proposed rule, we proposed to use a combination of the following variables when making determinations about an item's potential savings as a result of the application of competitive bidding:

- Annual Medicare DMEPOS allowed charges.
- Annual growth in expenditures.
- Number of suppliers.
- Savings in the DMEPOS competitive bidding demonstrations.
- Reports and studies.

We proposed that items with high allowed charges or rapidly increasing allowed charges would be our highest priority in selecting items for competitive bidding.

The number of suppliers furnishing a particular item or group of items would also be an important variable in identifying items with high savings potential. We believe that a relatively large number of suppliers for a particular group of items would likely increase the degree of competition among suppliers and increase the probability that suppliers would compete on quality for business and market share. We saw evidence in the competitive bidding demonstrations that products furnished by a large number of suppliers had large savings rates and fewer problems with quality. We understand that having a large number of suppliers is not always a necessary condition for competition. A CBA could be more concentrated and less competitive than the number of suppliers would predict if the market is dominated by only a few suppliers and the remaining suppliers have only minimal charges.

The DMEPOS competitive bidding demonstrations took place from 1999 to 2002 in two MSAs: Polk County, Florida and San Antonio, Texas. Five product categories containing items we might include in the Medicare DMEPOS Competitive Bidding Programs were included in at least one round of these demonstrations: oxygen equipment and supplies; hospital beds and accessories; enteral nutrition; wheelchairs and accessories; and general orthotics.

The results of the demonstrations provide useful information because they are based on actual Medicare competitive bidding and the amounts suppliers actually were willing to accept as payment from Medicare. However, we recognize that these results should be used with caution. The demonstrations occurred more than 3 years ago and the fee schedule has changed as a result of certain provisions in the MMA (for example, section 302(c)(2) of the MMA (codified at section 1834(a)(21) of the Act), which requires that CMS adjust the fee schedules for certain items based on a comparison to other payers such as the Federal Employees Health Plan (FEHP)).

The HHS Office of the Inspector General (OIG) and GAO frequently conduct studies that analyze the extent to which Medicare overpays for specific items, and we believe that these studies could assist with determining the saving potential for an item if it were included in competitive bidding. Examples of relevant OIG studies include the following:

- Medicare Allowed Charges for Orthotic Body Jackets, March 2000 (OEI–04–97–00391);

• Medicare Payments for Enteral Nutrition, February 2004 (OEI–03–02–00700); and

• A Comparison of Prices for Power Wheelchairs in the Medicare Program, April 2004 (OEI–03–03–00460).

In addition, CMS and the DME MACs obtain retail pricing information for items in the course of establishing fee schedule amounts and considering whether payment adjustments are warranted for items using the inherent reasonableness authority in section 1842(b)(8) of the Act. In the proposed rule, we indicated that we could use these studies to identify products where CMS pays excessively and where we could potentially achieve savings.

Excessive payments are only one factor to consider when evaluating whether savings will be realized by the application of competitive bidding to an item. However, these studies offer us a guide regarding which items may have the greatest potential for savings. We also recognize that some studies are older than others and that recent MMA and FEHP reductions in fees may affect whether the results of these studies are still relevant.

Comment: Many commenters objected to the proposed definition for OTS orthotics that would be subject to competitive bidding in accordance with section 1847(a)(2)(C) of the Act. They specifically objected to the discussion in the proposed rule that states that the expertise required to trim, bend, assemble, mold, or custom fit an orthotic device for an individual would be that of a certified orthotist. They pointed out that occupational therapists, physical therapists, and physicians are licensed and trained to trim, bend, mold, assemble, and customize some orthotics to fit a beneficiary. They indicated that under the Act, occupational and physical therapists are recognized as Medicare practitioners who furnish orthotics to Medicare beneficiaries pursuant to a written plan of care. The commenters added that the Act recognizes orthotists as suppliers of DMEPOS only and not as practitioners. They recommended revising the language to read: '' 'Minimal self-adjustment' means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a physician, physical therapist, occupational therapist, orthotist, or other professional designated by the Secretary.''

In addition, many commenters stated that there is no Federal definition of orthotists or their scope of practice and that a limited number of States have licensure or certification laws for orthotists. They added that, for those States that have such laws, the scope of practice varies considerably. The commenters recommended including the statutory definition of ''qualified practitioner'' located in section 1834(h)(1)(F)(iii) of the Act to identify those individuals with expertise in custom fitting orthotics. They believed that linking OTS orthotics to the work of a certified orthotist would dramatically expand the list of products that are considered OTS orthotics that would be subject to competitive bidding. They further noted that the list of OTS orthotics has yet to be published.

Response: We appreciate the comments. Section 1847(a)(2) of the Act describes OTS orthotics as those orthotics described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h) of the Act, which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Orthotics that are currently paid under section 1834(h) of the Act and are described in section 1861(s)(9) of the Act are leg, arm, back, and neck braces. The Medicare Benefit Policy Manual, Chapter 15, Section 130 provides the longstanding Medicare definition of ''braces.'' Braces are defined in this section as ''rigid or semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.'' To clarify the definition of OTS orthotics for purposes of competitive bidding, in this final rule we are defining the term ''minimal self-adjustment'' to mean an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who possesses specialized training. These individuals possess specialized skills and knowledge used to custom fit braces for individual beneficiaries so that they function appropriately. Therefore, if an adjustment to an OTS orthotic that requires expertise in trimming, bending, molding, assembling, or customizing to fit the individual such that it must be performed by a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification) or someone who possesses specialized training, it would not be an OTS orthotic that is eligible to be included in a competitive bidding program.

As we proposed, we will identify specific OTS orthotics that will be included in specific competitive bidding programs through program instructions.

Comment: Several commenters requested exemption of OTS orthotics that have the HCPCS codes L3908–L3954 (wrist, hand, and finger orthoses) and L3980–L3985 (upper extremity fracture orthoses). They believed that these codes should be exempted because clinicians and practitioners use them for short-term protection and stabilization of a joint or limb. They further indicated that practitioners do not dispense these items as a product or supply item but rather as part of the evaluation and treatment of beneficiaries.

Response: Section 1847(a)(2) of the Act provides that OTS orthotics described in section 1861(s)(9) of the Act, for which payment would otherwise be made under section 1834(h) of the Act, are to be included in the Medicare DMEPOS Competitive Bidding Program if they require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. Although the items identified by the commenters are orthotics as described in section 1861(s)(9) of the Act for which payment is made under section 1834(h) of the Act, we have not yet determined whether they require minimal self-adjustment. We have also not yet determined whether one or more of these items might not be appropriate for inclusion in the Medicare DMEPOS Competitive Bidding Program because it is not likely to produce significant savings. We will consider the commenters' suggestions and designate the items that will be included in each competitive bidding program through program instructions or by other means, such as the RFB or our Web site.

Comment: Several commenters believed that the selection of items for competitive bidding is being driven by allowed charges and utilization only. They believed that this poses a risk and allows competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. The commenters believed that consideration of clinical and service factors specific to the product should be part of the selection criteria.

Response: We do not have data on which we could evaluate clinical and service factors specific to individual items nor were any data submitted through the public comment process. In addition to allowed charges and utilization, we identified in the proposed rule the following variables that we will use to select items for competitive bidding: Annual growth in expenditures; number of suppliers; savings in the DMEPOS competitive bidding demonstrations; and reports and studies. We stated that we would use all of these variables to make determinations about an item's potential to reduce costs for the Medicare program. We note that the Medicare DMEPOS Competitive Bidding Program is not a coverage program, and that this final rule does not supersede in any way Medicare coverage laws, regulations, or policies.

Comment: Several commenters believed that ostomy products and supplies do not meet the definition of DME and, therefore, are not part of the items and services subject to the competitive bidding programs described in section 1847(a)(2)(A) of the Act.

Response: We believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS Competitive Bidding Program because the term ''medical supplies'' in the section heading could be interpreted either to modify the term ''durable medical equipment'' (meaning that the medical supplies would have to be associated with the DME to be included), or to be a separate category of items that are not associated with DME. In addition, although the definition of ''covered item'' in section 1834(a)(13) of the Act means ''durable medical equipment (as defined in section 1861(n) [of the Act]), including such equipment described in section 1861(m)(5) [of the Act] * * *,'' the term ''such equipment'' in section 1861(m)(5) of the Act could be interpreted to refer either to the term ''durable medical equipment'' or to the term ''medical supplies'' (which would include ostomy supplies) in that section. In light of these ambiguities, we believe we have discretion to interpret section 1847(a)(2)(A) of the Act to include or exclude ostomy products and supplies in the competitive bidding programs. We are not planning to exercise our authority to include these items at this time and will continue to review this issue.

Comment: Many commenters believed that the following items that are integral to beneficiary care should be exempted from competitive bidding: diabetic supplies; diabetic shoes; diabetic inlays; prosthetics for the foot; crutches; walkers; fracture ankle-foot orthoses; braces; splints; and surgical dressings. A few commenters requested exemption of products commonly provided directly by manufacturers. They believed that the products are available from relatively few suppliers and would not produce Medicare savings.

A few commenters requested the exemption of oxygen, continuous positive airway pressure devices, and invasive and noninvasive ventilation devices. They believed that these items are technologically complex devices. Several commenters recommended exempting negative pressure wound therapy (NPWT) devices from the first round of competitive bidding. They reported that in October 2000, a new HCPCS code (E2402) was established for NPWT. Since 2003, more than 3,000 physicians have ordered NPWT devices more than 36,000 times. They reported that new products have been added to HCPCS code E2402 despite the fact that these new products are clinically different from the original NPWT product. The commenters believed that the newer items are not yet well-understood or well-established and physician choice in selecting an item must be respected.

Many commenters requested exemption of power wheelchairs, including complex rehabilitative and assistive technology devices, for the first round of competitive bidding. They believed that competitively bidding these devices would result in a negative impact on the clinical outcome for the beneficiary. They described these items as being uniquely prescribed for the beneficiary. The commenters recommended exempting wheelchair cushions, adaptive seating, and positioning products. They indicated beneficiaries who require complex rehabilitative or assistive technology require a complete system to meet their functional and medical needs. The commenters pointed out that a complete system requires several pieces of equipment, each meeting a specific medical or functional need and determined to be compatible technologies. They believe that the recent changes in HCPCS codes for power mobility devices, a new local coverage determination policy, and new fee schedules will significantly impact the utilization and allowed charges for these items. They believe that, in light of these changes, there will be a lack of allowed charges and volume data that will make it difficult to determine which codes have the highest allowed charges and highest volume or potential for savings.

Many commenters requested the exemption of manual wheelchairs because as early as CY 2007, the HCPCS codes will be subjected to a recoding process that is similar to the recoding process that CMS recently undertook for power mobility devices. Under the proposed rule, a supplier that bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. They believed that the current HCPCS codes are too broad, encompassing items that represent vastly different technologies.

Several commenters requested the exemption of speech generating devices (SGDs). They stated the functional, physical, operational, and support characteristics of a specific SGD model are selected based on the individual needs of the beneficiary. The commenters reported that Medicare has purchased fewer than 5,000 SGDs since 2001. They indicated that, on average, 1,211 SGDs are purchased per year, and that in 2004, Medicare spent only $4,562 on SGDs (code E2511), less than $220,000 on mounting systems (code E2512), and less than $280,000 on all SGD accessories.

Some commenters requested that CMS not create a product category that consists of ''infusion pumps and related drugs.'' They pointed out that infusion drugs are covered under the DMEPOS benefit because they go through the pump, which is DME. They added that managed care plans include home infusion therapy coverage under either their major medical benefit or their prescription drug benefit and that Medicare Part D covers hundreds of home intravenous drugs. The commenters believed that there is confusion among beneficiaries who require Medicare Part B and Part D drugs, and that adding infusion pumps that are used for drug administration to competitive bidding will confuse both beneficiaries and referral agents further. They also indicated that these devices vary in drug therapy, technology, length of treatment, and site of care, and that the devices range from critical acute care to chronic infusion.

Some commenters requested the exemption of enteral nutrition equipment and supplies. They believed that the use of competitive bidding to set prices under Medicare has not been tested sufficiently or successfully. The commenters indicated that Medicare allowed charges for enteral nutrition decreased by approximately 5 percent from CY 2003 to CY 2004. They

reported that there is confusion among beneficiaries who require Medicare Part B and Part D drugs, and believed that adding competitive bidding will only confuse beneficiaries and referral agents further.

A few commenters requested the exemption of transcutaneous electrical nerve stimulator (TENS) devices from competitive bidding. They believed that these devices constitute a miniscule percentage of Medicare charges, and that including these devices in one product category will induce beneficiaries to purchase inferior services. They reported that some manufacturers include a post-sale periodic monitoring service, whereas others do not.

Some commenters requested the exemption of support surfaces until the completion of the Support Surface Standards Initiative. They indicated that data from the Agency for Healthcare Research and Quality showed an increase in hospitalizations for beneficiaries with pressure ulcers up to 63 percent during the period 1993 through 2003. The commenters recommended that if support surfaces are selected for competitive bidding, CMS subdivide the codes and evaluate separate bids for each subcategory. They also recommended that stakeholders be consulted regarding the subcategories.

Several commenters stated that Medicare should not subject vision-related DMEPOS commonly dispensed by optometrists to competitive bidding. They believed that optometrists should not be required to submit a bid.

Many commenters recommended the following sources for gathering information about various homecare services and allowed charges: American Society for Parenteral and Enteral Nutrition (ASPEN), American Association for Respiratory Care (AARC), American Nurses Association (ANA), American Dietetic Association (ADA), National Home Oxygen Patients Association (NHOPA), American Lung Association (ALA), American Diabetes Association (ADA), Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and other accrediting organizations.

Response: Section 1847(a)(3)(B) of the Act grants us the authority to exempt items and services for which the application of competitive bidding is not likely to result in significant savings. Section 1847(a)(1)(B)(ii) of the Act gives us the authority to phase in competitive bidding ''first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.'' As we stated in the May 1, 2006 proposed rule, we will consider annual Medicare allowed charges, annual growth in expenditures, the number of suppliers furnishing the item, reports and studies, and data showing whether we realized savings by including the item in the competitive bidding demonstrations to determine whether including an item(s) under the competitive bidding programs is likely to result in significant savings. As we evaluate specific items for inclusion in competitive bidding programs, we will also consider the recommendations offered by these commenters. We note that diabetic shoes and inserts, prosthetics for the foot, splints and casts, prosthetic devices that aid vision, and surgical dressings are not among the items and services described in section 1847(a)(2) of the Act and, therefore, cannot be included in the competitive bidding programs.

Comment: Some commenters recommended that CMS publish the items that will be included in the initial competitive bidding programs in an interim final rule. They also believed that a meeting should be scheduled with the PAOC to solicit additional public comment after product selections are announced.

Response: We intend to announce the product categories for competitive bidding on or shortly after the date of issuance of this final rule, and we will designate the items to be included in each competitive bidding program through program instructions or by other means, such as the RFB, and post them on our Web site. We do not believe that we need to publish the list of items in the form of an interim final rule in the **Federal Register**. We also note that the PAOC provided feedback on the criteria for item selection that we proposed in the May 1, 2006 proposed rule. Further, the public had the opportunity to comment on our proposed methodology for item selection through the public notice and comment rulemaking process, and the opportunity to participate in PAOC meetings that dealt with this subject. We will take under consideration the commenters' suggestion to hold future PAOC meetings on item selection.

Comment: Several commenters requested an explanation of the specific measure that will be used to identify an item's true potential savings after accounting for any recent policy changes and rate cuts. They asked if any thresholds would be used to measure the actual savings. They reported that changes in payment policy significantly decreased CY 2003 allowed charges for oxygen equipment, nebulizers, and inhalation drugs. The commenters also reported that payment for glucose meters, test strips, and lancets were previously frozen in CYs 1998, 1999, and 2000 and again in CY 2002. They indicated that these payment freezes call into question the feasibility of achieving significant additional Medicare savings through competitive acquisition. The commenters believed that the annual growth in expenditures for the above items could be attributed to other factors such as an increase in the number of new beneficiaries or the elimination of Medicare Advantage Plans in various markets. Many commenters recommended establishing a savings threshold that would use ongoing administrative allowed charges to assess the appropriateness of competitive bidding for each product category. They recommended using a threshold of a 10-percent margin to determine the net savings after excluding administrative costs associated with the ongoing support of the competitive bidding programs from the total savings incurred.

Response: We will determine which items offer the best savings potential. We disagree that an exact dollar threshold is appropriate for determining if significant savings will be achieved for an item under a competitive bidding program because it would be logistically difficult to set an exact number for what the savings will be for a particular item until we receive the bids. Once we receive the bids, we can estimate the dollar savings amount to determine whether that represents an appropriate savings. In addition to allowed charges and utilization, we identified in the proposed rule the following variables that we will use to select items for competitive bidding: annual growth in expenditures; number of suppliers; savings in the DMEPOS competitive bidding demonstrations; and reports and studies. We stated that we would use all of these variables to make determinations about an item's potential to reduce costs for the Medicare program. We will also assure savings because we will not accept a bid to furnish an item unless the submitted bid price is at or below the fee schedule amount for the item.

Comment: Some commenters suggested that the greatest potential for savings to the Medicare program could be achieved by eliminating coverage of specific DME items or entire product categories.

Response: We appreciate the comment. However, competitive bidding is a program for determining Medicare payment for covered items and services and does not supersede any

Medicare rules, policies, or procedures relating to coverage.

Comment: Some commenters reported that the proposed rule indicates Medicare expenditures for DME infusion pumps and related drugs in CY 2003 were approximately $149 million. They indicated that this number appears to include expenditures made for insulin and insulin pumps for beneficiaries with diabetes, which are not provided by infusion pharmacies and largely serve a different beneficiary market than infusion pumps and related drugs used by beneficiaries for other medical conditions. They believe that the more accurate amount of Medicare expenditures for CY 2003 for DME infusion pumps and related drugs was approximately $87 million.

Response: Insulin pumps are a type of infusion pump used by beneficiaries with diabetes and currently are included in the SADMERC policy group for external infusion pumps and related drugs. Although we will be using the SADMERC policy groups to identify groups of items that we will consider including in one or more competitive bidding programs, the actual product categories that we develop might be a subset of items from a SADMERC policy group or a combination of items from different SADMERC policy groups. In determining which items are appropriate to include in a product category, we will also evaluate its savings potential, as discussed above.

Comment: Many commenters believed that the OIG and GAO reports and studies focus largely on a narrow issue or a small subset of issues, and as a result, the reports often reflect a skewed perspective of the particular problem and the suggested solution to that problem. They believed that none of the historical OIG studies reflects the cost of accreditation or complying with the quality standards that are the bases of accreditation. They believed that the OIG studies do not focus on the services and functions required of suppliers, the allowed charges associated with these services and functions, or whether payment rates are limited to the allowed charges of items and equipment. In addition, they indicated that the OIG reports generally collect information from across the United States, while competitive bidding is market-specific. In light of these discrepancies, they recommended that our decisions should not rely heavily on OIG reports when we select items for inclusion in the competitive bidding programs.

Response: We believe that the OIG and GAO reports and studies provide useful information for identifying items with high expenditures. However, we will not rely solely on these reports. As we indicated in the proposed rule, we would rely on several variables in determining the savings potential for specific items or categories of items. Those variables include annual allowed charges, annual growth in expenditures, number of suppliers, savings under the demonstrations, and various reports and studies conducted by CMS and other Federal agencies.

After consideration of the public comments we received, we are adding a definition of the term ''minimal self-adjustment'' under § 414.402. We are also finalizing § 414.406(d), with a technical change. We are specifying that when we designate the items that will be included in each competitive bidding program, we will do so by program instructions or by other means, such as the RFB or our Web site.

G. Submission of Bids for Competitively Bid DMEPOS (§§ 414.404, 414.408, 414.412, and 414.422)

Sections 1847(b)(6)(A)(i) and (b)(6)(A)(ii) of the Act provide that payment will not be made under Medicare Part B for items furnished under a competitive bidding program unless the supplier has submitted a bid to furnish those items and has been selected as a contract supplier. Therefore, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract to do so by CMS (proposed § 414.412). In section II.C.6. of the May 1, 2006 proposed rule (71 FR 25664), we proposed that there would be limited exceptions to this requirement for items required by beneficiaries who reside in a CBA but are out of the area and need items (proposed § 414.408(f(2)(ii))). We also proposed that there would be an exception for suppliers that are grandfathered to continue to provide and service certain items (§ 414.408(f)(2)(i), as discussed in section VI.D.3. of this final rule.

1. Furnishing of Items (§§ 414.412(c) and 414.422(e))

In the May 1, 2006 proposed rule, under proposed § 414.422(e) we proposed that a contract supplier must agree to furnish the items included in its contract to all beneficiaries who maintain a permanent residence in, or who visit, the CBA and who request these items from the contract supplier. However, as we explained in the proposed rule (71 FR 25672 and 25681), we proposed that a skilled nursing facility (SNF) as defined in section 1819 of the Act that is also a contract supplier must only agree to furnish the items included in the contract to patients to whom it would otherwise provide Medicare Part B services (proposed § 414.422(e)(2)(i)). In addition, we proposed that a physician who is also a contract supplier must only agree to furnish the items included in the contract to his or her patients (proposed § 414.422(e)(2)(ii)). Because suppliers will have to factor this requirement into their responses to the RFBs, we have chosen to discuss this requirement in this section of the final rule.

a. Furnishing of Items to Medicare Beneficiaries Who Maintain a Permanent Residence in a CBA

In the May 1, 2006 proposed rule (71 FR 25681), we proposed that a contract supplier cannot refuse to furnish items and services to a beneficiary residing in a CBA based on the beneficiary's geographic location within the CBA (proposed § 414.422(e)(1)). We indicated that this rule would prohibit a contract supplier from refusing to furnish items to beneficiaries because they are not in close proximity to that supplier. In order to ensure beneficiary access to competitively bid items that are rented, we proposed that the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. This is particularly important in those cases where a supplier or noncontract supplier does not elect to continue furnishing the item in accordance with the grandfathering provisions discussed in section VI.D.3. of this final rule. Suppliers must factor the cost of furnishing items in these situations into their bid submissions.

In addition, in order to ensure beneficiary access to the competitively bid items in the inexpensive or routinely purchased DME payment category, or to a competitively bid power wheelchair, we proposed that the contract supplier must agree to give the beneficiary or his or her caregiver the choice of either renting or purchasing the item and must furnish the item on a rental or purchase basis as directed by the beneficiary or the beneficiary's caregiver. Suppliers must factor the cost of furnishing these items on both a rental and purchase basis into their bid submissions.

Comment: One commenter requested that CMS clarify that a contract supplier can limit the number of items it provides in each category to its contracted capacity.

Response: As part of a supplier's response to the RFB, a supplier will be

expected to state its projected capacity to furnish the items in each product category for which it is submitting a bid. The projected capacity submitted by a supplier would not become a binding term of the contract because contract suppliers will be required to furnish the items in their contract to all beneficiaries who maintain a permanent residence in the CBA, or who visit the CBA, and who request the items from them unless one of the exceptions discussed in this final rule applies.

b. Furnishing of Items to Medicare Beneficiaries Whose Permanent Residence Is Outside a CBA

In the May 1, 2006 proposed rule (71 FR 25681), we proposed that in order to obtain medically necessary DMEPOS items, a Medicare beneficiary whose permanent residence is located outside of a CBA must use a contract supplier to obtain all items subject to competitive bidding in the CBA that he or she visits. We considered allowing beneficiaries whose residence is outside of a CBA to obtain these items from noncontract suppliers when coming into a CBA. However, consistent with section 1847(b)(6) of the Act, we proposed that beneficiaries would be required to use a contract supplier because we believe that new business for competitively bid items should be directed only to contract suppliers. Noncontract suppliers would be allowed to continue servicing current beneficiaries who maintain a permanent residence in a CBA if they qualified for the grandfathering program discussed in section VI.D.3. of this final rule.

Comment: One commenter stated that CMS should indicate how the provision to furnish competitively bid items to Medicare beneficiaries whose permanent residence is outside a CBA will be communicated to beneficiaries who are visiting a CBA.

Response: Noncontract suppliers located in a CBA will be informed that they are not eligible to furnish competitively bid items to beneficiaries visiting the CBA and as we discussed earlier in this final rule, beneficiaries will not be held liable to make a payment for an item furnished in contravention of this rule, unless the beneficiary signs an ABN indicating the beneficiary's knowledge and understanding that Medicare will not pay for that item. Noncontract suppliers will be educated to refer beneficiaries to contract suppliers in these situations. We are also planning an extensive educational campaign to inform the public of the requirement that an item must be obtained from a contract supplier when a beneficiary is visiting a CBA, if the item that the beneficiary needs is included in the competitive bidding program for the CBA that the beneficiary is visiting. A list of all contract suppliers along with other competitive bidding information will be on the CMS and CBIC Web sites. This information will also be available to beneficiaries through the toll-free telephone number 1–800 Medicare.

Comment: One commenter stated that it was confused as to whether certain products might be drop-shipped into the area where the beneficiary is visiting. The commenter requested clarification on this because the commenter believed there are many types of equipment such as oxygen equipment that should not be drop-shipped. Another commenter stated that a beneficiary visiting in the CBA should not be required to use a contract supplier because such a requirement would confuse beneficiaries. The commenter recommended that CMS not adopt the proposed rule or modify it so that it only applies to beneficiaries who have resided in the CBA for 3 or more months. Two commenters stated that there will be an undue impact on ''snowbirds'' as a result of the requirement that contract suppliers furnish items to Medicare beneficiaries whose permanent address is outside the CBA and that this provision should not be adopted.

Response: The proposed requirement would establish a process whereby beneficiaries visiting a CBA must get a competitively bid item for that CBA from a contract supplier that furnishes the item in the CBA. If, however, the beneficiary needs an item that is included in the competitive bidding program for the CBA that the beneficiary is visiting (even if the item is not included in the competitive bidding program for the CBA where the beneficiary maintains a permanent residence), the beneficiary would be required to obtain the item from a contract supplier in the CBA where the beneficiary is visiting. Therefore, if a beneficiary is visiting a CBA, he or she may obtain the item from a contract supplier, and there would be no reason to drop-ship a product. As we explained in our response to the previous comment, we plan to implement a process by which beneficiaries will be able to locate contract suppliers in a CBA where they are visiting. We believe that a beneficiary who visits a CBA should be required to obtain competitively bid items for that CBA only from contract suppliers for that CBA because we believe that new business for these items should only be directed to contract suppliers. The purpose of competitive bidding is to award contracts to certain suppliers based upon their winning bids and to ensure the beneficiaries receive items from these suppliers.

Comment: One commenter suggested that CMS establish a system to ensure that all beneficiaries will continue to have access to their DMEPOS supplies, even while visiting an area that is not the beneficiary's CBA. The commenter stated that CMS should require that suppliers aggressively educate beneficiaries on the proper procedures for obtaining their supplies while away from home, and should allow beneficiaries to purchase extra supplies for extended vacations or temporary changes of residence. The commenter also urged CMS to allow beneficiaries to purchase their supplies from noncontract suppliers in the event of an emergency.

Response: As we discussed above, we will conduct an extensive education campaign to educate beneficiaries, suppliers, and referral agents on how beneficiaries who are away from home can obtain medically necessary items. As we proposed, our contract supplier selection methodology will ensure there are enough contract suppliers in each CBA to ensure beneficiary access to needed items and services. In addition, beneficiaries on vacation or who have temporary changes of residence will be able to obtain competitively bid items that are included in the competitive bidding program for the CBA that they are visiting from contract suppliers for that CBA. Contract suppliers will be listed on the Internet in order for beneficiaries to determine who the contract suppliers are in the CBA they are visiting. As we explained above, we will require that contract suppliers assist Medicare beneficiaries in locating contract suppliers while visiting other CBAs. We do not believe an exception is needed in the event of an emergency because we will ensure that there will be a sufficient number of contract suppliers in a CBA to meet the access needs of beneficiaries.

2. Requirements for Providers to Submit Bids (§§ 414.404(a) and 414.422(e)(2))

In the May 1, 2006 proposed rule (71 FR 25672), we proposed in § 414.404(a) that the Medicare DMEPOS Competitive Bidding Program would apply to suppliers, and in proposed § 414.404(b) that the program would apply to providers that furnish items under Medicare Part B as suppliers. Accordingly, providers that furnish Medicare Part B items are located in a competitive bidding area, and that are also DMEPOS suppliers would be

required to submit bids in order to furnish competitively bid items to Medicare beneficiaries. We also proposed that providers that are not awarded contracts must use a contract supplier to furnish these items to Medicare beneficiaries to whom they provide services. However, we proposed in new proposed § 414.422(e)(2)(i) that a SNF, as defined in section 1819(a) of the Act, would not be required to furnish competitively bid items to beneficiaries outside of the SNF if it elected not to function as a commercial supplier. We stated that this rule is consistent with the current practice of some SNFs to furnish Medicare Part B services only to their own residents.

Comment: Several commenters recommended that CMS exclude institutional providers, such as SNFs and other long-term care facilities, from competitive bidding or exempt products that are primarily used in institutional settings from competitive bidding. They stated that because the residents of these institutions are often among the most frail and critically ill the level of care required for these patients should not be threatened or compromised by rules whose impact, although well-intended, are not conducive to the long-term care environment. The commenters believed that competitive bidding may distort current institutional purchasing patterns and result in higher prices. Several commenters also suggested that CMS postpone bidding in long-term care settings until CMS convenes a working group of key stakeholders to examine how the requirements for competitive bidding impact these facilities. They further stated that CMS should phase in the program over at least 4 years. Others suggested delaying implementation of the program.

Response: Congress specifically provided that certain categories of items and services, specifically certain DME, medical supplies, enteral nutrients, equipment, and supplies, and OTS orthotics are subject to the Medicare DMEPOS Competitive Bidding Program and established phase-in implementation rules. Items and services may only be excepted from the program if we determine that they are not likely to result in significant savings if they are included. A large volume of enteral nutrients, equipment, and supplies are furnished to patients in SNFs and nursing facilities (NFs along with some OTS orthotics. Currently, we allow SNFs and nursing facilities (NFs) to choose whether to provide these services directly or under contract with an outside supplier. To avoid disruption of this practice, we will continue to provide SNFs and NFs with this choice.

We continue to believe that Medicare DMEPOS Competitive Bidding Program should apply to institutional providers to the extent they furnish items under Part B because section 1847 of the Act does not distinguish these providers from other types of Part B suppliers. However, we believe that SNFs and NFs should be treated differently from other providers in terms of who they must furnish items to because they generally do not use a commercial model of providing services throughout the community. Instead, they generally provide items only to patients that reside in their facility. We do not believe it would be in the best interest of the program to exempt institutional providers from participating or delay implementation in these settings because these providers furnish items subject to competitive bidding to their residents, and the category of enteral nutrition, as a whole, is made up of high-cost, high-volume items.

Therefore, we are finalizing our proposal under § 414.422(e)(2) to permit SNFs as defined in section 1819(a) of the Act, to furnish competitively bid items only to their own residents. We are extending this provision to NFs, as defined in section 1919(a) of the Act, because we believe the services they furnish, the customers they serve, and their business model are parallel to SNFs. A SNF or NF will still be required to submit a bid and have a bid in the winning range and the SNF or NF must indicate in its response to the RFB it intends to elect this option. If the SNF or NF is not selected as a contract supplier, it will have to use a contract supplier within the CBA to furnish competitively bid items to its residents. In addition, should a SNF or NF indicate in its response to the RFB that it plans to furnish items to beneficiaries who are not residents of its facility, this special rule will not apply and the SNF or NF will be required to furnish items to all beneficiaries who maintain a permanent residence in, or who visit, the CBA where the SNF or NF is located.

Comment: One commenter stated that section 1847 of the Act was never intended to apply to institutional providers and that the phrase ''items and services'' means those that are purchased directly by individuals and not by institutions on behalf of individuals. The commenter further stated that section 1847(b)(4)(A) of the Act requires that CMS ''take into account the ability of bidding entities to furnish items and services in sufficient quantities to meet the anticipated needs * * * in the geographical area covered under the contract on a timely basis.'' The commenter believed that this sentence could be interpreted to mean that institutional providers are outside the scope of the competitive bidding program. The commenter indicated that institutions already purchase items for their patients through arrangements made in a variety of ways and that requiring them to participate in the Medicare DMEPOS Competitive Bidding Program could result in actually raising prices of items purchased by institutions.

Response: We do not agree that sections 1847(a) and (b) of the Act only apply to items and services directly purchased by Medicare beneficiaries and does not apply to institutions that purchase on behalf of beneficiaries. Indeed, these sections identify the items and services subject to competitive bidding and provide that the program applies when these items are furnished under Medicare Part B. Therefore, to the extent that institutional providers are furnishing items as Part B suppliers, we believe that the Medicare DMEPOS Competitive Bidding Program should apply to them. However, as we explained above, we are allowing SNFs and NFs to elect to only furnish competitively bid items to residents in their facilities if they are selected as contract suppliers.

Comment: Several commenters stated that hospital-based suppliers should not have to bid, as hospital-based suppliers are not structured to compete for all beneficiaries in the region. Some commenters stated that hospital-based suppliers should be eligible to participate in the competitive bidding program, if they are willing to accept the single payment amount. Other commenters stated that CMS should exclude hospital-based suppliers from having to serve all beneficiaries in a CBA.

Response: Hospital-based suppliers provide the same ranges of items and services as other commercial suppliers. We believe hospital-based suppliers are different than SNFs and NFs because they do use a commercial model and do provide items to patients who do not reside in a hospital. Therefore, the hospital-based suppliers are competing with other commercial suppliers in the same area and should be considered as part of the same competitive bidding program for this reason.

Comment: One commenter stated that CMS should not combine SNFs and physicians in the same competition with commercial DMEPOS suppliers. The commenter believed that including all of these provider/supplier types in the same bidding will distort the bid evaluation and selection because SNFs

and physicians will have significantly lower operating costs arising from the fact that because they do not have to serve all beneficiaries and they do not have to accept beneficiaries from noncontract suppliers, regardless of rental month.

Response: We are establishing provisions that treat SNFs, NFs, physicians, and certain other nonphysician practitioners differently from other suppliers. As we discussed above, we are allowing SNFs and NFs that are selected as contract suppliers to furnish items only to their own patients. In addition, as we discuss more fully below, we will permit physicians and certain nonphysician practitioners to furnish certain competitively bid items to their own patients without submitting a bid and being selected as a contract supplier. We believe that it is appropriate to allow SNFs (and, as discussed above, NFs) to compete to serve their own patients, but we believe it is appropriate to include them in the same bidding process as other suppliers because the statute requires us to conduct bidding for items in which we expect savings.

Comment: One commenter stated that the requirement that suppliers that are not awarded contracts must use a contract supplier to furnish competitively bid items to Medicare beneficiaries to whom they do provide services conflicts with current Medicare policies. The commenter asked how such a supplier would be able to subcontract to use a contract supplier to furnish supplies without violating current policies.

Response: We do not believe that this requirement conflicts with current policy. Specifically, SNFs are currently allowed to have arrangements under which outside suppliers come to their facilities to provide enteral nutrients, equipment, and supplies. SNFs routinely engage in this practice. Under competitive bidding, SNFs that are not winning contractors must make arrangements to use a contract supplier in the community to furnish competitively bid items to residents of the facility.

Accordingly, we are revising § 414.404(a) to specify that the Medicare DMEPOS Competitive Bidding Program applies to providers that furnish items under Part B. In addition, we are redesignating proposed § 414.422(e)(2)(i) as § 414.422(e)(2) and finalizing that section with the modifications discussed above. Finally, as we discuss below, we are deleting § 414.422(e)(2)(ii) because we have modified our proposal regarding the applicability of the Medicare DMEPOS Competitive Bidding Program to physicians, and, as discussed below, placing the new provisions in § 414.404(b).

3. Physicians and Certain Nonphysician Practitioners (§§ 414.404(a) and (b))

In the May 1, 2006 proposed rule (71 FR 25672), we proposed in proposed § 414.404(c) that the Medicare DMEPOS Competitive Bidding Program would apply to physicians who furnish items under Medicare Part B as suppliers. Accordingly, physicians who are also DMEPOS suppliers would be required to submit bids and be awarded contracts in order to furnish items included in the competitive biding program for the area in which they provide medical services. We proposed that physicians who do not become contract suppliers must use a contract supplier to furnish competitively bid items to Medicare beneficiaries. However, in proposed § 414.422(e)(2)(ii), we proposed that these physicians would not be required to furnish these items to Medicare beneficiaries who are not their patients. In proposing this policy for physicians who are also DMEPOS suppliers, we recognized that the physician self-referral law (section 1877 of the Act, also known as the Stark law) generally prohibits physicians from furnishing to their office patients a variety of common DMEPOS items. Therefore, we proposed that physicians who choose to participate in the competitive bidding process must ensure that their arrangements for referring for and furnishing DMEPOS items under a competitive bidding program comply with the physician self-referral law as well as any other Federal or State law or regulation governing billing or claims submission.

Comment: Several commenters suggested that CMS not require physicians, including podiatric physicians, to participate in the competitive acquisition program for certain DMEPOS. The commenters noted that under the physician self-referral (''Stark'') provisions under section 1877 of the Act, a physician in a group practice may not refer Medicare beneficiaries to the group practice, and the group practice may not bill for any DME except crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors. The commenters also requested that CMS not require physician assistants, physical therapists, or occupational therapists to participate in the Medicare DMEPOS Competitive Bidding Program because those health care professionals are licensed by State boards. According to the commenters, if a physician or non-physician practitioner does not participate in the competitive bidding program, he or she should be reimbursed at the single payment amount for any DME items that are furnished to his or her own patients. In addition, the commenters requested that CMS clarify how the requirement for physicians to submit bids and provide all items within a product category does not violate the physician self-referral law.

Response: After considering the comments, in this final rule, we are deleting proposed § 414.404(c) and revising § 414.404(b) to give physicians (as defined at section 1861(r) of the Act, which includes podiatric physicians) and treating practitioners (defined in § 414.404 as physician assistants, clinical nurse specialists, and nurse practitioners) the option to furnish certain types of competitively bid items without participating in the Medicare DMEPOS Competitive Bidding Program, provided that certain conditions are satisfied. First, the items that may be furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME. Second, the items must be furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service. Third, the items must be billed using a billing number assigned to the physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment. We are adding a new § 414.404(b)(3) providing that the items furnished and billed in this manner will be paid at the single payment amount, which is the rate at which these items would otherwise be paid if this exception did not apply. We believe that physicians engaged in the practice of medicine (and their medical practices) should have the option not to participate in the competitive bidding program because, to comply with the physician self-referral prohibition, they generally provide to their own patients only the DMEPOS items noted above. Because physician assistants, clinical nurse specialists, and certified nurse practitioners furnish services under the supervision of, or in collaboration with, a physician, we believe they (and the group practices that may bill for their services) should similarly have the option to not become a contract supplier.

We are also modifying the regulation by adding § 414.404(b)(2) to give physical therapists in private practice and occupational therapists in private practice the option to furnish certain

types of competitively bid items without participating in the Medicare DMEPOS Competitive Bidding Program, provided that certain conditions are satisfied. First, the items that they may furnish without becoming a contract supplier are limited to OTS orthotics. Second, the items must be furnished only to their own patients as part of their professional service. OTS orthotics furnished in accordance with § 414.404(b) by physical and occupational therapists who are not contract suppliers will be paid at the single payment amount. We are limiting this exception to the bidding requirement to OTS orthotics because we have determined that these are the items that would ordinarily be furnished as an integral part of occupational therapy or physical therapy services.

We note that if a physician, treating practitioner, physical therapist in private practice, or occupational therapist in private practice wishes to furnish in a CBA a competitively bid item not specifically authorized by this rule, and can otherwise legally do so, the physician, treating practitioner, physical therapist in private practice, or occupational therapist in private practice would have to submit a bid and be awarded a contract to do so.

The Medicare DMEPOS Competitive Bidding Program does not affect the applicability of the physician self-referral provisions in section 1877 of the Act. All provisions of the physician self-referral law remain fully in effect. In other words, notwithstanding the requirement that a contract supplier must furnish all items in a product category, a contract supplier cannot furnish an item as a result of a referral prohibited under section 1877 of the Act. We are revising proposed § 414.422(e) to provide that a contract supplier must furnish all items in each product category to which the contract applies, ''except as otherwise prohibited under section 1877 of the Act or any other applicable law or regulation.''

Comment: Several commenters stated that there is no reason to treat occupational therapists and physical therapists differently from physicians. They stated that occupational therapists are not like ''commercial suppliers'' and should only have to furnish competitively bid items to their own patients. Several commenters requested that CMS exempt physical therapists in private practice from competitive bidding or give them special consideration under the competitive bidding program. They stated that physical therapists should be exempt from having to provide every item in a product category and CMS should allow them to participate even if they do not submit exactly the same type of bid required of large suppliers. Several commenters suggested that CMS exclude all occupational and physical therapists and hand therapists that provide pre-fabricated splints to Medicare beneficiaries from the competitive bidding program. They stated that CMS should ensure that occupational and physical therapists can continue to furnish orthotics to their patients. The commenters added that if they cannot dispense OTS orthotics to patients during visits, beneficiaries will need to make other arrangements to obtain the items.

Response: As we stated above, we are revising § 414.404(b) to give occupational therapists in private practice and physical therapists in private practice the option to furnish OTS orthotics to their own patients as part of their professional practice without participating in the Medicare DMEPOS Competitive Bidding Program. We agree with these comments, but only as they relate to furnishing of OTS orthotics by occupational and physical therapists that provide these items in the course of therapy. There is a specific statutory benefit to pay for the services of occupational therapists and physical therapists. However, there is no comparable benefit that only pertains to hand therapists. We are limiting this exception to the bidding requirement to OTS orthotics because we have determined that these are the items that would ordinarily be furnished as part of occupational therapy or physical therapy professional services. In addition, physical and occupational therapists in private practice who elect to operate under this special exception may not furnish these items and services to beneficiaries outside of their normal practice without submitting a bid and being awarded a contract to do so.

After consideration of the public comments, we are revising § 414.404(a) to specify that the Medicare DMEPOS Competitive Bidding Program generally applies to physicians, treating practitioners, physical therapists, and occupational therapists that furnish items under Part B. However, we are revising proposed § 414.404(b) to specify the terms and conditions under which physicians, treating practitioners, physical therapists, and occupational therapists do not have to participate in the program. Finally, to be consistent with our changes to § 414.404(b), we are not finalizing proposed § 414.422(e)(2)(ii).

4. Product Categories for Bidding Purposes (§§ 414.402 and 414.412(b)(1),(c) Through (e))

In the May 1, 2006 proposed rule (71 FR 25672), we proposed in §§ 414.412(b) through (d) to conduct bidding for items that are grouped into product categories. We proposed to require suppliers to submit a separate bid for all items that we specify in a product category. The submitted bid must include all costs related to the furnishing of each item such as delivery, set-up, training, and proper maintenance for rental items. However, we proposed to require suppliers to only submit bids for the product categories that they are seeking to furnish under the program. All items that would be included in a product category for bidding purposes would be detailed in the RFBs. We proposed to define the term ''product category'' (proposed § 414.402) as a group of similar items used in the treatment of a related medical condition (for example, hospital beds and accessories). We explained that we believe the use of product categories will allow Medicare beneficiaries to receive all of their related products (for example, hospital beds and accessories) from one supplier, which will minimize disruption to the beneficiary.

We also discussed in the proposed rule other design options that we considered but did not propose. One option was to require suppliers to submit a bid for all items in every defined product category. Another option was for suppliers to bid at the HCPCS level and submit a bid only for the individual items that they were seeking to furnish under the program.

There are currently approximately 55 separate policy groups already established by the DME MACs. However, these policy groups were not established for the purpose of competitive bidding. We proposed to specifically develop product categories for the purpose of competitive bidding. Each group would be defined and comprised of individual HCPCS codes.

Section 1847(a)(3)(B) of the Act gives us the authority to exempt items for which the application of competitive bidding is unlikely to result in significant savings. We proposed not to include items in a product category if they are rarely used or billed to the program. In addition, we did not propose to include items within a product category if we believed that these were items for which we might not realize savings. Therefore, under this approach, we proposed to establish product categories to identify those

items included in competitive bidding and stated that we might choose to establish different product categories from one CBA to another, as well as in different rounds of competitive bidding in the same CBA.

We proposed to allow suppliers to submit bids only for the product categories they are seeking to furnish under a competitive bidding program because this option accommodates DMEPOS suppliers that want to specialize in one or a few product categories. For example, if a supplier wanted to specialize in the treatment of respiratory conditions, the supplier could choose to bid on all items that fall within the oxygen product category, the continuous positive airway pressure product category, or the respiratory assist device product category. We believe that specialization at the product category level will make it easier for referral agents (entities that refer beneficiaries to health care practitioners or suppliers to obtain DMEPOS items) and other practitioners to order related products from the same supplier.

Establishing a bidding process that promotes specialization would allow suppliers to realize economies of scope within a product category, which means that a supplier may be able to furnish a bundle of items at a lower cost than it can produce each individual item. In our view, this approach would also be more favorable to small suppliers because they could choose to specialize in only one product category. It would be more difficult for a small supplier, as opposed to a large supplier, to furnish all product categories. This approach would also be more convenient for Medicare beneficiaries, as they could choose to receive all their related supplies from one supplier and would not have to deal with multiple suppliers to obtain the proper items for a single condition. We recognized the importance of the relationship between a DMEPOS supplier and the Medicare beneficiary. The supplier delivers the item to the beneficiary, sets up the equipment, and also educates the beneficiary on the proper use of the equipment. The use of product categories would facilitate the transition for those beneficiaries who have to change suppliers. We stated in the proposed rule that it was our goal to establish a productive relationship between the supplier and the beneficiary, and we believe we can accomplish this goal by designing the Medicare DMEPOS Competitive Bidding Program in a manner that would give the beneficiary the option of selecting one supplier that would be responsible for the delivery of all medically necessary items that fall within a product category.

Comment: Some commenters recommended revising proposed § 414.412(c) to read, ''Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category are identified in the RFBs document. The product categories should be consistent with the policy groups of the SADMERC, unless there is good cause to align items differently for a particular competitive bidding program.'' The commenters also recommended revising § 414.412(d) to read, ''Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program unless a bid is determined for a sub-category for bidding purposes.'' Many commenters believed it will cause confusion if new product categories are developed. They reported that the CMS Web site is organized by policy groups and accessed by suppliers frequently for information. The commenters believed that keeping track of old categories and new categories in a single market or State would be next to impossible. Many commenters believed combining medical policies may affect beneficiary access or quality of services. They believed the only providers and suppliers that are eligible to bid are those that carry the broadest product offerings, and sometimes these are not the providers or suppliers with the strongest expertise in a specific product or HCPCS code. One commenter suggested that CMS include subcategories within a product category.

Response: We have revised our proposed definition of ''product category'' to provide that product category is a grouping of related items that are used to treat a similar medical condition. The list of product categories and the items included in each product category that is included in each competitive bidding program will be identified in the request for bids document for that competitive bidding program and by other means. The DME MACs establish policy groups for the purposes of developing Medical review policies and for data analysis, and these policy groups will serve as the starting point for establishing product categories. Product categories will generally be consistent with these policy groups unless CMS determines that a policy group should be redefined for the purposes of competitive bidding because there may be items in the policy group that are either not subject to competitive bidding or that we would want to exempt from competitive bidding using our authority to exempt items. For this reason, the product categories for which we would request bids could also be a subset of items from a DME MAC policy group or a combination of items from different policy groups.

In response to the suggestion that we create subcategories within a product category, we do not believe this approach is necessary because if we believed that we needed to separate items in a policy group, we would create a new product category for each set of items instead of a product category with subcategories.

Comment: A few commenters believed that a product category such as ''oxygen equipment and related supplies'' is likely to contain different oxygen delivery modalities such as stationary oxygen concentrators and liquid oxygen systems. They indicated that, while this may appear logical on the surface, the groupings are, in fact, incompatible with accurate bidding. The commenters added that the costs of acquisition, beneficiary support, and equipment maintenance and servicing are different for modalities.

Response: We appreciate the comments and recognize that there are different costs associated with the different type of equipment that are used to furnish oxygen therapy. The standard payment methodology and monthly payment amount for oxygen and oxygen equipment have been modality neutral since 1989. It is our intention at this time to maintain the policy of modality neutral payments under the competitive bidding programs because this guards against suppliers attempting to furnish only the most expensive modalities that result in higher profits. For example, suppliers that submit bids for stationary oxygen and oxygen equipment will need to factor in the costs of furnishing all of the different modalities or delivering stationary oxygen to beneficiaries in the CBA because physicians may specify a specific oxygen modality when ordering the equipment.

Comment: One commenter stated that the majority of its clients do not purchase items from just one policy group but rather from several groups. The commenter believed that bidding per product category sends clients from one supplier to another as their needs change and is not favorable to beneficiaries.

Response: As stated above, we are revising § 414.402 to define a product category as a grouping of related items that are used to treat a similar medical

condition, for example, hospital beds and accessories. It is our goal to give beneficiaries an opportunity to receive all competitively bid items used to treat an individual medical condition from the same contract supplier, which will make the program convenient for them. This will be accomplished by requiring a supplier that chooses to bid on a particular product category to bid on every item within that category and to furnish every item within a product category for which it is awarded a contract. Suppliers currently specialize in particular products, and we do not see this process being interrupted by competitive bidding. In addition, suppliers will be able to choose which product categories for which they want to submit a bid.

Comment: Several commenters raised concerns regarding the development of product categories. The commenters believed that product categories should be defined narrowly, to make sure they are consistent and representative of the products that a supplier might actually furnish. One commenter suggested, for example, a broad category for wheelchairs or power wheelchairs could be problematic. The commenter added that suppliers that do not specialize in rehabilitation may not carry every brand name of power wheelchairs that fall under a particular code. The commenters stated that CMS should not combine products from multiple medical review policies into one product category because it adds complexity and risks to the beneficiary because it may not allow suppliers to specialize in certain products. The commenters further stated that bidding by specific medical policies ensures that suppliers that specialize can address the needs of individuals with specific disease states/conditions. Several commenters requested that CMS not establish broad product categories. They further stated that many suppliers structure their business around specific disease states and conditions. The commenters noted that CMS should identify the quantities of each item within the product category that CMS expects will be required by Medicare in the respective CBA. Several commenters indicated that the core product categories should have codes that include sufficiently similar items in terms of capability, function, and other relevant characteristics. Some commenters believed that having broad product categories will restrict a specialty practitioner's ability to submit a bid.

Response: As we stated above, we will generally make the product categories consistent with the policy groups that have been defined by our contractors and, in the future, will be established by our contractors. We do not plan to make product categories overly broad, and we do not intend to combine products from various policy groups into a single product category unless the product already falls in several policy groups. However, the use of product categories instead of policy groups will allow us to exclude from a product category low-volume items or items that we believe will not result in significant savings, and to add items that we believe are appropriate for inclusion because we believe that they are related items used to treat a similar medical condition. As we explain below, we will identify in the RFB and by other means such as our Web site or program instruction, the product categories for each competitive bidding programs, the items within each product category, the historic beneficiary demand for each item in the applicable CBA, and the item weight for each item within each product category.

Comment: One commenter noted that the requirement to bid on all HCPCS codes in a product category would be a major problem for manufacturers that also serve as suppliers. The commenter also recommended that CMS adopt special rules for manufacturers wishing to bid, permitting them to only bid on products they manufacture.

Response: The goal of product categories is to minimize the disruption to beneficiaries by allowing them to receive all related competitively bid items for a similar medical condition from one contract supplier. Therefore, we believe it would be in the best interest of beneficiaries if we require a contract supplier that is also a manufacturer to furnish all items within a product category. We also believe it would not be equitable to adopt special rules for manufacturers while requiring all other suppliers that are not physicians or certain nonphysician practitioners to furnish all items in a product category as defined for purposes of competitive bidding.

Comment: Several commenters were concerned that a supplier that wins a bid in the wheelchair category may lose the bid for the associated cushions that are necessary for wheelchairs. They believed this would cause the patient to need to deal with two or more suppliers for a single rehabilitation wheelchair.

Response: As explained above, product categories will be comprised of related items used to treat a similar medical condition. Our goal is to minimize beneficiary disruption. Therefore, product categories will generally be established so that beneficiaries can receive related items from the same contract supplier.

Comment: Some commenters stated that complex rehabilitation products such as wheelchairs should not be competitively bid. They indicated that the accessory codes are the same for the accessories whether they are provided for a standard wheelchair or a complex mobility system. Therefore, they believed that the same HCPCS code may fall into several categories.

Response: We recognize that certain accessories that can be used on manual wheelchairs can also be used with complex mobility systems. Under our revised definition of ''item'' a product might be identified by a HCPCS code that has been specified for competitive bidding (such as when the product is furnished through the mail). One way that we might choose to specify a product identified by a HCPCS code for competitive bidding is when an accessory such as the one identified by the commenters is needed for use with a particular item. When we announce the product categories and the items included in each product category, we will identify any items specified for purposes of competitive bidding, such as accessories used with certain base equipment in a specific product category. In this way, we will be able to ensure that each product category properly includes all the related items that are used to treat a similar medical condition.

Comment: One commenter argued that CMS should limit bids to one bid per supplier. The commenter expressed concerns regarding national chains with multiple supplier numbers and indicated that these chains could potentially submit multiple bids in a CBA and compromise competition. The commenter suggested that CMS require that a single entity that has multiple supplier numbers only be allowed to submit one bid in each CBA. Under the commenter's suggestion, affiliated entities that do not have their own Medicare supplier number, but that are part of a national supplier and operate under the national supplier's 6-digit supplier number, would not be allowed to bid separately in a CBA. The commenter further suggested that CMS include a requirement in the regulations that suppliers with common ownership of 5 percent may only submit a single bid for each product category in a given CBA.

Response: We agree with the commenter that commonly-owned suppliers or a supplier that has a controlling interest in another supplier should not be allowed to submit different bids for the same product

category in the same CBA. Therefore, we are requiring under revised § 414.412(e) that all bidding suppliers must disclose as part of their bid whether they have an ownership or controlling interest in one or more other suppliers or if one or more other suppliers has an ownership or controlling interest in it, CMS will reject multiple bids submitted by commonly-owned or controlled suppliers for the same product category in the same CBA because we believe that allowing these suppliers to bid against themselves will undermine the integrity of the bidding process. For purposes of this disclosure requirement, two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s). We are defining the term ''ownership interest'' as ''the possession of equity in the capital, the stock, or the profits of another supplier.'' This is consistent with how the term ''ownership interest'' is defined in 42 CFR § 420.201 of our regulations, which contains terms relevant to what certain entities, including DMEPOS suppliers, must currently disclose regarding ownership and control information. We believe it is a logical and appropriate approach to adapt definitions that apply to disclosure requirements in other parts of the Medicare program. In addition, the 5 percent requirement is consistent with what constitutes a ''person with an ownership or control interest'' in § 420.201. Finally , a supplier controls another supplier for purposes of these disclosure requirements if one or more of its owners is an officer, director, or partner in the other. This is also consistent with the definition of a ''person with an ownership or control interest'' in § 420.201.

Commonly-owned or controlled suppliers with multiple locations in the same CBA will be required to submit a single bid on behalf of all the locations and must indicate the combined capacity for all those locations. The bid must also include any locations outside the CBA that would be furnishing items in the CBA if a contract is awarded. Therefore, if we award a contract based on the single bid submitted by the commonly-owned or controlled suppliers, all of these suppliers would become contract suppliers. As stated above, we believe that these rules are necessary to prevent commonly-owned or controlled suppliers from bidding against themselves and undermining the integrity of the bidding process. In addition, contracting with all or none of the suppliers that are commonly-owned or controlled as described above will make it easier for beneficiaries to be informed regarding who is or who is not a contract supplier for their CBA.

We are also revising our definition of ''product category'' in § 414.402. We have combined proposed § 414.412(e) and proposed § 414.412(c) into a new § 414.412(c), but deleted the first sentence of proposed § 414.412(c) as redundant because we include the definition of ''product category'' in § 414.402, specified that the bid must include all costs related to furnishing an item to any beneficiary who maintains a permanent residence in, or who visits, the CBA where those items will be furnished and made additional technical changes. We are renumbering proposed § 414.412(b) a final § 414.412(b)(1), and finalizing § 414.412(d) with technical changes. Finally, we are finalizing § 414.412(e), which set forth our ownership rules, as discussed above.

We are redesignating proposed § 414.412(e) as final §§ 414.412(d) and adding a new § 414.412(e) to require that all bidding suppliers must disclose as part of their bid whether they have an ownership interest in one or more other suppliers that would be considered as contract supplier for the same CBA.

5. Bidding for Specific Types of Items and Associated Payment Rules (§§ 414.408(f) Through (j))

In the May 1, 2006 proposed rule (71 FR 25673 and 25674), we proposed that, in preparing a bid in response to the RFBs, suppliers would use our existing regulations at 42 CFR Part 414, Subparts C and Subpart D to determine whether a rental or purchase payment would be made for the item and whether other requirements would apply to the furnishing of that item, as further explained below.

a. Inexpensive or Other Routinely Purchased DME Items (§§ 414.408(f) and (h)(6))

The current fee schedule amounts for inexpensive or other routinely purchased DME items are based on average reasonable charges for the purchase of new items, purchase of used items, and rental of items from July 1, 1986, through June 30, 1987. In those cases where reasonable charge data from 1986/1987 are not available, the fee schedule amounts for the purchase of new items are currently based on retail purchase prices deflated to the 1986/1987 base period by the percentage change in the CPI-U, the fee schedule amounts for the purchase of used items are generally based on 75 percent of the fee schedule amounts for the purchase of new items, and the fee schedule amounts for the monthly rental of items are generally based on 10 percent of the fee schedule amounts for purchase of new items. This method of establishing fee schedule amounts in the absence of reasonable charge data has been in use since 1989. Under the Medicare DMEPOS Competitive Bidding Program, we proposed that bids be submitted only for the furnishing of new items in this category that are included in a competitive bidding program. Based on the bids submitted and accepted for these new items, we proposed to also calculate a single payment amount for used items based on 75 percent of the single payment amount for new items. In addition, we proposed to calculate a single payment amount for the rental of these items based on 10 percent of the single payment amount for new items. We stated our belief that calculating single payment amounts for used items and items rented on a monthly basis based on bids submitted and accepted for new items will simplify the bidding process and will not create problems with access to used items or rented items in this category.

Comment: One commenter stated that inexpensive and routinely purchased DME items included in competitive bidding should be purchased items only. The commenter believed that the additional expense for contract suppliers to bill for rental items is prohibitive. The commenter added that, for inexpensive and routinely purchased items, the cost of billing and collection must be done numerous times at a substantial cost to the supplier.

Response: There are certain items, such as pneumatic compression devices, that are routinely purchased but very expensive and may only be needed on a short-term basis. We believe that the option for renting these items is necessary in order to enable beneficiaries to save money, and we will allow beneficiaries to continue to do so under the competitive bidding programs.

b. DME Items Requiring Frequent and Substantial Servicing (§ 414.408(h)(7))

In the May 1, 2006 proposed rule (71 FR 25673), we proposed that bids be submitted for the monthly rental of items in this payment category with the exception of continuous passive motion exercise devices. We proposed that bids be submitted for the daily rental of continuous passive motion exercise devices. For items in this category other than continuous passive motion exercise devices, we stated that this proposal would be consistent with § 414.222(b) of our existing regulations.

Coverage of continuous passive motion exercise devices is limited to 21 days of use in the home following knee replacement surgery. Therefore, payment can only be made on a daily basis as opposed to a monthly basis for this item.

Based on the bids submitted and accepted for these items, we would calculate single payment amounts for the furnishing of these items on a rental basis.

c. Oxygen and Oxygen Equipment (§ 414.408(i))

If included under a competitive bidding program, we proposed that the single payment amounts for oxygen and oxygen equipment would be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services described in § 414.226(b)(1)(i) through (b)(1)(iv).

Subsequent to the publication of the May 1, 2006 proposed rule, we issued a final rule that implemented new payment classes for oxygen and oxygen equipment furnished for years after 2006 (CMS–1304–F: Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005; Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical equipment (71 FR 65884)). In accordance with these new rules, we will now calculate the single payment amounts for oxygen and oxygen equipment based on the separate bids submitted and accepted for the furnishing on a monthly basis of each of the oxygen and oxygen equipment payment classes described in §§ 414.226(c)(1)(i)–(v).

We refer the reader to section VI.D.1. of this final rule where we discuss a new provision at § 414.408(i)(2) relating to additional payments to contract suppliers that must begin furnishing oxygen equipment after the rental period has already begun to a beneficiary who is no longer renting the item from his or her previous supplier because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers.

d. Capped Rental Items (§ 414.408(h))

With the exception of power wheelchairs, payment for items that fall into this payment category is currently made on a rental basis only. The rental fee schedule payments for months 1 through 3 are based on 10 percent of the purchase price for the item as determined under § 414.229(c) of our existing regulations. The rental fee schedule payments for months 4 through 15 are based on 7.5 percent of the purchase price for the item as determined under § 414.229(c) of our existing regulations. Section 5101(a) of the DRA of 2005 amended section 1834(a) of the Act to require that on the first day that begins after the 13th continuous month during which payment is made for a capped rental item, the supplier of the item must transfer title to the item to the individual. Since this change does not apply to beneficiaries using a capped rental item prior to January 1, 2006, these beneficiaries may still elect either to take ownership of the item after 13 months of continuous use or to continue renting the item beyond 13 months of continuous use. In addition, the DRA leaves intact the rule under which a supplier must offer the beneficiary the option to purchase a power wheelchair at the time the supplier initially furnishes the item (in which case payment would be made for the item on a lump-sum basis). However, with regard to all other capped rental items for which the rental period begins after January 1, 2006, the DRA requires the supplier to transfer title to the item to the beneficiary after 13 months of continuous use.

We proposed that the lump sum purchase option for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program. At the time we issued the May 1, 2006 proposed rule, this purchase option could be found in § 414.229(d) of our regulations. In accordance with a final rule that we subsequently published in the **Federal Register** on November 9, 2006 (71 FR 65884), the purchase option for power wheelchairs furnished beginning on or after January 1, 2006, can be found in § 414.229(h). We also proposed that separate payment for reasonable and necessary maintenance and servicing only be made for beneficiary-owned DME and that payment for maintenance and servicing of rented items would be included in the single payment amount for rental of the item.

We also proposed in the May 1, 2006 proposed rule that ''purchase'' bids be submitted for the furnishing of new items in the capped rental category. Based on these bids, a single payment amount for purchase of a new item will be calculated for each item in this category for the purpose of determining both the single payment amount for the lump sum purchase of a new power wheelchair, and for calculating the single payment amounts for the rental of all items in this category. In cases where the beneficiary elects to purchase a used power wheelchair, the single payment amount for the lump sum purchase of the used power wheelchair would be based on 75 percent of the single payment amount for a new power wheelchair. In the case of all items in this category that are furnished on a rental basis, the single payment amount for rental of the item for months 1 through 3 would be based on 10 percent of the single payment amount for purchase of the item, and the single payment amount for rental of the item for months 4 through 13 would be based on 7.5 percent of the single payment amount for purchase of the item. We stated our belief that calculating single payment amounts for used items and items rented on a monthly basis based on bids submitted and accepted for new items will simplify the bidding process and will not result in problems with access to used items or rented items in this category.

Comment: One commenter believed that the rule does not address situations when a supplier has to rent an item to a beneficiary and the item is defined by the manufacturer as ''single patient use only.'' The commenter also believed that the rule does not address what happens to those products should the patient die. The commenter also questioned how CMS will handle the rental of products that have limited manufacturer warranties.

Response: If a beneficiary dies during the period in which he or she is renting an item, the contract supplier would retain ownership of the item. As is the case today, if the item is designated by the manufacturer for a ''single patient use only,'' meaning that it cannot be used by other beneficiaries, the contract supplier may not furnish it to a new beneficiary. Medicare currently does not pay for costs that are covered by manufacturers' warranties and this policy will not change under competitive bidding.

Comment: One commenter suggested that CMS limit to discrete situations a requirement that contract suppliers of power wheelchairs offer rental items. The commenter was concerned that this rule would require suppliers to float a large volume of loans to subsidize rentals. The commenter further believed that most beneficiaries requiring power mobility have chronic progressive conditions that require them to keep the equipment for a long period of time.

Response: We disagree with the commenter. Power wheelchairs are very expensive and may only be needed on a short-term basis. The option for renting these items is necessary to enable beneficiaries to save money, and

for this reason, we will allow them to be rented under the competitive bidding programs.

We refer readers to section VI.D.1. of this final rule where we discuss additional payments to contract suppliers for capped rental DME when a contract supplier must begin furnishing a capped rental item during the rental period to a beneficiary who is no longer renting the item from his or her previous supplier because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers.

e. Enteral Nutrients, Equipment, and Supplies (§§ 414.408(f), (g)(2)–(3), and (h)(4))

Enteral nutrients, equipment, and supplies are currently paid under Medicare Part B on a purchase or rental basis. Section 6112(b)(2)(A) of the OBRA '89 limits the rental payments to 15 months. To be generally consistent with the bidding requirements discussed above for capped rental DME, in the May 1, 2006 proposed rule (71 FR 25674), we proposed that bids be submitted for the purchase of new items in this category. Based on the bids submitted and accepted for new items, we would calculate a single payment amount for rented items for months 1 through 3 based on 10 percent of the single payment amount for new items. The single payment amount for rented items for months 4 through 15 would be based on 7.5 percent of the single payment amount for new items. In cases where the beneficiary elects to purchase enteral nutrients, equipment, and supplies the single payment amount for new enteral nutrients, equipment, and supplies would be based on the bids submitted and accepted for new enteral nutrients, equipment, and supplies, and the single payment amount for used enteral equipment would be based on 75 percent of the single payment amount for the purchase of new enteral equipment.

Based on the bids submitted and accepted for new items, we would calculate a single payment amount for purchase of enteral nutrients, equipment, and supplies.

Comment: One commenter noted that intravenous medication and enteral nutrients, equipment, and supplies should not be included in competitive bidding. The commenter did not believe it is appropriate to revise the payment methodology in this rule. The commenter suggested that CMS should not revise the enteral nutrients, equipment, and supplies fee schedule without formal comments from the industry.

The commenter stated that because parenteral nutrients, equipment, and supplies were never intended to be included in competitive bidding, it is unclear why CMS proposed to revise this payment methodology at this time when some beneficiaries are attempting to coordinate their intravenous therapy needs between Medicare Part B and Part D.

Several commenters stated that, under the proposed rule, payment for enteral pumps would be determined as if enteral pumps were a capped rental item. They stated that enteral pumps fall under the prosthetic device benefit and are paid under a specific fee schedule. These commenters added that there is no basis for the change in payment methodology for enteral nutrients, equipment, and supplies. Another commenter noted that CMS should modify the proposed payment structure for enteral pumps consistent with current fee schedule policy.

Response: In accordance with section 1847(a)(2)(B) of the Act, parenteral nutrients, equipment, and supplies cannot be part of the Medicare DMEPOS Competitive Bidding Program. However, the same section directs that enteral nutrients, equipment, and supplies be included in the program. In accordance with section 1847(a)(6) of the Act, the payment basis determined under the Medicare DMEPOS Competitive Bidding Program for enteral nutrients, equipment, and supplies replaces the payment basis that would otherwise apply under section 1842(s)(1) of the Act and 42 CFR Part 414, Subpart C of our regulations. Therefore, the payment methodology we establish for enteral nutrients, equipment, and supplies furnished under this program will replace the fee schedule methodology for those items. We proposed to retain many of the same rules that currently govern the rental or purchase of enteral nutrients, equipment, and supplies to make the transition to competitive bidding easier for both suppliers and beneficiaries. However, under § 414.408(f), we are establishing a process for a supplier to bid on the purchase price for a new enteral pump. However, payments will be made on a rental basis if the beneficiary chooses to obtain the item on a rental basis or a purchase basis if the beneficiary chooses to obtain the item on a purchase basis. We also note that this rule does not supersede any laws for rules that govern whether a particular drug is covered under Medicare Part B or Part D.

f. Maintenance and Servicing of Enteral Nutrition Equipment (§ 414.408(h)(5))

Section 6112(b)(2)(B) of OBRA '89 requires that we pay for maintenance and servicing of enteral nutrition equipment after monthly rental payments have been made for 15 months. The maintenance and servicing payments are to be made in amounts that we determine are reasonable and necessary to ensure the proper operation of the equipment. Since October 1, 1990, program instructions have specified when and how these payments are made. These program instructions are currently found at section 40.3 of Chapter 20 of the Medicare Claims Processing Manual (Pub. 100–04). These instructions provide that maintenance and servicing payments may be made beginning 6 months after the last rental payment for the equipment and no more often than once every 6 months for actual incidents of maintenance where the equipment requires repairs and/or extensive maintenance. Extensive maintenance involves the breaking down of sealed components or performance of tests that requires specialized testing equipment not available to the beneficiary or nursing facility. The program instructions also state that the maintenance and servicing payments cannot exceed one-half of the rental payment amounts for the equipment.

Under the Medicare DMEPOS Competitive Bidding Program, we proposed at § 414.408(i)(3) (redesignated as § 414.408(h)(4) in this final rule) that the monthly rental payments for enteral nutrition equipment for months 1 through 3 be equal to 10 percent of the single payment amounts for the purchase of the new enteral nutrition equipment. We proposed that for months 4 through 15, the monthly rental payment amounts would be equal to 7.5 percent of the single payment amounts for the purchase of new items. We proposed that the contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain, and service the pump for as long as the equipment is medically necessary. In addition, we proposed to establish the maintenance and service payments under proposed § 414.408(i)(4) (redesignated as § 414.408(h)(5) in this final rule) for enteral nutrition equipment so that they are equal to 5 percent of the single payment amounts for the purchase of new enteral nutrition equipment. This would limit the payment rate for maintenance and service to one-half of the rental payment amount for the first

month of rental, which is similar to the program instructions mentioned above. The provisions of the proposed rule are similar to current Medicare payment rules in section 40.3 of Chapter 20 of the Claims Processing Manual.

g. Supplies Used in Conjunction With DME (§ 414.408(g)(1))

We proposed under proposed § 414.408(h)(1) that bids be submitted for the purchase of supplies necessary for the effective use of DME, including drugs (other than inhalation drugs). Based on the bids submitted and accepted for these items, we would calculate single payment amounts for the furnishing of these items on a purchase basis.

h. Off-the-Shelf (OTS) Orthotics (§ 414.408(g)(4))

We proposed under proposed § 414.408(h)(4) that bids be submitted for the purchase of OTS orthotics. Based on the bids submitted and accepted for these items, we would calculate single payment amounts for the furnishing of these items on a purchase basis.

Comment: One commenter agreed with the proposed distinction for prosthetics and orthotics.

Response: We agree with the commenter because the statute distinguishes between prosthetics and orthotics.

In summary, after consideration of all of the public comments received on the bidding requirements and associate payment rules described above, we are renumbering proposed §§ 414.408((g) through (j) as §§ 414.408(f) through (i), respectively, and finalizing these sections (with the exception of § 414.408(h)(2) and (i)(2)), which have been added and finalized as described above, and with additional changes.

VII. Conditions for Awarding Contracts for Competitive Bids

In proposed § 414.414, we set forth a series of proposals regarding how we would evaluate and select suppliers for contract award purposes under the Medicare DMEPOS Competitive Bidding Program. Proposed § 414.414(a) provides generally that the rules in § 414.414 govern the evaluation and selection of suppliers under the program. The specifics of our other proposals are discussed below:

A. Quality Standards and Accreditation

Section 1847(b)(2)(A)(i) of the Act specifies that a contract may not be awarded to any entity unless the entity meets applicable quality standards specified by the Secretary under section 1834(a)(20) of the Act. Section 1834(a)(20) of the Act instructs the Secretary to establish and implement quality standards for all DMEPOS suppliers in the Medicare program, not just for suppliers subject to competitive bidding or in CBAs. All suppliers must meet these quality standards to be eligible to submit claims to the Medicare program, irrespective of the Medicare DMEPOS Competitive Bidding Program. The quality standards are to be applied by recognized independent accreditation organizations that have been designated by the Secretary under section 1834(a)(20)(B) of the Act. Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the quality standards by program instruction or otherwise after consultation with representatives of relevant parties. We proposed that a grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, we will suspend or terminate the supplier contract. The length of time for the grace period will be determined by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area. The length of time of the grace period will be specified in the RFB for each competitive bidding program.

In the May 1, 2006 proposed rule, we indicated that we had consulted with the PAOC and determined that it is in the best interest of the industry and beneficiaries to select the accreditation organizations and publish the quality standards through program instructions in order to ensure that suppliers that wish to participate in competitive bidding will know what standards they must meet in order to be awarded a contract. We proposed in § 414.414(c)(1) that all bidding suppliers must satisfy the quality standards in order to be eligible to participate in the Medicare DMEPOS Competitive Bidding Program. In proposed § 414.414(c)(2), we proposed that all bidding suppliers must be accredited by a CMS-approved accreditation organization, as defined under 42 CFR 424.57(a), but stated that a supplier would be considered to be grandfathered if it had received a valid accreditation before the CMS-approved accreditation organizations were designated and the accreditation was granted by an organization that CMS designates as a CMS-approved accreditation organization under 42 CFR 424.58.

To expedite the accreditation process for contract suppliers under the Medicare DMEPOS Competitive Bidding Program, we finalized the requirements for accreditation organizations as a new § 424.58 as part of the DMEPOS provisions in the FY 2007 IRF final rule (71 FR 48354). We published the list of the selected accreditation organizations and the final quality standards through program instructions and posted the response to comments document on the quality standards. The names of the accreditation organizations and the final quality standards and our responses to public comments on the quality standards and on the portion of the proposed rule pertaining to the quality standards are posted on the CMS Web site at: *http://www.cms.hhs.gov/competitiveAcqforDMEPOS*.

B. Eligibility (§ 414.414(a) Through (c))

In the May 1, 2006 proposed rule (71 FR 25675), we proposed in § 414.414(b)(1) that all bidders must meet enrollment standards to be considered for selection as a contract supplier under the Medicare DMEPOS Competitive Bidding Program. These standards are included in the supplier standards regulation at § 424.57. In addition, we proposed § 414.414(b)(2), that each bidder must certify in its bid that its high level employees, chief corporate officers, members of board of directors, affiliated companies and subcontractors are not now and have not been sanctioned by any governmental agency or accreditation or licensing organization. In the alternative, the bidding supplier must disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

In the preamble to the May 1, 2006 proposed rule (71 FR 25675) we stated that sanctions would include, but are not limited to, debarment from any Federal program, OIG sanctions, or sanctions issued at the State or local level. In addition, we proposed that the bidder must have all State and local licenses required to furnish the items that are being bid (proposed § 414.414(b)(3)). Finally, we proposed that the supplier must agree to all of the terms in the contract outlined in the RFBs (proposed § 414.414(b)(4)). We stated in the preamble to the May 1, 2006 proposed rule (71 FR 25675) that we would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency.

Comment: Several commenters suggested that CMS require all contract suppliers to be physically located in the CBA for which they were awarded a

contract. Other commenters believed that relying on physical location would prevent participation of many suppliers, including several suppliers with capacity to operate on a national scale. The commenters believed that relying on physical location could cause product supply issues. Other commenters requested that CMS clarify whether a supplier can submit a bid if the supplier is not physically located in the CBA, but can show that it has a presence within the CBA. They asked whether CMS would quantify this for evaluation purposes.

Response: We continue to believe that it is appropriate to allow suppliers that do not maintain a physical location in a CBA to submit a bid to furnish items in that CBA. One of the purposes of the program is to create a competitive bidding payment structure that is more reflective of a competitive market. By accepting bids from all suppliers that can meet the requirements of the program, regardless of their physical location, we believe that we will encourage a more robust competition that will result in the best possible prices for beneficiaries without compromising their access to DMEPOS. It is our intent to review each bidder to determine whether it can meet the requirements of the competitive bidding program for which they submit a bid. One of these requirements will be that the supplier must be able to demonstrate that it maintains a presence in the CBA. In other words, the supplier must be able to furnish items to all beneficiaries who maintain a permanent residence in the CBA, regardless of where that beneficiary is located, including delivering items and providing necessary training and ensuring that items are appropriately set-up in the beneficiary's home. Thus, a supplier's ability to furnish items to all beneficiaries in the CBA, and not its physical location, will be evaluated to determine whether the supplier meets this requirement. We would reject a bid if we determined that the bidding supplier did not meet this bidding requirement, or any other bidding requirement.

Comment: Several commenters stated that CMS should apply an appropriate screening process to determine which bidder qualifies for consideration. They recommended that the bidding process include a 3-step elimination process in this order: Accreditation; financial standards; capacity assessment. The commenter suggested that only after this 3-step screening is applied should CMS accept a bid.

One commenter asserted that a supplier's financial stability and accreditation must take place before bid prices are arrayed and the pivotal bid selected. Otherwise, the commenter believed the bidding pool will be tainted by bids from suppliers that are not qualified. The commenter suggested that bids from suppliers that have not satisfied the quality standards, are not accredited, and/or that do not meet CMS' financial and eligibility standards should not be considered in selecting winning bids and setting payment amounts. The commenter also suggested that the rule should clarify that the establishment of a composite bid should only be completed for suppliers that meet the bidding requirements.

Response: We will not award a contract to any supplier that does not meet our bidding requirements. Those requirements include complying with our eligibility standards, including compliance with the enrollment standards in § 424.57(c) of our regulations and disclosure of certain compliance-related issues, financial standards, quality standards, and accreditation standards unless a grace period for obtaining accreditation applies. We may allow a grace period for suppliers that have not yet been accredited at the time they submit their bid. To qualify for this grace period, a supplier must have submitted its application for accreditation to a CMS-approved accreditation organization and be waiting for the accreditation process to be completed by that organization. We expect that suppliers will have obtained their accreditation before they are awarded a contract under the Medicare DMEPOS Competitive Bidding Program. We will evaluate a supplier's compliance with our bidding requirements before we finalize the pivotal bids as well as the single payment amounts. We will reject a bid that does not demonstrate that the supplier has met our bidding requirements. As a result, only bids from eligible, qualified, and financially sound suppliers will be used to determine the single payment amounts and select contract suppliers.

We note that although we will be considering each supplier's projected capacity as part of our determination of where to set the pivotal bid.

Comment: One commenter stated that the proposed rule indicated that suppliers would have to disclose information on debarments, sanctions, or other legal actions affecting them. However, Form A, the application section of the RFB, requires suppliers to disclose information about pending or prior investigations. The commenter noted that investigations are merely fact-finding tools that do not presume guilt and should not be used to negatively impact a supplier's bid evaluation. Another commenter stated that the term ''sanctioned'' is subject to being interpreted differently by each supplier. The commenter suggested that CMS detail what specific types of ''sanctions'' should be included in the disclosure. In addition, the commenter suggested that CMS more clearly define what it meant when it stated that bidding suppliers would have to ''certify'' in their bids that they, their high-level employees, chief corporate officers, members of the board of directors, affiliated companies, and subcontractors are not, and have not been, sanctioned by any governmental agency or accreditation or licensing organization. The commenter also wanted to know if CMS intends for the certification to take the form of a simple attestation or whether CMS would require suppliers to sign a prescribed legal statement testifying to the veracity of the disclosures or lack of disclosures.

Response: We agree with this comment that investigations are not in themselves evidence of guilt. We did not propose in the May 1, 2006 proposed rule to require a bidding supplier to disclose information in its bid about pending and prior investigations, and this final rule likewise does not require such disclosures. The RFB will conform to this final rule. We are revising proposed § 414.414(b)(2)(ii) so that it clarifies what disclosures a supplier must make in its response to the RFB. Specifically, we will require that each bidding supplier must disclose information regarding—(1) Any revocations of a supplier number; and (2) sanctions, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions, or debarments imposed against the supplier, its high-level employees, chief corporate officers, members of the board of directors, affiliated companies, and subcontractors by any Federal, State, or local agency. We are finalizing proposed § 414.414(b)(2)(i) to require a supplier to certify in its bid that this information is complete and accurate. We might reject a bid based on these disclosures. As discussed more fully below, we might conclude that a contract supplier has breached its contract if we discover that the contract supplier did not fully comply with these disclosure requirements, or if it is sanctioned or debarred, has legal action taken against it, or falls out of compliance with the Medicare program requirements (compliance with which we characterized in the proposed rule as

the supplier being in ''good standing'' with CMS), including enrollment requirements set forth at §§ 424.500 et seq., during the contract term.

We have added a cross-reference to final § 414.414(b) to indicate that networks (discussed more fully in section XII. of this final rule) must also meet the network requirements found in final § 414.418.

After consideration of public comments, we are finalizing § 414.414(a) without modification. We are finalizing §§ 414.414(b)(1)–(3) with the changes discussed above and with additional technical changes.

C. Financial Standards (§ 414.414(d))

Section 1847(b)(2)(A)(ii) of the Act specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers. Applying financial standards to suppliers assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, we believe that financial standards for suppliers will help maintain beneficiary access to quality services.

Therefore, as part of the bid selection process, we proposed that the RFBs would identify the specific information we will require to evaluate suppliers (proposed § 414.414(d)). We noted that this information may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to fulfill the contract successfully, net worth, and solvency. We welcomed comments on the financial standards, in particular the most appropriate documents that would support these standards. We found that, in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency were important considerations for evaluating financial stability.

Comment: Several comments argued that the financial standards were too strict for certain suppliers and should be flexible enough to regulate mail order suppliers, small local suppliers, SNFs, departments of hospitals, retail pharmacies, and publicly-traded and privately-held family firms. The commenters stated that if financial standards are too restrictive, qualified suppliers might not be able to participate in the Medicare DMEPOS Competitive Bidding Program. They added that, conversely, if financial standards are too lax, suppliers may be financially unable to meet the challenges of a competitive market.

Response: We have revised proposed § 414.414(d) to indicate that the RFB form will specify the documents required as part of the bid application and that each supplier must submit this documentation along with its bid. We agree with the commenters that it is important to have financial standards that ensure suppliers are able to meet the challenges of competitive bidding and can fulfill their contract obligations. However, we also agree that our financial standards should not be so burdensome that suppliers, and especially small suppliers, cannot satisfy them. After further consideration and in response to comments, we believe that the proposed financial documentation discussed in the preamble to the proposed rule (71 FR 25675) would be too burdensome, particularly for small suppliers. Therefore, in order to obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded) certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian; Equifax; or TransUnion. All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting. This financial information will allow us to determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier's financial viability.

We will generally require that suppliers submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a suppler is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter suggested that CMS also publish the criteria it will use to assess supplier's financial stability and how it will rank suppliers based on these criteria. The commenter stated that bank statements should only be requested when we need to resolve doubts about the supplier's other submissions. The commenter believed that if we maintain the requirement for bank statements, the statements need to be defined for the period for which we are requesting the financial information.

Response: As we explained above, we recognize that our collection of financial information must be comprehensive enough to allow us to assess a supplier's financial soundness, but not so burdensome as to encumber the bidding process (especially for small suppliers) and the bid evaluation process. Therefore, as stated above, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of their 10K filing report from the 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded), certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian; Equifax; or TransUnion.

We will generally require that suppliers submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a suppler is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters stated that CMS should consider the supplier's debt-to-equity ratio (long-term debt divided by shareholders' equity). They indicated that this is a measurement of a supplier's capacity to borrow and expand. One commenter indicated, however, that this measurement will be problematic when applied to private firms. The commenters suggested that an alternative would be to require the EBITDA (earnings before interest, taxes, depreciation and amortization)-to-debt ratio because this is more difficult to manipulate. The commenter suggested that CMS could also use the quick ratio (current assets minus inventory divided by current liabilities) because this measurement is favored by lending institutions. Some commenters

indicated that CMS should also define the accounts receivable as the quick ratio (less than 180 days sales outstanding). They indicated that this ratio shows how long it takes the supplier to collect money owed and measures a supplier's liquidity and ability to meet short-term operating needs. Some commenters also suggested that CMS inquire as to how long a supplier has been in business.

Commenters also suggested that the information that CMS collects should include 2 years of financial statements prepared in accordance with generally accepted accounting principles. Some commenters recommended the financial statements be accompanied by a compilation, review, or audit report from an independent certified public accountant, a certificate of insurance verifying a minimum of $1 million of liability coverage, and a letter from a primary institutional lender verifying current lending relationship and the potential borrowing capacity of the supplier. Commenters also recommended that CMS receive a credit report from a recognized credit rating organization. One commenter wanted CMS to define a set ratio, for example, asset ratio should be not be higher than (X percent) and the asset to liability ratio should be no lower than (X percent).

Response: We will use appropriate financial ratios to evaluate suppliers. If suppliers do not meet certain ratios, they could be disqualified from the competition. Examples of ratios we might consider include a supplier's debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company. The supplier standards in § 424.57(c)(10) require that the supplier carry a $300,000 comprehensive liability policy. We believe that imposing an additional cost for maintaining $1 million in liability coverage is not necessary. We will be reviewing all financial information in the aggregate and will not be basing our decision on one ratio but rather overall financial soundness.

As we noted above, we will require for CY 2007 competition that suppliers submit a credit report from one of three credit bureaus identified above to assist in determining a supplier's financial soundness. For all competition rounds, we will specify in the RFB what financial information must be submitted.

Comment: Several commenters recommended that CMS consider using Dunn and Bradstreet accounts payable ratings (paydex score) which measures how quickly a company pays its accounts payable. The commenters indicated that this information provides an additional measure of whether the supplier is, in fact, able to meet its current obligations.

Response: We will require suppliers to provide us with information which is included on a supplier's credit report when they submit their bids to assist us in determining their financial soundness.

Comment: One commenter argued that CMS must recognize that publicly traded companies are different from privately held community pharmacies, as they have fiduciary obligations to shareholders. Other commenters argued that the financial standards proposed are too burdensome and discourage small suppliers from participating. They recommended that CMS define different standards for small suppliers and pharmacies. The commenters suggested that the standards be limited to credit report, lien searches, credit references and 3 years' worth of tax returns.

Response: We are committed to ensuring the financial soundness of contract suppliers in the competitive bidding program. In previous responses, we have described the financial documentation that will generally be required for the competitions. We have determined that we can obtain the necessary information through collection of a limited number of financial documents and believe that the submission of this information will be less burdensome for all suppliers, including small suppliers. We believe we have balanced the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier.

After consideration of the public comments received, we are revising discussed proposed § 414.414(d) so that it now specifies that a supplier must submit the financial information specified in the RFB. For purposes of the CY 2007 competition, the financial documents discussed in this section will be those that the RFB will require. These requirements are as follows:

- Suppliers that file individual tax returns that include business taxes are required to submit the Schedule C (the Profit and Loss Statement) from their 1040 Tax Return for the 3 years immediately prior to the date on which the bid is submitted. In addition to the tax return information, these suppliers are also required to submit a Compiled Balance Sheet (Statement of Financial Position), a Statement of Cash Flow (Statement of changes in Financial Position) and a Statement of Operations (Income Statement) for the three years immediately prior to the date on which the bid is submitted. Suppliers are also required to submit a copy of their current credit report, which must have been completed within 90 days prior to the date on which the bid is submitted. The credit report must be prepared by one of the following: Experian; Equifax; or TransUnion.
- Limited partnerships and partnerships must submit their Schedule L from their 1065, U.S. Return of Partnership Income for the 3 years immediately prior to the date on which the bid is submitted, along with all other financial documentation that must be submitted by a supplier that files an individual tax return.
- Suppliers that file corporate tax returns are required to submit the Schedule L (Balance Sheet) from their tax return for the 3 years immediately prior to the date on which the bid is submitted. In addition to the tax return information, these suppliers are also required to submit a Statement of Cash Flow (Statement of Changes in Financial Position), and a Statement of Operations (Income Statement) for the 3 years immediately prior to the date on which the bid is submitted. Suppliers are also required to submit a copy of their current credit report, which must have been completed within 90 days prior to the date on which the supplier submits its bid. The credit report must be prepared by one of the following: Experian; Equifax; or TransUnion.
- All documents that are not prepared as part of a tax return must be certified as accurate by the supplier and must be prepared on an accrual or cash basis of accounting.
- Suppliers that are publicly traded companies must additionally submit a copy of their 10–K Filing Reports filed with the Securities Exchange Commission for the 3 years immediately prior to the date on which the bid is submitted. If a supplier is a wholly owned subsidiary of a publicly traded company, it must submit the parent company's 10-K reports.
- If a supplier does not have financial documentation for one or more of the 3 years immediately prior to the date on which the bid is submitted, then in addition to submitting the financial documentation for the years in which it is available, the supplier must also submit projected financial statements. The projected financial statements must show what is likely to occur in the future based on key financial and business assumptions of the present, and must include a description of the financial and business assumptions.

• For networks, the legal entity that submits the bid must submit financial statements on behalf of each network member in one complete package.

• If a supplier is submitting an individual bid and is also part of a network, the supplier must submit financial statements along with both the individual bid and the network bid.

D. Evaluation of Bids (§ 414.414(e))

In the May 1, 2006 proposed rule (71 FR 25675), we proposed to select the product categories that include individual items for which we will require competitive bidding. We stated that individual products would be identified by the HCPCS codes and would be further described in the RFBs. We proposed that suppliers would be required to submit bids for each individual item within each product category they are seeking to furnish under the program, but would not be required to bid for every product category.

1. Market Demand and Supplier Capacity (§§ 414.414(e)(1) and (e)(2))

Section 1847(b)(4)(A) of the Act requires that in awarding competitive bidding contracts, the Secretary may limit the number of contract suppliers in a CBA to the number necessary to furnish items to meet the projected demand for items covered under the contract for the CBA. Therefore, we proposed in proposed § 414.414(e)(1) to calculate expected beneficiary demand in a CBA for items in a product category. We stated that in order to fulfill this statutory mandate, the first step would be to determine the expected demand for an item in a CBA. We proposed to calculate expected demand in each CBA in a relatively straightforward way using existing Medicare claims. We proposed to examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years, and then to determine the number of new beneficiaries who have entered the market during the last 2 years. We believed that 2 years' worth of data would be sufficient to allow us to identify trend analyses and utilization measurements. We also indicated that we would gather data on the number of new FFS Medicare enrollees coming into a CBA and use this number to project the number of new enrollees.

We discussed in the preamble to the May 1, 2006 proposed rule (71 FR 25675) how we proposed to calculate 2 years of claims on a monthly basis to determine beneficiary demand. We stated that we would take into consideration the expected demand over the total duration of the contract and the seasonal effects (for example, an increase in beneficiary population in Florida during the winter), and proposed to use 2 years of data to identify any time trends. If there were no seasonal effects or time trends, we proposed to use the average monthly total and new patient figures as the market demand measures. However, if there were seasonal effects or changes identified only during certain months, we proposed that the maximum monthly total and new patient figures would be used as the market demand measures. If trends showed that there was noticeable growth or reduction in beneficiary demand for products in an area, we proposed to take these factors into consideration when developing estimates of beneficiary demand for competitively bid items.

We proposed to adopt the following approach to estimate supplier capacity to meet the projected demand in a CBA. First, we proposed to analyze Medicare claims to determine how many items a supplier was currently providing in the CBA, as well as in total. Second, as part of the bid, we would ask suppliers to indicate how many units they were willing and capable of supplying at the bid price in the CBA. We would compare this information to what the supplier has dispensed to Medicare beneficiaries in the past and what it specified in its response to the RFB as its projected capacity. We proposed to require evidence of financial resources to support market expansion, such as letters from investors or lending agents. We would use this information to evaluate the capacity of the bidder. Third, we proposed to compare expected capacity and Medicare volume to determine how many suppliers we would need in an area. For new suppliers, we would ask them for their expected capacity, look at trend data for new suppliers in that area, and examine the capacity of other suppliers in that area. We would need to use these data to make estimates about capacity because we believe that suppliers might have more capacity potential than they are currently exhibiting.

During the DMEPOS competitive bidding demonstrations, demonstration suppliers were able to expand their output to meet market demand and replace market share previously provided by nondemonstration suppliers; indeed, some demonstration suppliers were disappointed that they did not gain more market share during the demonstration. We presented numerous issues to the PAOC where we requested advice on issues such as market capacity and demands. During the February 28, 2005 PAOC meeting, we asked the panel to discuss the issue of demand and capacity. Several members of the committee, based upon their expertise and knowledge of the industry, suggested that most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor.

We welcomed comments on our proposed approach for calculating market demand and estimating supplier capacity. We were especially interested in any information that would help us compare current Medicare volume with potential capacity, including potential formulas we could apply to determine capacity.

Comment: Several commenters argued that there was insufficient information given as to how CMS will determine a supplier's capacity. The commenters wanted to know if the projected capacity that suppliers must identify in their responses to the RFB form was a bid commitment or estimation. The commenters also noted that CMS did not describe what criteria it will use to compare bidders (aside from bid price) and how these criteria will be applied. They further suggested that CMS look at a supplier's history and allow a 20-percent growth rate to determine the supplier's capacity.

Response: We proposed that suppliers would have to estimate in their response to the RFB how many items they would be able to furnish in the CBA for the bid price. We also proposed that suppliers would be required to submit documentation evidencing any planned business expansion, such as letters from investors or lending agents. We will look at this documentation, as well as the supplier's other financial documentation to determine the ability of that supplier to furnish its projected capacity. The capacity identified in the supplier's response to the RFB form should represent the supplier's best estimation of the number of items it can provide to Medicare beneficiaries in a given CBA. We might, however, make two types of adjustments to a supplier's projected capacity for purposes of finalizing the pivotal bid. First, if a supplier estimates that it can furnish more than 20 percent of what we determine to be the expected beneficiary demand for the product category in the CBA, we will lower that supplier's capacity estimate to 20 percent. We believe that this capacity adjustment is necessary to ensure that at least 5 suppliers have composite bids at or

below the pivotal bid for the product category, which will then enable us to award contracts to at least those 5 suppliers. By awarding contracts to at least 5 suppliers per product category, we expect that there will be sufficient contract suppliers in the CBA to provide beneficiaries with more variety and choice. However, we are confident that, due to the nature of supplies that can be furnished via mail order (for example, diabetic supplies) national or regional mail order suppliers will easily be able to expand to meet very large demands. Therefore, we do not believe it is necessary to ensure that there are at least five national or regional mail order suppliers. If we were to require at least five such suppliers, we believe it would dilute our savings.

Second, we might further adjust a supplier's capacity if, after making the initial adjustment discussed above, we conclude that the supplier's financial and business expansion documentation do not support the projected capacity stated in its bid. In determining whether this further adjustment is necessary, we will give consideration to the suggestion of the PAOC that a supplier's capacity could easily be increased by up to 20 percent. We believe, however, that this further adjustment may be necessary to limit the potential that we would award contracts to an inadequate number of suppliers based on inflated capacity projections that the suppliers would not be able to actually meet. If we believe that this further adjustment is necessary, we will lower the supplier's projected capacity to its historical capacity, as evidenced by its financial documentation and past claims data.

We note that after making these adjustments, if we are still unable to award five contracts in a CBA because there are not enough qualified suppliers, we will award at least 2 contracts to qualified suppliers for the furnishing of that product category under a competitive bidding program.

We also note that the adjustments we might make to a supplier's projected capacity would not impact the supplier's ability to actually furnish items if it is awarded a contract. In other words, a contract supplier will be able to furnish items to all beneficiaries who wish to receive them from it.

Comment: Some commenters stated that CMS must consider how changes in coding, utilization, and documentation may affect the utilization data for the last 2 years. They cited, for example, that changes in wheelchair cushions and respiratory coding may affect the utilization data.

Response: We proposed that we would calculate the expected beneficiary demand for a product category in a CBA by using two years of existing Medicare claims data, which we believe is sufficient to allow us to identify changing trends in utilization. In calculating the expected beneficiary demand for a product category in a CBA, we might also evaluate data showing beneficiary demand for key high volume items in the product category.

After consideration of the comments received, we are adopting as final § 414.414(e)(1), which provides that we will calculate the expected beneficiary demand for items within a product category in each CBA as part of the bid evaluation process. In addition, we are adding a new § 414.414(e)(2) to finalize our proposal to evaluate the total supplier capacity that would be sufficient to meet beneficiary demand for items in the CBA for the items in a product category.

2. Composite Bids (§§ 414.402, 414.414(e)(3) and (4))

Because suppliers will be bidding for multiple items in a product category, the lowest bid for each item will not always be submitted by the same supplier. In this case, looking at the bids for individual items would not tell us which suppliers should be selected since different suppliers may submit the lowest bids for different items. Therefore, in proposed §§ 414.414(e)(2) and (e)(3) (redesignated as § 414.414(e)(3) and (e)(4) in this final rule), we proposed to use a composite bid to compare all of the suppliers' bids submitted for an entire product category in a CBA. We stated that using a composite bid would be a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This would allow us to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category. To compute the composite bid for a product category, we would multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. The weight of an item would be based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. Item weights would be used to reflect the relative market importance of each item in the product category. We would select item weights that ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier. The sum of each supplier's weighted bids for every item in a product category would become the supplier's composite bid for that product category.

We sought comment on the best method of weighting individual items within a product category to determine the composite bid. We indicated that one approach we were considering would be to set the weight for each item based on the volume of the individual item's share compared to the total utilization of the product category. Under this weighting system, the composite bid would be exactly proportional to the expected cost of furnishing the entire bundle of items. Therefore, if supplier 1 had a lower composite bid than supplier 2, it would also have a lower expected cost of furnishing the entire product bundle that makes up the product category. Another approach we considered was to set the weight based on the payment amounts attributable to each DMEPOS fee schedule item relative to the overall payment amount for the total product category. We stated that this approach might better reflect the relative value of each item because it is based on how much we actually pay for an item, and that this was the approach that we used in the first round of bidding in Polk County under the competitive bidding demonstration program. However, we stated that we also found that this approach could result in too much weight being placed on low-volume and high-priced items. The first year evaluation report also found that using the allowed charges as the weights could result in a supplier that offered lower bids having a higher composite bid than a supplier that offered a higher bid for individual items.

In the May 1, 2006 proposed rule, we used the volume of items or units displayed in Table 5 of that rule (and as republished below) as the basis of our examples, but we requested comments on which weighting method should be used in calculating the composite. We also requested comments on other methods of weighting that could be applied to individual items.

TABLE 5.—ITEM WEIGHTS

Item	A	B	C	All
Units	5	3	2	10
Item Weight	0.5	0.3	0.2	1

The example above shows how our proposed weight-setting methodology would work. The expected volume for Items A, B, and C are 5, 3, and 2 units, respectively, for a total volume of 10 units. The item weight for Item A is 0.5

(5/10), the weight for Item B is 0.3 (3/10), etc.

As explained above, the composite bid for a supplier would equal the item weight times the item bid amount summed across all items in the product category. The item weights would be the same for bidders for the same product categories. In our example, supplier 1 bid $1.00 for item A, $4.00 for item B, and $1.00 for item C. The composite bid for Supplier 1 = (0.5 * $1.00) + (0.3 * $4.00) + (0.2 * $1.00) = $1.90. Table 6 shows the expected cost of the bundle based on each supplier's bids. The expected costs are directly proportional to the composite bids; the factor of proportionality is equal to the total number of units (10) in the product category. We used the composite bid to determine the expected costs for all of the items in the product category based upon expected volume.

TABLE 6.—COMPOSITE BIDS

Item	A	B	C	Composite bid	Expected cost of bundle
Units	5	3	2	.....	.....
Item weight	0.5	0.3	0.2	.....	.....
Supplier 1 bid	$1.00	$4.00	$1.00	$1.90	$19.00
Supplier 2 bid	$3.00	$3.00	$2.00	$2.80	$28.00
Supplier 3 bid	$2.00	$2.00	$2.00	$2.00	$20.00
Supplier 4 bid	$1.00	$2.00	$2.00	$1.50	$15.00

Under the proposed methodology, bid selection would proceed by ranking the composite bids from lowest to highest (Table 6). In order to ensure that we would pay less under competitive bidding than we would under the current fee schedule, as is required under section 1847(b)(2)(A)(iii) of the Act, we would compute the expected cost of the bundle of goods for comparison purposes. This would require us to calculate the bid amount times the expected number of units that we expect suppliers will furnish based on the most current Medicare claims data and sum across each item by supplier. For example, if supplier 1 bid $1.00 for item A and we expected to purchase 5 units—$1.00 × 5 units = $5.00, item B—$4.00 × 3 units = $12.00, item C—$1.00 × 2 units = $2.00, the sum for these 3 items would be $19.00. As previously noted, prior to selecting a supplier for a contract, we would ensure that suppliers meet quality and financial standards.

Comment: One commenter stated that the bidding should not be so complex. The commenter stated that the use of a weighted composite bid is confusing and cumbersome. The commenter also stated that the weights should be provided to each supplier prior to bidding. Other commenters indicated that if the median methodology is used, bids should be weighted by proposed capacity so that payment rates more accurately represent the market of successful bidders.

Response: We understand the commenters' concern and believe we have simplified the methodology as much as possible. We plan to provide the weights for each item prior to bidding, so that bidders will be aware of the weight given to each item. We stated in the proposed rule that using a composite bid would be a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This would allow us to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category. To compute the composite bid for a product category, we would multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. In the proposed rule, we defined the term ''item weight'' as a number assigned to an item based on its beneficiary utilization rate in a competitive bidding area when compared to other items in the same product category.'' We are revising this definition to indicate that we will use national beneficiary utilization data to determine the item weights for the CBA because we believe that it results in a more representative number that reflects the utilization rate for the item. We believe that this weighting methodology will best reflect the relative market importance of each item in the product category.

After consideration of the comments received, we are redesignating proposed § 414.414(e)(2) and (e)(3) as § 414.414(e)(3) and (e)(4) and adopting them as final with a technical change to paragraph (e)(4) to clarify that we will array the composite bids from the lowest ''composite bid price'' to the highest ''composite bid price.'' We are also revising the definition of ''item weight'' in § 414.402.

3. Determining the Pivotal Bid (§§ 414.414(e)(5) and (e)(6))

We proposed that the pivotal bid would be the point where expected combined capacity of the bidders would be sufficient to meet expected demands of beneficiaries for items in a product category. In the example below, the projected demand would be for 1,000 units. Therefore, the supplier 10's composite bid would represent the pivotal bid, because that supplier's cumulative capacity of 1,100 would exceed the projected demand of 1,000. The statute requires multiple winners, so in all cases where we award contracts, we stated that we would need to accept at least two winning bidders. All bidders that were eligible for selection and whose composite bid for the product category was less than or equal to the pivotal bid would be selected as winning bidders. In the Table 7 below, for example, $135.00 would be the pivotal bid. Suppliers 2, 3, 1, and 10 would then be selected as winning bidders with supplier 10's composite bid becoming the pivotal bid. We acknowledged that this approach may leave out other suppliers with very close, but slightly higher bids.

TABLE 7.—DETERMINING THE PIVOTAL BID

[Point where beneficiary demand is met by supplier capacity—For this example, beneficiary expected demand is 1,000 units—Supplier 10's bid is the pivotal bid]

Supplier No.	Eligible for selection	Composite bid	Supplier capacity	Cumulative capacity
2	Yes	$100	100	100
3	Yes	115	300	400
1	Yes	120	400	800
10	Yes	135	300	1100
4	Yes	140	500	1600
7	Yes	150	100	1700
No longer being considered				
5	No	120	n.c.	n.c.
6	No	130	n.c.	n.c.
8	No	175	n.c.	n.c.
9	No	200	n.c.	n.c.

n.c. = not calculated.

We also noted that we had considered the use of a competitive range to determine the contract suppliers. In this approach, we would determine a competitive range for the composite bid. We would array all suppliers by their bids and eliminate all suppliers whose composite bid is greater than the competitive range. We would then evaluate the quality and financial standards only for those remaining suppliers.

During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel and required bidders to provide extensive information on quality and finances. The last two rounds of the demonstration used a competitive range to reduce the burden on the bid evaluation panel and bidders. After evaluating basic eligibility requirements, the composite bids were calculated and arrayed, and a competitive range was selected with more than enough suppliers to serve the market. Suppliers whose composite bids were clearly outside of this range were not required to provide detailed financial information, and the bid panel was not required to evaluate the eligibility of these suppliers to participate. Suppliers within the competitive range provided detailed financial information and had their quality rigorously evaluated. The remaining suppliers were only selected as contract suppliers if they met the quality and financial standards and their composite bids were at or below the pivotal bid.

We also discussed in the proposed rule other options that we considered to determine the pivotal bid. One of these options would have been to make the pivotal bid depend on one of the summary statistics (for example, mean, median, 45th percentile) associated with the distribution of bids from eligible suppliers. For example, the pivotal bid could have been set equal to the median bid submitted by eligible suppliers. We stated that the advantage of this option would have been that the pivotal bid could be set near the central distribution of bids. We also considered including additional suppliers whose bids were close to the central distribution as being eligible to become a contract supplier. Both options would likely have affected the number of contract suppliers. Finally, we noted that the exact summary statistic or percentile could have been increased or decreased to reflect the trade-off between the number of winners and program costs. One negative aspect of this approach would have been that winners might have insufficient capacity. In addition, with a given percentile cutoff, the pivotal bid might have included an excessive number of winning bidders. As the number of eligible bidders increased, so would the number of winners. If additional bidders had higher costs, and their bids fell into the upper half of the distribution, the pivotal bid would increase, resulting in greater payments by the Medicare program and a loss of savings.

Another option we discussed would have been to base the pivotal bid on a target number of winners. For example, we might have decided to select five winners in each product category. Suppliers might have responded to this approach by bidding aggressively, knowing that only a fixed number of winners would be guaranteed to be selected. A negative aspect of this approach would have been that there is no assurance that a predetermined target number of winners would have had sufficient capacity to meet projected market demand. In addition, the target number of winners must somehow be selected and this could have resulted in selecting an arbitrary number. If too high, suppliers might have had little incentive to bid aggressively.

We also considered an option to base the pivotal bid on a target composite bid; for example, we could have chosen a target that was 20 percent below the DMEPOS fee schedule amount for that product category. A possible advantage of this approach would have been that the target composite bid could be set to ensure savings for the program. On the other hand, we believed that suppliers might perceive this approach to be anticompetitive. Rather than letting bidding and the market forces determine the pivotal bid and fee schedule, we might have been viewed as pre-ordaining the outcome. In addition, suppliers that bid below the target composite bid might have had insufficient capacity to meet projected market demand.

Comment: One commenter requested additional explanation as to what cumulative capacity is and how it is calculated in the competitive bidding program.

Response: The cumulative capacity is determined by arraying the composite bids from the lowest to the highest, then calculating the pivotal bid for the product category by ensuring that the number of suppliers selected to furnish items for that product category in a CBA have sufficient cumulative capacity to do so. We will determine the cumulative capacity of bidding suppliers for the product category by adding each supplier's projected or adjusted capacity. For example, if supplier 1 states it can provide 15 units, supplier 2 states it can provide 40 units, and supplier 3 states it can provide 35

units, the cumulative capacity of those suppliers is 90 units.

After consideration of the public comments we received, we are redesignating proposed § 414.414(e)(4) as § 414.414(e)(5), and finalizing newly redesignated § 414.414(e)(5) with the changes discussed above. We also are redesignating proposed § 414.414(e)(5) as § 414.414(e)(6) and revising newly redesignated § 414.414(e)(6) so that it now provides that the only suppliers we will select for contract award purposes will be those suppliers that have satisfied our eligibility, quality, accreditation (unless a grace period applies), and financial requirements.

4. Assurance of Savings (§ 414.414(b)(2), 414.414(f))

Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. Under proposed § 414.414(f), we proposed to interpret this requirement to mean that contracts will not be awarded to any entity unless the amounts to be paid to contract suppliers in a CBA are expected to be less for a competitively bid item than would have otherwise been paid. Therefore, we stated that we would not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach would ensure that the single payment amount for each item in a product category is equal to or less than our current fee schedule amount for that item.

We acknowledged that an alternative interpretation of ''less than the total amounts that would otherwise be paid'' could mean contracts would not be awarded to an entity unless the amounts paid to contract suppliers in a CBA for the product category are expected to be less than what would have otherwise been paid for the entire product category. During the demonstration, several product categories received overall savings, whereas payment amounts increased for a few individual items within those product categories. One concern we had with this approach was that there might be a greater potential for shifting of utilizations from one item to another higher priced item. We stated that this approach might not result in adequate savings, and that we believed a reasonable interpretation of the Act would be one in which ''the total amounts'' mean payment at the item level.

We specifically requested comments on the various methods for assuring savings under the Medicare DMEPOS Competitive Bidding Program.

Comment: Numerous commenters disagreed with the proposed requirement that bids must be at or below the current fee schedule for an item. The commenters believed that this places artificial constraints on a process that is designed to harness market forces. They indicated that, if bids are submitted higher than the current fee schedule, CMS should choose not to include that particular item in the bidding product category.

Response: Section 1847(b)(2)(A)(iii) of the Act prohibits CMS from awarding a contract to a supplier under a competitive bidding program unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. In order to ensure that the requirement is met and to guarantee savings for the Medicare program, we must require the bids for each item to be at or below the current fee schedule amount for the item in order to preclude increases that may occur due to shifting to items priced above the fee schedule. Without this safeguard, we are concerned that suppliers might simply start furnishing the items priced above the fee schedule rather than those that would normally be furnished because of the potential for higher profits. In addition to increased expenditures, because of a shift to items with higher payment amounts, we might exceed the total amounts that we had been paying for particular products as a group within a product category. This could also result in less appropriate products being furnished to Medicare beneficiaries. We believe that this requirement is necessary to structure a competitive bidding program that reflects the requirements of the statute.

Accordingly, we are adding a new § 414.412(b)(2), which provides that the bid for an item cannot exceed the payment amount that would otherwise apply if the item was not included in the competitive bidding program. In addition, we are finalizing proposed § 414.414(f) with only technical changes.

5. Assurance of Multiple Contractors (§ 414.414(h))

Section 1847(b)(4)(B) of the Act specifies that the Secretary will award contracts to multiple entities submitting bids in each area for an item. In addition, section 1847(b)(2)(A)(iv) of the Act specifies that contracts may not be awarded unless access of individuals to a choice of multiple suppliers is maintained. As a result, we proposed under proposed § 414.414(g) (redesignated as § 414.414(h) in this final rule) that we would have multiple contract suppliers in each CBA for each product category if at least two suppliers met all requirements for participation, and the single payment amounts to be paid to those suppliers did not exceed the fee schedule amounts for the items that were bid. We acknowledged that offering choices to beneficiaries, referral agents, and treating practitioners that order DMEPOS for Medicare beneficiaries is important to maintain competition among suppliers based on the quality of items. We stated that we had to weigh that advantage against the disincentive for a supplier to submit its best bid if we select too many suppliers to service a CBA. We believe we will be able to have multiple suppliers servicing one product category in a CBA and still accomplish the goals of competitive bidding.

Comment: Several commenters recommended that CMS select more suppliers than necessary to meet minimum demand. The commenters believed that this will ensure a sufficient number of suppliers to address contingency or emergency situations, such as a natural disaster. Several commenters recommended that CMS use 130 percent of anticipated capacity. A few commenters requested that CMS cap estimated capacity per supplier when selecting winning bidders to preserve competition and beneficiary choice. Some commenters recommended that CMS cap each supplier's capacity at 20 percent, or 25 percent, of anticipated demand to ensure that a small number of very large suppliers do not become the only winning bidders.

Response: We anticipate that we will select a sufficient number of suppliers to ensure beneficiary access. As we have explained above, we may make adjustments to a supplier's projected capacity in order to ensure that we award contracts to a sufficient number of suppliers. As explained below, we are also modifying our proposed rule for participation by small suppliers to set a small supplier target which will be calculated by multiplying 30 percent times the number of winning suppliers at or below the pivotal bid for each product category. As a result, we will be able to ensure that small suppliers have an opportunity to participate in the programs.

Comment: Several commenters observed that the proposed rule does not mention whether CMS will consider the geographic distribution of suppliers when determining the number of contract suppliers for each product

category in each CBA. They believed that geographic distribution is important to maintain local presence and for beneficiary convenience. They suggested that CMS analyze capacity at the zip code level to ensure that each zip code is served by several contract suppliers. They also stated that there is precedent for determining geographic distribution, citing that the TRICARE standard and the Medicare Part D program have established guidelines for the required number of retail pharmacies, depending on the type of area. One commenter also suggested that any competitive bidding program for diabetic testing supplies include a requirement that a minimum number of community-based suppliers be included and those suppliers be geographically dispersed within the CBA to provide convenient access for Medicare beneficiaries.

Response: We believe that we have created a contract supplier selection methodology that will ensure that beneficiaries have convenient access to competitively bid items. Contract suppliers will also be required to furnish all items to all beneficiaries who maintain a permanent residence in a CBA (or who visit a CBA) unless an exception set forth in this final rule applies. If a beneficiary is unable to come to the storefront of the contract supplier, we would expect that the contract supplier would deliver the item to the beneficiary and, if necessary, set up the item in the beneficiary's residence and train the beneficiary how to use the item. This will ensure beneficiary convenience and access to competitively bid items. We reviewed the TRICARE access standards and believe the standards are not appropriate for meeting the purposes of the Medicare DMEPOS Competitive Bidding Program. The retail pharmacy industry is different from the DMEPOS supplier industry. The retail pharmacy industry provides access through storefront presence where they provide a variety of consumer products. In contrast, most DMEPOS suppliers deliver medical products to the beneficiaries' homes.

After consideration of the public comments we received, we are redesignating proposed § 414.414(g) as § 414.414(h)(1) and revising it to provide that CMS will award at least five contracts for the furnishing of a product category under a competitive bidding program if the requirements in §§ 414.414(b) through (f) are met by at least 5 suppliers. We are also adding a new § 414.414(h)(2), which provides that if the requirements in §§ 414.414(b) through (f) are not by at least 5 suppliers, we will award contracts to at least 2 qualified suppliers. Finally, we are adding a new § 414.414(h)(3), which provides an exception for mail order suppliers to the requirement that if there are at least 5 qualified suppliers, we will award contracts to at least 5 qualified suppliers.

6. Selection of New Suppliers After Bidding (§ 414.414(i))

In the May 1, 2006 proposed rule (71 FR 25678), we proposed to select only as many suppliers as necessary to ensure we have enough capacity to meet projected demand. However, we noted that we might have to suspend or terminate a contract supplier's contract if that supplier falls out of compliance with any of the requirements identified in the regulation and in the bidding contract. Alternatively, we recognized that we could later determine that the number of contract suppliers we selected to furnish a product category under a competitive bidding program was insufficient to meet beneficiary demand for those items. In situations where CMS determines that there is an unmet demand for items, for example, if CMS terminates a contract supplier's contract, we proposed to contact the remaining contract suppliers for that product category to determine if they could absorb the unmet demand. If the remaining contract suppliers could not absorb the unmet demand in a timely manner, we proposed to refer to the list of suppliers that submitted bids for that product category in that round of competitive bidding in that CBA, use the list of composite bids that we arrayed from lowest to highest, and proceed to the next supplier on the list. We would contact that supplier to determine if it would be interested in becoming a contract supplier. If the supplier was interested, we proposed to require the supplier to provide updated information to ensure its continued eligibility for participation. A condition for acceptance of a contract would be that the supplier must agree to accept the already determined single payment amounts for the individual items within the product category in the CBA. We would continue to go down the list until we were satisfied that the expected demand would be met and beneficiary access to the items in the product category would not be a problem. After consultation with the DMEPOS industry and PAOC, we were informed that additional capacity should not be a problem as suppliers would be willing and able to handle the expected demand.

Another option that we considered, but did not propose, was to conduct a new round of bidding to select additional suppliers. However, we did not choose this option because it would delay the resolution of an access problem and place an additional administrative burden on the program.

Comment: One commenter argued that it would be a violation of the statute to award contracts to a new supplier after contracts have been awarded without conducting a new competition. The commenter stated that the law requires that CMS conduct a competition for the award of any contracts for a competitively bid item. Therefore, the commenter believed an award to the bidder next-in-line when a contract supplier leaves the program or CMS find that it needs additional suppliers would not constitute a competitive acquisition.

Response: We agree that contracts cannot be awarded to a supplier that did not compete. We disagree that this regulation requirement results in awarding a contract to a supplier that did not submit a bid. These suppliers have competed and met all applicable eligibility, quality, financial, and accreditation requirements to be awarded a contract. We intend to only use this methodology when we find that there is a need for additional contract suppliers because a contract supplier's contract is suspended or terminated or when CMS finds it needs additional contract suppliers to meet beneficiary demand for a particular product category in a CBA. It would not be in the best interest of beneficiaries to delay awarding the additional contracts when we need to ensure sufficient capacity because a contract supplier's contract has been suspended or terminated or there is greater need in an area than we anticipated.

Comment: One commenter stated that CMS should have a process identified if there are no suppliers located in a CBA willing to accept the single payment amount and enter into a competitive bidding contract.

Response: We would not be able to have competitive bid pricing in a CBA in which no suppliers could accept the single payment amount.

In summary, after consideration of the public comments received, we are redesignating proposed § 414.414(h) as § 414.414(i) and adopting it as final with only technical changes.

VIII. Determining Single Payment Amounts for Individual Items

A. Setting Single Payment Amounts for Individual Items (§§ 414.416(a) and (b))

Section 1847(b)(5)(A) of the Act requires that the Secretary determine a

single payment amount for each item in each CBA based on the bids submitted and accepted for that item, and we proposed in § 414.416(a) and (b) to implement this statutory requirement. Once contract suppliers are selected for a product category based on their composite bid and the pivotal bid, single payment amounts for individual items in the product category must be determined. We considered several different methodologies for determining the single payment amounts. Each of the options we considered is discussed in detail in this section. After careful consideration of these options, we proposed to adopt the following principles to determine the single payment amounts for individual items in a product category:

Principle 1

Bid amounts from all winning bids for an item in a CBA will be used to set the single payment amount for that item in the CBA.

Principle 2

We must expect to pay less for each individual item than we would have otherwise paid for that item under the current fee schedule. Single payment amounts cannot be higher than our current fee schedule amounts for individual items within a product category.

To satisfy these principles, we evaluated several different approaches to setting payment amounts. As a result of our review, we decided on a preferred approach that would determine the single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category. The individual items would be identified by the appropriate HCPCS codes. The median of the bids submitted by the contract suppliers for a particular item would be the single payment amount that we would establish under the competitive bidding program for the HCPCS code that describes that item. In cases where there is an even number of winning bidders for an item, we would employ the average (mean) of the two bid prices in the middle of the array to set the single payment amount. In addition, we proposed that the single payment amount for each item must be less than the current fee schedule amount for that item.

We believe that setting the single payment amount based on the median of the contract suppliers' bids satisfies the statutory requirement that single payment amounts are to be based on bids submitted and accepted. This will result in a single payment for an item under a competitive bidding program that is representative of all acceptable bids, not just the highest or the lowest of the winning bids for that item.

TABLE 8.—MEDIAN OF THE WINNING BIDS

Item	A	B	C	Actual composite bid
Supplier 4 bid	$1.00	$2.00	$2.00	$1.50
Supplier 1 bid	1.00	4.00	1.00	1.90
Supplier 3 bid	2.00	2.00	2.00	2.00
Median of winning bids—Single payment amount	1.00	2.00	2.00	

While this was our proposed approach, we solicited comments on other methodologies for setting the single payment amount, including using an adjustment factor as part of the methodology for setting the single payment amount. This was the methodology we used for the competitive bidding demonstrations, and it would have required the following steps. The first step of this methodology would have been to calculate the average of the winning bids per individual item. The second step would have been to calculate the average of the composite bids by taking the sum of the composite bids for all contract suppliers in the applicable CBA and dividing that number by the number of contract suppliers. The third step would have been to determine an adjustment factor, the purpose of which would be to bring every winner's overall bids for a product category up to the pivotal bidder's composite bid. Once we determined the adjustment factor, we would have taken the average of the winning bids per item and multiplied that by the adjustment factor to adjust all bids up to the point of the pivotal bid, so that all winners would be paid by Medicare as much for the total product category as the pivotal bidder. This amount would have become the single payment amount for the individual item. This is the price that all contract suppliers within a CBA would have been paid for that product as illustrated in Table 9. ?≤

TABLE 9.—ADJUSTING THE AVERAGE WINNING BIDS

Item	A	B	C	Average composite bid	Actual composite bid
Supplier 4 bid	$1.00	$2.00	$2.00	.....	$1.50
Supplier 1 bid	1.00	4.00	1.00	.....	1.90
Supplier 3 bid	2.00	2.00	2.00	.....	2.00
Supplier 2 bid	N/A	N/A	N/A	.....	N/A
Average of winning bids	1.33	2.67	1.67	1.80	.....
Adjustment factor = (Pivotal Composite Bid)/(Average Composite Bid)	1.11	1.11	1.11	.....	.....
Adjusted average bids-single payment amount per item	1.48	2.96	1.85	.....	.....

This approach would have ensured that the overall payment amounts that contract suppliers received were at least as much as their bids. As a result, this may have guarded against suppliers leaving the Medicare program because the payment amounts are not sufficient. However, we did not favor this alternative because, in general, most payment amounts would have been higher than the actual bids as a result of the adjustment factor being greater than

zero. This would have been true because the purpose of the adjustment factor would have been to make the composite bid of all winning suppliers equivalent to the composite bid of the pivotal supplier. We chose not to propose this approach because we believe that this approach is not reflective of all of the winning bids accepted. In addition, we stated that we were concerned that this methodology might be confusing and overly complicated.

We also considered taking the minimum winning bid for each item in a CBA and not applying an adjustment factor. We did not favor this alternative because we also did not consider it as being reflective of the actual bids accepted because it is only reflective of the lowest bid. The lowest bid would not be reflective of what suppliers would sell the item for as most of them bid higher.

Finally, we considered taking the maximum winning bid for each item. However, this approach would have led to program payment amounts that were higher than necessary because some suppliers were willing to provide these items to beneficiaries at a lower cost.

In the proposed rule, we indicated that we were still in the process of determining the appropriate approach for setting payment amounts, as well as the alternatives considered and outlined above, and invited comments on our proposed methodology.

Comment: Several commenters expressed concerns that the proposed method to determine the single payment amount would result in suppliers submitting low bids and only offering the lowest cost devices. They believed that quality and access would be impacted by the use of the median bid. They further indicated that requiring savings on each item rather than in the aggregate encourages suppliers to bid on the oldest, lowest priced product within each HCPCS code. The commenters suggested that CMS base savings at the product category level and not for each individual code.

Response: We disagree with these commenters. We recognize the necessity for a process to identify and eliminate irrational, infeasible bids. As required in § 414.414(b)(4), each supplier must submit a bona fide bid that is complies with all the terms and conditions contained in the RFB. Also, as discussed in section XIV of this final rule, we will establish a formal complaint and monitoring system for each CBA. Specifically, we will direct the CBIC to establish a monitoring program that includes beneficiary satisfaction indicators and supplier performance indicators.

The Medicare DMEPOS Competitive Bidding Program is designed to ensure that the Medicare payment amounts are appropriate and reasonable. In addition, competitive bidding will harness market forces and create competition among suppliers. We believe that this competition will prevent suppliers from offering the lowest cost devices, as suppliers will be interested in increasing their market share by offering appropriate services and high quality products to maintain and increase their customer base.

In addition, and as discussed more fully in section IX. of this final rule, we will include a nondiscrimination clause in the contracts we enter into with contract suppliers. Under that provision, contract suppliers will be obligated to make the same items available to beneficiaries under the Medicare DMEPOS Competitive Bidding Program that they make available to other customers. We believe that the inclusion of this clause will help to ensure that Medicare beneficiaries have access to the highest quality DMEPOS items. Section 1847(b)(2)(A)(iii) of the Act states that the total amounts to be paid to contractors in a competitive acquisition area are expected to be less that the total amounts that would otherwise be paid. In order to guarantee that we implement this section to ensure that we achieve savings for the Medicare program, we must require bids to be at or below the current fee schedule for the item. This will preclude our setting single payment amounts for certain items above the fee schedule and causing contract suppliers to attempt to shift utilization to these items because of the higher payment amounts. Without this safeguard, we are concerned that suppliers might simply start furnishing an alternative item, because the physician's order may not be item specific, within the same product category because the item may have a greater potential for higher profits. In addition to increased expenditures, this could also result in less appropriate items being furnished to Medicare beneficiaries.

In addition, we believe that basing product savings at the item level will guarantee assurance of savings for the Medicare DMEPOS Competitive Bidding Program because accepting bids above the fee schedule for certain products may result in these items being furnished as an alternative to other items within the product category, which would increase their utilization and expenditures compared to the current levels.

Comment: Several commenters argued that the use of the median bid to set the single payment amount is flawed because the median bid could be vulnerable to a variety of gaming strategies. They noted that, when using the median, 50 percent of winning bidders would have to accept less than their bids to participate. They indicated that if a contract supplier is not able to provide the items at the median, demand would not be met and access would be impaired. The commenters raised concerns that all bids would have the same weight, and bids from small suppliers, which only serve a few Part B beneficiaries, would have the same impact on the calculation as bids from suppliers responsible for a large number of beneficiaries, which would give too much weight to small suppliers. Other commenters suggested that the use of the median bid favors large chain suppliers that deliver large volume of items. Other commenters suggested that CMS include a mechanism to ''rationalize'' bids to ensure there are no unreasonably low bids. They added that CMS should have a mechanism to eliminate outlier bids. One commenter suggested that CMS calculate the single payment amount only from among those bids that are ''reasonable.'' Numerous commenters suggested that CMS use the Adjustment Factor Method (AFM) that was used during the demonstration. Because suppliers were paid at least as much as they bid in aggregate, commenters believed that the AFM would provide sufficient protections to encourage small suppliers to bid. One commenter suggested setting the payment amount at the 90th percentile of winning bids or not lower than 5 percent below the highest winning bid. Another commenter recommended calculation of the single payment amount only from those bids that lie within one standard deviation of the mean of the bids. One commenter supported the use of a median calculation as a statistically valid method for determining the single payment amount. Lastly, some commenters recommended that CMS pay contract suppliers their bid amounts or the single payment amount, whichever is lower. These commenters believed that this would be consistent with the statutory payment basis of the fee schedule or the actual charge, whichever is less.

Response: We disagree with the concerns raised by commenters regarding the use of median bid to set the single payment amount. We believe that the use of the median takes into consideration all bids submitted and accepted and not just the high and low bids. We further believe that the median

is not influenced by outliers at the extremes of the data set. For this reason, the median is often used when there are a few extreme values that could greatly influence the mean and distort what might be considered typical. We believe the median of the accepted bids would represent a reasonable payment amount and does not favor large or small suppliers, and we believe this approach is more equitable than other approaches suggested in the comments. Regarding access, if a winning supplier does not enter into a contract because it is not able to furnish the items at the median, we believe that access will not be adversely affected because we will be selecting a sufficient number of contract suppliers to ensure that demand is met in the CBA. In addition, we believe that most, if not all, of the winning suppliers will be willing to furnish items in the product category at the single payment amounts.

In addition, section 1847(b)(5)(A) of the Act states that payment shall be based on bids submitted and accepted. The single payment amount will be determined from only those bids that are considered ''acceptable,'' meaning that the supplier meets all quality, financial, and eligibility standards and that the bid is in the wining range. For this reason, we believe that the single payment amount should be representative of all of the accepted bids and not just the highest or the lowest bids. We further believe that using the adjustment factor is not reflective of the actual bids accepted because it is only reflective of the pivotal bid. We do not believe that the adjustment factor is necessary to ensure that small suppliers have the opportunity to be considered for participation in the competitive bidding program because the median represents a reasonable payment based on accepted bids from suppliers that are at or below the pivotal bid. We note that we discuss special provisions for small suppliers in section XI. of this final rule. We will only be entering into contracts with those suppliers that agree to accept the single payment amount. Moreover, as we explain above, we believe that using the median bid would not result in an insufficient payment, and we also believe that our contract supplier selection methodology will ensure that we have a sufficient number of contract suppliers to meet the demand for competitively bid items in each product category in each CBA.

Further, we disagree with the commenters' suggestion that we would have the authority under the Act to pay suppliers the lower of their bid amounts or the single payment amount. Section 1847(b)(5)(A) of the Act requires the Secretary to determine a single payment amount for each item in each CBA based on the bids submitted and accepted for that item. A ''single payment amount'' is one amount, and does not lend itself to an interpretation that would allow us to pay the lesser of the two amounts.

We recognize the necessity for a process to identify and eliminate irrational, infeasible bids. Accordingly, we will be evaluating bids to ensure that they are bona fide, and we may request that a supplier submit additional financial information, such as manufacturer invoices, so that we can verify that the supplier can provide the product to the beneficiary for the bid amount. If we conclude that a bid is not bona fide, we will eliminate the bid from consideration.

Comment: Several commenters suggested that a flaw in using the median methodology is that it is highly dependent on whether there are an even or odd number of suppliers in the final array.

Response: As included in our discussion in the preamble of the proposed rule regarding the use of the median, in cases where there is an even number of winning bidders for an item, we would employ the average (mean) for the two bid prices in the middle of the array to set the single payment amount. We are adding this rule to the final regulations at § 414.416(b)(1). As noted in the response to the previous comment, we believe that the use of the median is not a flawed methodology.

Comment: One commenter suggested that CMS follow defined procedural rules to select winning suppliers and determine the single payment amount, similar to the process that it has developed for the National Coverage Determination (NCD) process. For example, the commenter suggested that CMS ensures that the public is informed at the time it initiates the process, provides for public input, and arranges for all of these processes to occur during a defined time period.

Response: This final rule outlines a defined process that we will follow to select contract suppliers and determine the single payment amounts for each item in each product category in each CBA. In addition, we are developing an extensive educational program that will educate and inform the public about the processes that will be used to conduct the bidding and to determine the winning suppliers. Our plans for education are described in more detail in the DMEPOS section of the FY 2007 IRF final rule (71 FR 48354).

After consideration of the public comments we received, we are finalizing our methodology for setting the single payment amount in §§ 414.416(a) and (b), by adopting paragraph (a) in final (with technical revisions), revising paragraph (b)(1) to address how the single payment will be computed when there is an even number of winning bids. We are also adding new § 414.414(b)(4), which provides that each supplier must submit a bona fide bid that complies with all of the terms and conditions in the RFB.

B. Rebate Program

In the May 1, 2006 proposed rule (71 FR 25680), we proposed to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate (proposed § 414.416(c)). We stated in the preamble of the proposed rule that the rebate would be equal to the difference between their actual bid amount and the single payment amount. The following example illustrates how the rebates would be applied under this proposed approach:

If, based on the bids received and accepted for an item, we determined that the single payment amount for the item was $100, Medicare payment for the item would be 80 percent of that amount, or $80, and the coinsurance amount for the item would be 20 percent, or $20. However, if a contract supplier submitted a bid of $90 for this item and chose to offer a rebate, the rebate amount would be equal to the difference between the single payment amount ($100) and the contract supplier's actual bid ($90), or $10. Therefore, after the contract supplier received the Medicare payment of $80 and the $20 coinsurance, the contract supplier would be responsible for providing the beneficiary with a $10 rebate. We solicited comments on how to handle those cases in which the rebates would exceed the copayment amount.

Before deciding to propose this methodology, we considered whether to make the rebates mandatory or voluntary. We proposed that the rebates be voluntary but that contract suppliers could not implement them on a case-by-case basis. If a contract supplier submitted a bid below the single payment amount and chooses to offer a rebate, it must offer the rebate to all Medicare beneficiaries receiving the competitively bid item to which the rebate applies. This commitment would be incorporated into the contract supplier's contract. Stated another way, while the decision to offer rebates might be voluntary, once a contract supplier decides to provide rebates, the rebates would become a binding contractual

condition for payment during the term of the contract with CMS. Moreover, the contract supplier could not amend or otherwise alter the provision of rebates during the term of the contract. Contract suppliers would also be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals. However, this would not preclude CMS from providing to beneficiaries comparative information about contract suppliers that offer rebates.

We proposed that only contract suppliers that submitted bids below the single payment amount for a competitively bid item would have the choice to offer rebates. Contract suppliers that submitted bids above the single payment amount would not be allowed to issue rebates because their actual bids for an individual item would be above this amount.

Our reason for proposing to allow these contract suppliers to offer rebates was to allow beneficiaries the ability to realize additional savings and the full benefits of the Medicare DMEPOS Competitive Bidding Program.

We solicited comments concerning the rebate process outlined in the proposed rule. We indicated that we would continue to evaluate the fraud and abuse risks of the proposed rebate program, and we specifically solicited comments on such risks.

Following is a summary of the public comments received.

Comments: Several commenters expressed concern over the proposed rebate program. They argued that the rebate program would be illegal and violate the antikickback statute, the beneficiary inducement statute, and the Medicare provisions of the Social Security Act governing the waiver of copayments. They argued that the rebate program would promote fraud and abuse by encouraging beneficiaries to purchase unnecessary supplies and the program will entice suppliers to ''game'' the program. They further stated that the OIG has issued numerous opinions that emphasize ''that providing things of value to beneficiaries in exchange for referrals is unlawful.'' The commenters believed that rebates also create tension with the Federal Anti-Kickback safe harbor statute. They pointed out that, to qualify for a safe harbor, a rebate must be disclosed in writing prior to the initial purchase. They added that the proposed rule expressly prohibits a supplier from advertising either directly or indirectly to beneficiaries. One commenter supported the inclusion of the rebate provision in the program as an innovative means to control beneficiary's out-of-pocket expenses and to reward bidders that submit good faith, competitive bids.

Several commenters suggested that rebates encourage suppliers to offer lower cost, less innovative products, particularly from large manufacturers. Several commenters suggested that the use of rebates leads to beneficiaries selecting suppliers based solely on availability of rebates, rather than quality of care. The commenters indicated that this could lead to poorer patient outcomes. They added that large manufacturers can spread the cost of discounts across many products, but small manufacturers may have only one or two products that would not support rebates. The commenters asserted that OIG states that the use of giveaways also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses. They further added that the rebate program may provide an incentive to large suppliers to ''lowball'' their bids, resulting in reduced marketplace competition by small suppliers.

One commenter suggested that if CMS offers a rebate, it should not be voluntary. Requiring suppliers to supply a rebate would assure that the suppliers are not bidding low just to be selected and then have their payments raised to the median level automatically. The commenter believed that this would prevent deliberate low-ball bidding.

Several commenters questioned whether rebates should become a binding contractual commitment when an express contractual provision would not exist.

Several commenters suggested that a rebate would be logistically impossible for a supplier to implement in its information system, branch operation, and accounts receivable processes. They added that physicians would have no way of keeping the rebate logistics straight. The commenters believed that CMS would also experience difficulties in monitoring the program. Another commenter inquired in what form CMS would require the rebate to be distributed, that is, gift certificate to family store, a money order, check, cash, among others. The commenter also asked if claims are denied and a rebate already paid, who would be responsible for collecting from the patient.

Several commenters suggested that suppliers that pay rebates are less likely to provide service in those areas where the supplier has bid above the contract price and will focus on those items where the payment amount is greater than the supplier's bid amount.

Several commenters suggested that logistical challenges would exist with implementation of rebates. The commenters stated that one supplier serving beneficiaries within the CBA and outside the CBA would have two different sets of rules because only CMS may inform the beneficiaries which suppliers offer a rebate. They asked how a supplier should answer a direct question about rebates when posed by a referral source or patient. They added that often the cost to issue a rebate check exceeds the value of the check issued and asked how suppliers will integrate a rebate with the patient's Part B supplemental insurance plan where the plan pays 100 percent of the copayment or when the copayment is waived because of financial hardship.

One commenter suggested that the rebate provision violates the single payment amount provision of the Act by permitting different payment amounts for different contract suppliers.

One commenter suggested that the rebate proposal may also have the effect of allowing retail store DMEPOS suppliers to ''cherry pick'' that portion of the DMEPOS business that is least costly to provide, driving up the costs of providing full-line services without any comparable savings to the program.

Several commenters suggested that rebates should not exceed the copayment amount in order to reduce risks of overutilization. They believed that the current proposal could eliminate all copayments in some cases and lower the copayment below the amount that would otherwise typically apply in every case. Several commenters suggested that the rebate runs counter to a fundamental principle of the Medicare program that requires beneficiary coinsurance. They pointed out that the purpose behind the 20-percent copayment is to discourage excessive or unnecessary utilization and stated that CMS is not authorized to change the Medicare Part B plan design by using rebates that would reduce or eliminate copayments.

Although we proposed that the rebate program be voluntary, one commenter suggested that our proposal to disseminate information about suppliers that participate in the rebate program would create an unfair marketing advantage to those suppliers.

Response: After considering the comments we received, we have decided that rebates will not be authorized under the Medicare DMEPOS Competitive Bidding Program and the provisions of proposed § 414.416(c) are not included in this final rule. We believe that competition will drive suppliers to compete for beneficiaries based on value and quality. We also recognize that requiring

rebates might raise fraud and abuse concerns. In addition, we have concerns that rebates may provide incentives to beneficiaries to obtain unnecessary items.

In summary, we are not adopting in this final rule the provisions of proposed § 414.416(c).

IX. Terms of Contracts

Section 1847(b)(3)(A) of the Act gives the Secretary the authority to specify the terms and conditions of the contracts used for competitive bidding and we proposed in § 414.422(a) to implement this provision. Section 1847(b)(3)(B) of the Act requires the Secretary to recompete contracts under the Medicare DMEPOS Competitive Bidding Program at least every 3 years and we proposed in § 414.422(b) to implement this provision. The length of the contracts may be different for different product categories, and we proposed to specify the length of each contract in the RFBs.

A. Terms and Conditions of Contracts (§§ 414.422(a) Through (c))

In the May 1, 2006 proposed rule (71 FR 25680), we proposed that the competitive bidding contracts will contain, at a minimum, provisions relating to the following:

- Covered product categories and covered beneficiaries operating policies.
- Subcontracting rules.
- Cooperation with us and our agents.
- Potential onsite inspections.
- Minimum length of participation.
- Terms of contract suspension or termination.
- Our discretion not to proceed if we find that the Medicare program will not realize significant savings as a result of the program.
- Compliance with changes in Federal laws and regulations during the course of the agreement.
- Nondiscrimination against beneficiaries in a CBA (so that all Medicare beneficiaries inside and outside of a CBA area receive the same products that the contract supplier would provide to other customers).
- Supplier enrollment and quality standards.
- The single payment amounts for covered items.
- Other terms as CMS may specify.

Comment: One commenter asked if a supplier that is a subcontractor to another supplier can submit a bid to furnish items in one product category in a CBA and also be a subcontractor to another supplier that submits a bid to furnish items under another product category. Another commenter also asked if a losing bidder can become a subcontractor to a contract supplier. One commenter asked about the ramifications to a subcontractor if the contract supplier violates its contract with CMS. One commenter stated that the requirements for subcontractors need to be clearly defined. The commenter asked if subcontractors would need to satisfy the same accreditation and financial standards required of contract suppliers and, if so, how CMS would enforce this.

Response: Our rules would not preclude a supplier from submitting an individual bid for a product category in a CBA and also becoming a subcontractor to another supplier that submits a bid in the same CBA for the same product category. As an example, a supplier can bid to become an oxygen contract supplier and be awarded a contract and still be a subcontractor for another oxygen contract supplier. In addition, a supplier that submits a bid and loses can become a subcontractor to a contract supplier. We will not evaluate subcontractors to determine if they meet the accreditation, quality, financial, and eligibility standards because a subcontractor to a contract supplier cannot itself be a contract supplier and cannot submit claims under the Medicare DMEPOS Competitive Bidding Program. However, a supplier may not subcontract with any supplier that has been excluded from the Medicare program, any State health program or any other government executive branch procurement or nonprocurement activity. In addition, the subcontractor will not have to submit a bid to be a subcontractor. However, the contract supplier will be responsible for fulfilling all of the terms of its contract, even if it uses one or more subcontractors. In other words, if a contract supplier breaches its contract due to its subcontractor's failure to perform, the contract supplier will be held liable for the breach. Therefore, the contract supplier needs to ensure that the subcontractor is performing its duties appropriately. In their response to the RFB, bidders must submit any plans for subcontracting.

Comment: One commenter stated that a number of different proposed contract terms were not listed in the proposed rule. The commenter presumed that the actual contract provisions will be subject to a separate notice of proposed rulemaking in order to permit suppliers to offer more productive comments. One commenter suggested that CMS clearly define contract requirements so that suppliers can ensure that they meet Medicare guidelines.

Response: In the proposed rule, we discussed the details of the Medicare DMEPOS Competitive Bidding Program and identified a number of provisions that will be included in the contract. We also stated that we might specify other terms in the contracts themselves. We do not believe that an additional rulemaking is required in order to specify other terms and conditions that might be included in the contracts. In addition, we believe that our discretion to specify the contract terms and conditions would allow us to specify the terms and conditions for each new competition.

Comment: One commenter stated that some bidders are likely to be large nationwide or regional entities that are publicly traded companies. The commenter encouraged CMS to limit information concerning ownership to those owners required to be disclosed in regular filings with the Securities and Exchange Commission.

Response: Our purpose for requesting information about key personnel is not the same as that for the Securities and Exchange Commission. We need to obtain information about key personnel, both corporate and local, in order to determine the appropriateness of the bid submission and to ensure no key personnel have been the subject of legal actions, or have been sanctioned or convicted of a crime. This information will also be useful in determining common ownership to ensure that companies are not bidding against themselves to furnish the same product categories in the same CBA by submitting different bids for commonly owned separate locations.

Comment: Numerous commenters urged that the contract length be the same for all products in a CBA to minimize confusion among beneficiaries, referring physicians, and suppliers. The commenters stated that, because there are many variables that stakeholders will have to understand (such as which products are part of competitive bidding, boundaries of CBAs, among others), contracts of different lengths of time within a CBA will be time consuming, costly, and confusing for all involved. One commenter stated that the length of each contract should be specified in the RFB. Another commenter recommended that CMS recompete the contracts more frequently in the early stages of the competitive bidding program, in order to capitalize on what it learns during this initial period.

Response: We agree that it is important that we capitalize on what we learn during the early stages of competitive bidding. However, we want to retain the option for staggering the contract period for different product categories to allow for any changes in

coding or in technology and to facilitate use of the authority to phase in items under the programs. We would not have different contract lengths for items within the same product category within the same CBA. The length of each contract will be specified in the RFB; however, no contract will be longer than 3 years because section 1847(b)(3)(B) of the Act requires us to recompete the competitive bid contracts no less often than every 3 years.

Comment: One commenter proposed that CMS require all suppliers in a single CBA to be accredited in the same year and then to place the contracts for all product categories in that CBA on the same 3-year cycle as the accreditation requirement.

Response: We believe that this commenter's suggestion would be too difficult to implement from a logistical standpoint and too regimented an approach to adopt. Suppliers have the option of pursuing accreditation at any time. However, they must be accredited before we can award contracts under the Medicare DMEPOS Competitive Bidding Program, unless a grace period applies. As we explained above, in the first round of bidding, a supplier's accreditation must at least be pending before a bid can be submitted. In addition, a contract supplier that obtains its accreditation must maintain that accreditation for the remainder of the contract period.

Comment: One commenter recommended that no new products should be added during a contract term. The commenter stated that suppliers may or may not have access to the new products and, as a result, may not be able to furnish them.

Response: We agree with this comment. If a new product does not fit under a code for which we have conducted competitive bidding a single payment amount will not be applied until we conduct another round of bidding A further discussion of our rules regarding HCPCS codes changes can be found in section VI.D.4 of this final rule Under section 1847(b)(3)(B) of the Act, we are required to recompete the contracts no less often than every 3 years. For purposes of competitive bidding, we cannot add additional codes for items for which we have not done bidding because we need to conduct bidding before we can determine the single payment amount for these items. We would pay for these codes under the DMEPOS fee schedule.

Comment: Several commenters stated that our proposal to include in each contract a nondiscrimination provision, which would require that the competitively bid items furnished by a contract supplier to Medicare beneficiaries be the same items that the contract supplier furnishes to other customers is unrealistic. The commenters argued that this provision would impair beneficiary access to DMEPOS and would limit the savings that otherwise would be achieved through competitive bidding. Another commenter stated that the proposed rule provided very little detail about what would be expected or how CMS would ensure that the nondiscrimination contract provision is being met and urged CMS to discuss the nondiscrimination clause in more detail so that suppliers and beneficiaries will be able to understand what CMS has in mind, and know what protections are being afforded to beneficiaries by this provision.

Response: We believe that Medicare beneficiaries should receive the same items that the contract supplier would furnish to other customers and, therefore, we proposed to include a nondiscrimination provision in the contracts. One of the main objectives of the Medicare DMEPOS Competitive Bidding Program is to ensure that beneficiaries have access to quality DMEPOS. Therefore, we have built safeguards into the competitive bidding program to ensure there is continued access to quality medical equipment and supplies. We believe the nondiscrimination clause will ensure that Medicare beneficiaries have access to the same items as other individuals. One mechanism that we would use to enforce the nondiscrimination clause is the complaint and monitoring system that we plan to implement. Under this system, which is discussed more fully in section XIV. of this final rule, beneficiaries, referral agents, providers, and suppliers can assure us that the supplier conducts business in a manner that is beneficial to Medicare and beneficiaries. We have added this proposed requirement to the final regulation at § 414.422(c).

Comment: One commenter noted that CMS should consider nonprice variables, such as a supplier's compliance with Medicare program requirements when awarding contracts for certain DMEPOS. The commenter also recommended that CMS revise § 414.422(a) of the proposed regulations so that it would require a contract supplier to comply with the accreditation requirements specified in § 414.414(c) for the duration of the contract period. One commenter suggested that CMS retain the discretion to determine the likely value a particular supplier's compliance program brings Medicare and consider its value as an individual variable in determining whether the supplier is eligible to receive a contract award.

Response: As proposed in § 414.422(a), contract suppliers must comply with all the terms of their contracts, including any option exercised by CMS, for the full duration of the contract period. Once accredited, contract suppliers will be required to retain that accreditation throughout the duration of the contract. Accreditation requirements are mandatory and an important step forward to make sure we have quality suppliers. Compliance plans may be helpful to suppliers in meeting Medicare requirements; nevertheless, all suppliers have to meet our applicable standards and accreditation requirements. Therefore, we do not consider it appropriate to give extra weight in the selection process to suppliers with compliance programs.

Comment: One commenter suggested that CMS require contractors to subcontract portions of contracts to minority or female-owned businesses to comply with Federal contracting requirements.

Response: Due to size, complexity and nature of this program, we do not believe it would be feasible to require subcontracting with minority or female owned businesses and still meet our other goals. We also note that these contracts are not procurement contracts and, therefore, are not subject to the SBA or FAR requirements. Pursuant to section 1847(b)(6)(D) of the Act, we are only required to give small suppliers certain considerations.

Comment: One commenter urged CMS not to prohibit contract suppliers from turning away beneficiaries, since there will be more than one contract supplier per CBA. The commenter stated that there may be circumstances in which a contract supplier is already operating beyond capacity and would not be able to furnish items to additional beneficiaries. In addition, the commenter noted that a contract supplier may not believe that a requested item is appropriate for the beneficiary.

Response: We continue to believe that contract suppliers should not be able to turn away beneficiaries because we do not want to create an opportunity for contract suppliers to turn away beneficiaries who have the most difficult medical conditions or are otherwise difficult to serve. We note that we proposed that there would be a limited exception to this requirement if there is a particular item that a physician or treating practitioner has ordered to avoid an adverse medical outcome, but is an item that the contract

supplier does not normally furnish. In this case, if the contract supplier could not furnish the item, the requirements at § 414.420(b) of this final rule would apply.

Comment: One commenter suggested there be some mechanism in place to prevent the awarding of contracts to suppliers that do not provide at least some percentage of the services themselves. The commenter believed that quality will be lost if winning bidders are allowed to subcontract the entire or a large portion of the product category, and that beneficiaries will receive lower quality items because the winning bidder will make a profit on items that it does not actually furnish. Another commenter suggested that in order to prevent abuse of the bidding process, the competitive bidding contracts should allow a winning supplier to subcontract a portion of its services only if the subcontractor entities satisfy the same quality and accreditation standards that must be satisfied by the winning suppliers.

Response: As explained above, we will request information on the RFBs about the use of subcontractors. We believe that the eligibility standards, applicable accreditation standards and financial standards will ensure that contract suppliers are reputable, viable businesses and not just companies that subcontract their work. In addition, we will hold the contract supplier responsible for meeting all the terms and conditions of its contract, whether or not one of those terms is actually performed by a subcontractor.

Comment: One commenter stated that lack of timely DMEPOS access would be harmful for beneficiaries who are clinically ready to return to home or to the community from the hospital. The commenter also noted that delaying the discharge of Medicare beneficiaries due to restricted and untimely availability of specific DMEPOS would produce serious problems for beneficiaries' continuity of care and also for the hospital. The commenter stated that, from a hospital perspective, it is essential for CMS to ensure that DMEPOS be available on a timely basis and to sanction providers for untimely service. The commenter recommended that CMS take additional steps to prevent these problems, including imposing specific sanctions on contract suppliers that fail to timely furnish DMEPOS to these hospital patients, because such delays would delay discharge and jeopardize a patient's clinical progress. Another commenter stated that beneficiaries should be guaranteed prompt receipt of items, if in stock, within a specified period of time after the order is received. The commenter stated that delays could lead to adverse events for beneficiaries.

Response: We do not believe it is appropriate to establish a general timeframe within which all competitively bid items must be delivered to beneficiaries. Due to the individual characteristics of the products and beneficiary circumstances, the items will vary widely in terms of whether they are in stock and must be customized. However, a contract supplier should furnish items to beneficiaries in accordance with timeframes that meet the ordering physician's, or treating practitioner's, prescription. We also note that under the final quality standards (under Consumer Services) that we issued, in August 2006, and with which suppliers must comply in order to participate in the Medicare DMEPOS Competitive Bidding Program, the supplier must ensure it provides beneficiaries with information regarding expected timeframes for receipt of delivered items and the supplier must verify that beneficiaries have received the items. In addition, under § 424.57(c)(12) of our regulations, which suppliers must also satisfy in order to participate in the program, suppliers are responsible for the delivery of Medicare-covered items to beneficiaries and must maintain proof of delivery. The quality standards also require the supplier to ensure that it provides beneficiaries with the necessary information and instructions on how to use Medicare-covered items safely and effectively.

Comment: One commenter stated that FDA regulations require manufacturers, not suppliers, to evaluate product complaints and inform the FDA if the problems are considered to be reportable events. The commenter noted that CMS should require suppliers to inform the relevant DMEPOS manufacturer of any problem with equipment or supplies, including any adverse effects involving Medicare beneficiaries, so that the manufacturers will be in a position to address the problem, report to the FDA, or take other corrective action if needed. The commenter also noted that CMS should in no way imply that a product warranty is the supplier's legal obligation, as opposed to that of the product manufacturer.

Response: The Medicare Claims Processing Manual, Chapter 20-Section 40.1 provides that suppliers are prohibited from submitting a claim for a payment for items and services that are covered by manufacturer or supplier warranties. The supplier on record is responsible for ensuring that a claim is not submitted for items covered under a manufacturer's product warranty. To be eligible to submit a bid, DMEPOS suppliers must meet the supplier standard found in 42 CFR 424.57(c)(1), which require them to comply with applicable Federal and State licensure and regulatory requirements. FDA regulations and requirements are applicable to items paid for under the competitive bidding program just as they currently apply to items paid for under the fee schedule methodology.

Comment: One commenter noted that the proposed rule would require suppliers to provide information as requested regarding the integrity of each product sold and billed under the Medicare DMEPOS Competitive Bidding Program, as well as information on the integrity of the suppliers' businesses as a whole. The commenter believed that suppliers should not be required to provide information on product integrity as long as there is a SADMERC coding verification that the product has been approved for billing under a particular HCPCS code. The commenter also believed that a rule that would require suppliers to provide information on their business integrity was inappropriate because it would duplicate information provided during certification and accreditation.

Several commenters requested that CMS clarify whether it intends for all suppliers to have a corporate compliance program, a mission statement and operating principles, and/or other ethical aspects of their business; or clearly defined organizational conflicts of interest. One commenter recommended that the definition of ''affiliate'' be simplified for public companies with multiple locations tied to a single tax identification number so that suppliers do not have to provide the names or supplier numbers of all locations on an application for a single CBA. The commenters requested that CMS provide additional detail regarding the level of employee information it expects to be specified, for example, the highest ranking local manager and title or the chief executive officer or chief operating officer of a public company; and that CMS define the term ''customer service protocol'' because different companies define the customer service process differently.

Several commenters recommended that CMS also require each supplier to provide: a description of its corporate compliance program; its procedure for ensuring that it does not knowingly employ any individuals who have been debarred from participating in government programs; its procedure for

conducting background checks on employees who will have direct contact with beneficiaries; awards, honors, or other distinctions issued to the company; a description of its credentialing program if a subcontractor will be used to furnish items to beneficiaries; a description of its emergency preparedness plan; and a description of its process for selecting products. These commenters also recommended that CMS independently verify each supplier's disclosure by using objective measures. Two commenters suggested that CMS explain and define the requirements and terms that would be included in the RFBs, including the conflicts of interest and affiliated companies of the supplier. One commenter suggested that CMS consider requesting complete disclosure on corporate integrity agreements, entered into by the supplier as well as OIG convictions against the supplier, and that CMS conduct criminal background checks.

Response: We appreciate these comments. After consideration of the comments, we believe that the most appropriate place to list the specific information that we will need from each supplier is in the RFB. Our purpose in collecting such information is to evaluate suppliers' bids, and we have attempted to minimize the burden on bidders as much as possible. Therefore, the specific information to be collected will be detailed in the RFB. We will be requesting information such as: the supplier's identifying information; information regarding the items that the supplier would furnish if awarded a contract; financial information; and corporate integrity information

We believe that many of these items are best addressed in the quality standards and accreditation standards. We are using the RFB notice and comment period to finalize the list of items that we are going to require.

We are adding a clause to § 414.422(a) which provides that we will specify the terms and conditions in the competitive bidding contacts, and finalizing the remainder of § 414.422(a) which provides that a contract supplier must comply with all terms of its contract, including any option exercised by CMS for the full duration of the contract period and adopting revised § 414.422(a) as final.

We are adopting as final, without modifications, § 414.422(b), which provides that we will recompete the competitive bidding contacts at least once every 3 years.

We are finalizing § 414.422(c) which provides that a nondiscrimination provision will be included in each contract we enter into with a supplier under the Medicare DMEPOS competitive bidding program.

B. Change in Ownership (§ 414.422(d))

In the May 1, 2006 proposed rule, under proposed § 414.422(d), we proposed to evaluate a supplier's ownership information, its compliance with appropriate quality standards, its financial status, and its compliance status with government programs before we determine that a supplier can qualify as a contract supplier if there is a change of ownership. For this reason, we proposed that suppliers would not be granted winning status by merely merging with or acquiring a contract supplier's business. We do not want to allow suppliers to adopt a strategy of circumventing the regular bidding process by gaining winning status through acquisitions of or mergers with contract suppliers or to violate any anticompetition prohibitions. Therefore, we proposed that contract suppliers must notify CMS in writing 60 days prior to any changes of ownership, mergers, or acquisitions being finalized.

We proposed that we would have the discretion to allow a successor entity, after a merger with or acquisition of a contract supplier, to function as contract supplier when—

- There is a need for the successor entity as a contractor to ensure Medicare's capacity to meet expected beneficiary demand for a competitively bid item; and
- We determine that the successor entity meets all the requirements applicable to contract suppliers.

We proposed that the successor entity must agree to assume the contract supplier's contract, including all contract obligations and liabilities that may have occurred after the awarding of the contract to the previous supplier. The successor entity is legally liable for the nonfulfillment of obligations of the original contract supplier.

In addition, we proposed to only allow the successor entity to function as a contract supplier if it executed a novation agreement with CMS.

Comment: Numerous commenters objected to the proposed provision that would require contract suppliers to notify CMS in writing 60 days prior to any changes of ownership, mergers, or acquisitions being finalized and recommended that the 60-day prior notice provision be modified to a notice period of no more than 30 days. The commenters also recommended that if the transaction is set to close within less than 30 days, the parties should have an obligation to provide notice as soon as the parties sign a letter of intent to change ownership. One commenter suggested that notification regarding change of ownership be required within 30 days after change has occurred. The commenters believed that the proposed rule fails to take into consideration the short time period in which acquisitions/mergers occur. The commenters added that the 60-day requirement is a burdensome restraint on legitimate corporate transactions, and that acquisitions and mergers frequently occur in a much more compressed timeframe. They believed that our proposed timeframes are unrealistic, and as a result, CMS could be notified of numerous acquisitions that are not consummated. They emphasized that it is important that the prior notice requirement be optional and that notice promptly after transaction would be appropriate to protect the Medicare program and beneficiaries.

The commenters pointed out that there generally is no advance notice requirement prior to completing an acquisition and/or merger. They requested clarification that any such notices furnished to Medicare will remain confidential until the successor entity notifies CMS that the transaction has been completed. To the extent notice is required they recommended that the final rule should make it clear that notice will be confidential and exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) and implementing HHS regulations as trade secrets. The commenters also recommended that commercial or financial information obtained from a person should be privileged or confidential and that this is necessary so that public companies can appropriately maintain sensitive nonpublic information and at the same time ensure that disclosure is made appropriately when that disclosure is timely under applicable securities regulations that protect shareholders.

Response: We continue to believe that sufficient advance notice is necessary to allow us to evaluate whether a new owner will meet all of the requirements to be a contract supplier under the Medicare DMEPOS Competitive Bidding Program. However, we are revising the language under § 414.422(d)(1) to clarify what a contract supplier's obligations are in the event of a change of ownership. Specifically, § 414.422(d)(1) now provides that if a contract supplier is considering or negotiating a change in ownership, the contract supplier must notify CMS 60 days before the anticipated effective date of the change. Under § 414.422(d)(2), if the supplier that acquires or merges with the

contract supplier wishes to itself become a contract supplier, it must meet all of our requirements, including compliance with applicable quality standards, accreditation, eligibility standards, and financial standards, and must submit the documentation required in § 414.414. The new supplier that seeks to become a contract supplier must also submit a novation agreement to CMS 30 days prior to the anticipated effective change of ownership, indicating that it will assume all duties and obligations of the previous contract supplier. We have clarified in § 414.422(d) that if a new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement for CMS review. The successor entity shall submit to CMS within 30 days after the effective date of the change of ownership an executed novation agreement acceptable to CMS. We understand that the change of ownership information is highly confidential, and will make every effort to protect it as required by law.

Comment: Numerous commenters recommended that CMS retain the authority to disallow a successor entity to participate as a contract supplier only if CMS determines that allowing the successor entity to participate as a contract supplier would have significant anticompetitive effects. The commenters indicated that CMS should not unreasonably withhold its approval of a change of ownership and that CMS does not have the authority to, and, in any event, should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the CBA. They added that contract suppliers in CBAs will most likely experience an increase in the value of their business and, therefore, should be able to take advantage of the marketplace without interference from government agencies if they wish to lawfully transfer ownership.

Several commenters agreed that CMS should not allow a supplier to circumvent the bidding process through mergers or acquisitions, but suggested that the proposed rule creates a restraint of trade situation and/or devalues the business of a supplier that decides to sell the company.

In addition, several commenters recommended that CMS revise the proposed change in ownership rules so that they are consistent with existing requirements for DMEPOS suppliers. Other commenters suggested that CMS apply the change of ownership rules found in 42 CFR 489.18(a), which provides that a change of ownership for a corporation occurs when the merger or provider corporation merges into another corporation or the consolidation of two or more corporations, results in the creation of a new corporation, and states that the transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

Response: We want to evaluate whether a supplier that acquires or merges with a contract supplier and that wants to become a contract supplier itself meets our standards for being a contract supplier under the Medicare DMEPOS Competitive Bidding Program. These requirements serve the needs of the program because we do not want to encourage suppliers to adopt a strategy of circumventing the regular bidding process by gaining winning status through acquisitions of or mergers with contract suppliers not to violate any anticompetitive prohibitions.

We disagree with the commenter that suggested that we apply the change of ownership rules found in 42 CFR 489.18(a) because this section of our regulation applies only to Medicare Part A providers, such as hospitals, SNFs, and HHAs, but competitive bidding applies to Medicare Part B suppliers.

Comment: One commenter stated that the change of ownership provision should not apply when a contract supplier, as opposed to a noncontract supplier, purchases or acquires another supplier. The commenter noted that if a supplier that purchases or acquires a contract supplier does not intend to be a contract supplier, there is no reason for this requirement to apply, and if the acquiring supplier is already a contract supplier, there is no reason to require an additional review as to its qualifications. The commenter stated that while it understands the need to conduct oversight and diligence if the acquiring supplier is not a contract supplier, it requested that CMS clearly specify requirements for approval of the acquisition if the acquiring party is a contract supplier but does not intend for the supplier it acquires to be a contract supplier.

The commenter also urged that the final rule clarify that the requirements for an acquirer would be no more burdensome than the requirements to be a contract supplier because such requirements could result in an unequal burden on entities that acquire contract suppliers. The commenter stated that, if additional requirements are to be imposed, CMS should state what they are explicitly so that the public understands and can comply with them in advance of incurring substantial transaction costs.

Response: As stated in response to the previous set of comments, we plan to evaluate the same information required to be submitted by a bidding supplier if a contract supplier purchases a noncontract supplier or if a noncontract supplier purchases a contract supplier. However, if a contract supplier purchases another contract supplier, we will not ask the contract supplier to duplicate information we already have on file.

Comment: One commenter stated that CMS should be able to assure itself that the acquired supplier continues to meet all obligations and requirements for contract suppliers, and its review should be limited to a consideration of whether, post acquisition, the acquired supplier: (1) Meets all the requirements of a contract supplier; (2) is willing to assume all obligations under the contract; and (3) has executed a novation agreement. The commenter stressed that if CMS desires to encourage all suppliers to bid, the contract supplier's status as the winning bidder should be preserved as a valuable asset for consideration in any commercial transaction.

Other commenters were concerned about the following issues: the successor's liability for potentially fraudulent activities that could have occurred on the previous company's watch; instances where the new contract supplier determines a revised Certificate of Medical Necessity (CMN) is needed and the physician or treating practitioner is no longer in practice or refuses to execute a new CMN; and the tax implications of restricting change of ownership transactions to only stock transactions. The commenter observed that there may be instances where the sale of a supplier because of the death of the owner would be prohibitively expensive if executed as a stock transaction, leaving the widow with little money and no recourse to dispose of the business.

Response: As we stated earlier, our requirements regarding change of ownership are intended to provide us with assurance that the successor entity meets all of our requirements before we can consider it to be eligible to assume the previous contract supplier's contract. A new contract supplier will be responsible for meeting all CMS program requirements.

After consideration of the public comments received, in this final rule we are finalizing § 414.422(d) as discussed above.

C. Suspension or Termination of a Contract (§§ 414.422(f) and (g))

In the May 1, 2006, proposed rule (71 FR 25682), we specified that contract suppliers would be held to all the terms of their contracts for the full length of the contract period (proposed § 414.422(f)). Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, would constitute a breach of contract. We indicated that, if we conclude that the contract supplier has breached its contract, the actions we might take include, but are not limited to, asking the contract supplier to correct the breach condition, suspending the contract, terminating the contract for default (which might include reprocurement costs), precluding the supplier from participating in the competitive bidding program, or availing ourselves of other remedies permitted by law. We indicated that we also would have the right to terminate the contract for convenience (proposed § 414.422(g)).

Comment: Several commenters believed that CMS must include additional procedural safeguards for contract suppliers before terminating their contracts. The commenters suggested that CMS give a contract supplier notice that it believes the supplier has breached its contract, an opportunity and adequate timeframe for the contract supplier to cure the breach, and a review or appeal mechanism if the contract supplier's contract is terminated. One commenter stated that contract suppliers should only be terminated for ''material breach'' of their contracts.

Another commenter noted that the proposed rule grants CMS the unilateral right to terminate a contract without cause which eliminates a principal advantage for contract suppliers. The commenter stressed that without modification of the proposed rule, suppliers would be dissuaded from submitting the lowest bid possible because they would have to calculate the financial risk of termination and compensate for this uncertainty in their bid prices.

Another commenter stated that it is reasonable for CMS to expect that contract suppliers will be held to all the terms of their contracts for the full length of the contract period. Two commenters objected to the provision stating that CMS may include reprocurement costs if a contract supplier's contract is terminated because the contract supplier cannot know Medicare's reprocurement cost structure. One commenter asked whether the provision stating that CMS could preclude a contract supplier that breached its contract from participating in the competitive bidding program referred only to the program in the supplier's CBA or the entire Medicare DMEPOS Competitive Bidding Program.

Response: We believe that defining a breach of contract as any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, will help ensure that contract suppliers do not breach their contract requirements. We have set out a variety of potential actions of varying levels of severity that we could take in the event of a breach of contract, such as requiring that contract supplier submit a plan to correct the deficiency that created the breach of contract, suspending the contract, precluding the contract supplier from participating in the competitive bidding program in the future, revoking the supplier number of the contract supplier, and/or availing ourselves of other remedies allowed by law. In deciding which course of action to take, we will consider the nature of the breach, including whether the breach is indicative of a substantial failure to comply with the terms of the supplier's contract, and the extent to which the efficient and effective administration of the Medicare program has been compromised by the breach.

We are making several changes to the proposed rule. In response to the comments which addressed the potential problems that might stem from our proposal to permit CMS to require terminated suppliers to reimburse CMS for reprocurement costs, proposed at § 414.422(f)(2)(iii), we are deleting that proposal. We are also making several revisions to our proposal to permit CMS to terminate a contract with a contract supplier in the event of a breach of contract or to take other action against a supplier after a breach of contract has occurred. We have eliminated the phrase ''for default'' from § 414.422(f)(iii). We have revised the wording to state that CMS may ''[t]erminate the contract.'' We believe that this is consistent with CMS' approach to contracts and agreements with providers, suppliers and other contracted entities in other areas of the Medicare program. CMS will have the authority to terminate a contract with a contract supplier where a breach of contract has occurred.

CMS is making several other minor clarifications to the language at § 414.422(f). Specifically, at § 414.422(f)(2)(i), we proposed that CMS could require a contract supplier to ''correct the breach condition'' where a breach of contract had occurred. We are revising this language to state that CMS may ''[r]equire the contract supplier to submit a corrective action plan.'' Also, at § 414.422(f)(2)(ii), we proposed that in the event of a breach of contract, CMS could ''[s]uspend performance under the contract.'' We are revising this language to state that in the event of a breach of contract, CMS can ''suspend the contract supplier's contract.''

CMS agrees with the need for procedural safeguards where CMS is taking action to terminate a contract supplier's contract. CMS will provide further guidance regarding the appeal procedures available to contract suppliers for termination actions, as well as other enforcement actions involving contract supplier contracts, at a future date.

Comment: One commenter requested greater clarification of the phrase ''for convenience'' used in the preamble to the proposed rule (71 FR 25682) to describe a basis for CMS to terminate a contract. The commenter stated that at a minimum there should be an explicit notice period required prior to termination. Another commenter recommended deleting this provision.

Response: In response to comments, CMS has decided to delete this provision.

Comment: One commenter stated that the proposed rule does not explicitly prohibit the Secretary from unilaterally changing the price of an item in a CBA during the term of the competitive bidding contract. Several commenters also stated that there should be a provision that allows suppliers to terminate, without being in breach of contract, in cases of hardship or material change in circumstances that are not the fault of or within the control of the supplier if unexpected circumstances arise that hinder its ability to render performance. Another commenter stated that the lack of parity in the ability of the contracting parties to terminate may serve as an impediment to many potential bidders' submission of the lowest possible bid.

Response: Each supplier contract under each competitive bidding program will identify the product categories, items, and single payment amounts for items furnished under that program. The single payment amount for each item in each contract will not change for the duration of the contract, with the only exception being in limited cases where a HCPCS code is divided or merged as provided in § 414.426. However, even where § 414.426 applies, the total single payment amounts for the sum of the item components, the newly

separated item(s), or the newly combined item will be equal to the single payment amounts that were originally listed in the contract. Contract suppliers will be held to all of the terms of their contracts for the length of the contract period and we will not allow them to suspend their performance under their contracts without consequences because of the potential hardship that the Medicare program and beneficiaries could suffer if there were no longer enough contract suppliers to furnish one or more product categories in a CBA. If a supplier breaches its contract with CMS, we have the right to ask the contract supplier to correct the breach, suspend the contract, terminate the contract, or preclude the supplier from participating in the Medicare Competitive Bidding Program. We do, however, recognize the hardships may arise for contract suppliers and we will take this into consideration as we decide what appropriate actions should be taken in the event of a breach.

Comment: One commenter suggested that contract suppliers should have the ability to exit the program with a 90-day notice. The commenter stated that this will allow the bidders that may have failed to meet quality standards and reach their market expectations to exit in a business-like manner.

Response: As we explained above, we are selecting a sufficient number of contract suppliers to furnish each product category in each CBA, and allowing contract suppliers to terminate their contracts may impede beneficiary access to competitively bid items and otherwise result in a hardship for the Medicare program. Contract suppliers are expected to comply with their contracts for their entire duration.

After consideration of the public comments received, in this final rule, we are finalizing the breach of contract and termination provisions in §§ 414.422(f) and (g) with the changes described above.

X. Administrative or Judicial Review of Determinations Made Under the Medicare DMEPOS Competitive Bidding Program (§ 414.424)

Section 1847(b)(10) of the Act provides that there will be no administrative or judicial review of determinations made under section 1869, section 1878, or any other section of the Act, for the—

- Establishment of payment amounts under a competitive bidding program;
- Awarding of contracts under a competitive bidding program;
- Designation of CBAs for the Medicare DMEPOS Competitive Bidding Program;
- Phased-in implementation of the Medicare DMEPOS Competitive Bidding Program;
- Selection of items for a competitive bidding program.
- Bidding structure and number of contract suppliers selected under a competitive bidding program.

In the May 1, 2006, proposed rule (71 FR 25682), we proposed to incorporate in a new proposed § 414.424 the provisions for no administrative or judicial review of the determinations specified in section 1847(b)(10) of the Act listed above. We indicated that the proposed regulation would have no impact on the current beneficiary or supplier right to appeal denied claims. However, neither the beneficiary nor the supplier would be able to bring such an appeal if a competitively bid item was furnished in a CBA in a manner not authorized by this rule.

Comment: A number of commenters agreed that the proposed rule tracked the provisions of the Act, which does not provide for administrative or judicial review under the Medicare DMEPOS Competitive Bidding Program. However, many of the commenters believed that CMS should establish some type of grievance and review process to provide contract suppliers an opportunity to review the competitive bidding process and to challenge the outcome of the bid evaluation process and the selection of contract suppliers. One commenter added that because Medicare is required to make available to the public the final process documentation under the Freedom of Information Act requirements, it is only fair that CMS also provide an opportunity for suppliers to challenge any decisions in this documentation.

Two commenters asserted that the statutory limitations on administrative and judicial review do not preclude the establishment of a process that would give suppliers an opportunity to communicate with CMS regarding grievances and seek redress. They asserted that the implementation of such a process would be consistent with Constitutional due process rights. One commenter recommended that CMS establish some type of expedited review process specific to contract award decisions and urged full transparency of factors influencing contract award decisions in order to support the highest level of integrity in the process. One commenter recommended that CMS keep in place all current mechanisms to defend the supplier's rights, including the Administrative Law Judge review.

One commenter believed that the nonavailability of administrative review violates not only the Administrative Procedure Act but also individual and corporate rights to due process and to redress grievances. The commenter recommended that appeal rights be restored as these rights exist elsewhere in the Medicare program.

Response: We understand the commenters' concerns. However, we believe that Congress enacted section 1847(b)(10) of the Act to avoid any delay or disruption in the implementation of the program caused by challenges and appeals regarding specified aspects of the Medicare DMEPOS Competitive Bidding Program. We intend to conduct an extensive education and outreach program to ensure that the suppliers are educated about the rules and provisions of the program and understand the contract selection process and what is required of bidding suppliers. In addition, we will be providing the suppliers with a 60-day open bidding period during which they can change, update, or correct their bid packages before certifying their final submissions.

Comment: Numerous commenters recommended that CMS include a procedure for debriefing suppliers that were not selected as contract suppliers and provide an opportunity for a review to determine, at a minimum, whether an error on the part of CMS or its contractors was the reason that the supplier lost the bid.

Several commenters recommended that CMS put appropriate procedures in place for bidders to ensure that calculations related to their bids are reviewed for accuracy and that these procedures provide suppliers an opportunity to redress issues such as simple calculation errors. One commenter pointed out that because the review and award of contracts under the competitive bidding program will be labor intensive, it is likely that there will be many inadvertent human and computer errors and/or indisputably arbitrary decisions. The commenter pointed out that while the statute grants CMS discretion in making determinations under the competitive bidding program, Congress has not granted CMS the authority to render moot the authority of published regulations by using known improper or erroneous information to implement those regulations. Therefore, the commenter recommended a ''reconsideration process'' with regard to the award of contracts only, and delegation of authority to the Provider Reimbursement Review Board or some similar body within the Medicare program to hear such requests for reconsideration. The commenter acknowledged that under this process,

the agency's decisions would not be administratively or judicially appealed. However, the commenter pointed out that the establishment of a reconsideration process would, at least, enable errors to be corrected.

Response: In accordance with section 1847(b)(10) of the Act, we proposed that there will be no administrative or judicial review for the awarding of contracts or the establishment of payment amounts under a competitive bidding program. We believe that Congress enacted section 1847(b)(10) of the Act to avoid any delay or disruption in the implementation of the program that could arise if we had to defend numerous challenges and appeals brought by losing bidders. We intend to conduct an extensive education and outreach program to ensure that suppliers are educated about the rules and provisions for the program. In addition, we are developing a quality assurance system to ensure that bids submitted to us are correctly identified and recorded. We intend to allow bidders to submit electronic bids. Bidders will have an opportunity to review their bids and certify their accuracy prior to submission. Bidders will be able to modify or change their bids at any time during the bidding window. In addition, the CBIC will have in place an auditing system and quality assurance program to monitor and ensure that it accurately records and calculates the information furnished by suppliers. We will also be notifying all losing bidders, but believe it would not be administratively feasible to provide debriefings for all losing bidders, due to logistics, volume of bidders, and time constraints.

Comment: One commenter strongly objected to the lack of administrative or judicial oversight of the process. The commenter stated that the Medicare DMEPOS Competitive Bidding Program is a procurement program by which CMS seeks to acquire the same types of commercial items that it acquires for itself in accordance with the FAR. The commenter firmly believed that considering the number of procurements that are set aside each year by GAO and the United States Court of Federal Claims based on government error, CMS should allow administrative or judicial review. The commenter believed that the proposal could lead to arbitrary and erroneous awards, if not fraud. The commenter suggested that CMS clarify that all contract awards and invitations to participate will be subject to the traditional review of procurements conducted by the Government. The commenter added that regardless of whether CMS possesses the right to waive the FAR and avoid judicial or administrative oversight, prudence and the obligation to maintain integrity in the procurement process that it is developing require that CMS open the process up to protect review.

Response: We disagree with these comments. The Medicare DMEPOS Competitive Bidding Program is a unique program that differs in many ways from traditional government procurement. We are bound to implement this program in accordance with the statute, which as noted earlier in this section, provides that there will be no administrative or judicial review of certain functions. In the proposed rule we provided notice to the public of how we intend to implement the Medicare DMEPOS Competitive Bidding Program, and this final rule responds to the public's comments.

Comment: A number of commenters pointed out that even though CMS acknowledged in the preamble of the proposed rule that the existing rights of beneficiaries and suppliers to appeal denied claims are undisturbed by competitive bidding, the proposed regulatory language of § 414.424 as written does not make clear that these existing rights are unaffected. The commenters suggested the addition of language in § 414.424 to clarify that these rights would be preserved. Three commenters also indicated that the statement in the regulation that ''[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart'' is vague as written and suggested that the statement be rewritten for clarification or removed. One commenter suggested that CMS add language to state that ''A claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.''

Response: In this final rule, we have revised the language in § 414.424(b) to clarify that there are no appeal rights for claim denials if the denial is based on our determination that a competitively bid item was furnished in a CBA in a manner not authorized by 42 CFR Part 414 Subpart F.

After consideration of the public comments we received, we are adopting as final, with technical clarifications, the provisions of proposed § 414.424.

XI. Opportunity for Participation by Small Suppliers (§§ 414.402, 414.414(g))

Section 1847(b)(6)(D) of the Act requires us, in developing bidding and contract award procedures, to take appropriate steps to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards.

Size definitions for small businesses are, for some purposes, developed by the Small Business Administration (SBA) based on annual receipts or employees, using the North American Industry Classification System (NAICS). Based on the advice from the SBA, we expect that most DME suppliers will fall either into NAICS Code 532291, Home Health Equipment Rental, or NAICS Code 446110, Pharmacies, since the SBA defines these small businesses as businesses having less than $6.5 million in annual receipts.

In the May 1, 2006 proposed rule (71 FR 25682), we proposed using the SBA's small business definition when evaluating whether a DMEPOS supplier is a small supplier. We relied on the expertise of the SBA to determine what constitutes the appropriate definition of a small supplier. We proposed that all contract suppliers would be expected to service the whole CBA. However, we considered allowing a small supplier that has fewer than 10 full-time equivalent (FTE) employees to designate a geographic service area that is smaller than the entire CBA. We did not propose this approach because we want to ensure that beneficiaries have the choice of going to any contract supplier in their respective CBA. Carved-out areas could lead to confusion for beneficiaries faced with multiple competitive bidding subareas. Further, we believe such an approach would allow selection of more favorable market areas by smaller businesses potentially leading to an unfair market advantage. We sought comments on this issue.

Information available to us on the size distribution of businesses that provide DMEPOS indicates that the majority of suppliers in the DMEPOS industry qualify as small businesses according to the SBA definitions. Our analysis of DMEPOS claims data suggests that at least 90 percent of DMEPOS suppliers had Medicare allowed charges of less than $1 million in CY 2003. The figure of $1 million could be an underestimate of total receipts because it does not include non-Medicare receipts and non-DMEPOS receipts, but it does suggest that most DMEPOS suppliers are small.

Although section 1847(b)(6)(D) of the Act focuses on ensuring participation in the bidding, and not on bidding outcomes, we believe that it is worth

noting how small suppliers fared in the bidding in the Medicare competitive bidding demonstration projects. Both small and large suppliers were selected as demonstration suppliers. Some small suppliers that were selected as demonstration suppliers were able to increase their market share substantially during the demonstration. Others experienced little change in market share.

We recognize the importance, benefits, and convenience offered by the local presence of small suppliers. In the May 1, 2006 proposed rule, we proposed to take the following steps to ensure that small suppliers have the opportunity to be considered for participation in the program.

First, as required by section 1847(b)(4)(B) of the Act, we will select multiple winners in each CBA. If a single winner was selected in an area, a small supplier would have difficulty participating in the competition because the supplier, as a minimum, would have to demonstrate that it could rapidly expand to serve the entire projected demand in the area. Selecting multiple suppliers should make it easier for small suppliers to participate in the program.

Second, we proposed to conduct separate bidding competitions for product categories, allowing suppliers to decide how many product categories for which they want to submit bids, rather than conduct a single bidding competition for all DMEPOS items and other equipment. We believe that separate competitions for product categories will encourage participation by small suppliers that specialize in one or a few product categories. If a single competition was held for all DMEPOS items and other equipment, small, specialized suppliers would have to either significantly expand their product and service offerings or submit bids for items they currently do not provide.

We stated that we recognize the importance of small suppliers in the DMEPOS industry, and we welcomed comments on the options identified in the proposed rule. We also expressed interest in other ways to ensure that small suppliers have opportunities to be considered for participation in the program.

To collect additional information on this issue, we contracted with RTI International to conduct focus groups with small suppliers. The purpose of the focus groups was to gather input on ways to facilitate participation by small suppliers in the program. The focus groups also discussed the impact of the requirement for the quality standards and accreditation, which will affect all small suppliers, regardless of whether they seek to participate in a competitive bidding program. As we indicated in the proposed rule, we reviewed our efforts to ensure participation by small suppliers in the Medicare DMEPOS Competitive Bidding Program after we reviewed public comments on the proposed rule and the results of the focus groups. We also considered the findings of the focus groups, along with the additional options and comments presented on the proposed rule, in developing this final rule.

Comment: Several commenters requested that CMS share the findings of the focus groups.

Response: Nine focus groups were conducted, during April and May 2005, with DMEPOS suppliers that had less than $3 million in gross revenue and employed up to 10 FTE employees. The purpose of the focus groups was to explore small DMEPOS suppliers' thoughts and opinions on the potential impact of quality standards, accreditation, competitive bidding, and financial standards requirements on their businesses. We presented an overview and results of the focus groups related to quality standards and accreditation to the PAOC on September 26, 2005. This PowerPoint Presentation can be accessed at http*://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp#TopOfPage*.

The results of the focus groups related to competitive bidding and financial standards were presented to the PAOC on May 23, 2006. Several focus group participants remarked that the competitive bidding process would force many small suppliers out of business. The participants suggested alternatives to competitive bidding, including: (1) CMS should determine product prices and allow all willing suppliers to provide products at the set price; and (2) CMS should reserve a percentage of winning bids for small suppliers. Many participants believed that lower payment rates for suppliers would inevitably lead to lower quality goods and services. Participants were particularly emphatic in their belief that CMS continues to neglect the valuable service component that small suppliers provide to their customers. They believed that it is their commitment to service that sets them apart from the national companies. A number of participants were concerned about the possibility of requiring small supplier bid winners to furnish items in the entire MSA, given the fact that some MSAs cross State boundaries. There was also a consensus among these small suppliers that the impact of competitive bidding would differ by product line. They believed that items involving high-end technology equipment, respiratory equipment, and customized products are more service intensive than other products, such as standard wheelchairs, that involve fewer repairs, set-up time, and patient education.

Inclusion of mail order businesses in competitive bidding was also a controversial issue for many participants. Because mail order businesses often do not have a physical storefront and do not provide patient education, small suppliers argued that such businesses are in violation of the 21 Medicare supplier standards.

Finally, many participants in the focus groups believed that tax returns, quarterly standard financial statements, and Dun & Bradstreet were helpful sources of information about a business's credit history and cash flow. The participants noted that suppliers that grossed over $3 million in revenue used audited financial statements, whereas suppliers that grossed less than $3 million in revenue used cash basis accounting principles. A summary of the PAOC discussion related to the focus group results can be accessed at http*://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/PAOC_summary.pdf*. We have used the comments from the focus groups and the public comment process in developing our final policies for the Medicare DMEPOS Competitive Bidding Program.

Comment: Several commenters noted that section 1847(b)(6)(D) of the Act is entitled ''protection'' of small suppliers and not the mere identification of small suppliers. They reported that there are currently 40,000 practitioners, providers and suppliers enrolled as Medicare suppliers, including approximately 1,078 physical therapists. They agreed with the option to define small supplier as fewer than 10 FTE employees. The commenters stated that health care practitioners who provide DMEPOS as an integral part of their professional services specialize in providing items for specific conditions. They added that these suppliers offer considerable expertise in evaluating both the patient and the item in order to provide the patient with the best possible outcome. They also believe that small suppliers serve rural and underserved urban communities where larger suppliers may not operate.

The commenters proposed the following alternative policies: (1) At least 50 percent of suppliers that receive a contract should be small suppliers (based on $3 million or less in revenue or less than 10 FTE employees); (2) CMS should allow suppliers with less than 10 FTE employees to furnish items to less

than the entire CBA; (3) CMS should award contracts to small suppliers with the lowest bids that exceed the pivotal bid; (4) CMS should allow truly small suppliers to promise to accept the single payment amount; and (5) CMS should establish a certain volume of items in each geographic area that will be ''set-aside'' for small suppliers.

Response: We agree that section 1847(b)(6)(D) of the Act is entitled ''Protection of Small Suppliers.'' We recognize the concerns raised by the commenters and have considered the suggested alternatives provided during the small supplier focus groups and through the public comment process. We also recognize the importance of maintaining storefront capabilities to meet the needs of beneficiaries. In this final rule, we are revising our proposed policies to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. As of January 2006, the SBA defines a small business as generating less than $6.5 million in annual receipts. The SBA definition refers to small businesses rather than ''small suppliers.'' We believe that $6.5 million is not representative of small suppliers that provide DMEPOS items to Medicare beneficiaries, as it would encompass too many suppliers. In coordination with the SBA, we are defining a small supplier as a supplier that generates gross revenue of $3.5 million or less in annual receipts and we are revising § 414.402 to include this definition. We would accept relevant documentation from a supplier that shows its sales volume, including information that would qualify as a ''receipt'' under 13 CFR 121.104 to determine if the supplier meets this definition. Before we receive supplier bids, we would not have information on each supplier's total revenue. We only have information on suppliers' Medicare revenues. As a result, we had to make an assumption about what percent of a supplier's revenues come from Medicare. We looked at filings by public DMEPOS companies and, based on that information, we assume one-half of the average supplier's revenues come from Medicare DMEPOS.

To ensure the participation of multiple suppliers and storefront locations, beneficiary access, and increased participation by small suppliers, we have revised our rules as noted below:

- The definition of a ''small supplier'' is a supplier that generates gross revenue of $3.5 million or less in annual receipts.
- To help small suppliers to have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program and to generally support HHS' goals for contracting with small businesses, we have also established a target number for DMEPOS small supplier participation in each competitive bidding program. Our target number for small supplier participation will be determined by multiplying 30 percent times the number of suppliers that have met our bidding requirements and whose composite bids are at or lower than the pivotal bid for each product category in each CBA. The number resulting from this multiplication represents our goal for small supplier participation for that product category. We will then count to see if the number of suppliers whose composite bids are at or below the pivotal bid is equal or greater than the target number we have computed for that product category. If the number of suppliers is lower than the target number, we will give the small supplier whose composite bid is above the pivotal bid, but closest to it of all the small suppliers whose composite bids are above the pivotal bid for the product category, the option of accepting a contract to furnish the product category at the single payment amounts. If the target number is still not met, we will offer a contract to the small supplier whose composite bid is the next closest to, but above, the pivotal bid, and will use this methodology until we reach the target number or there are no additional small suppliers that submitted a bid for the product category. We are codifying this methodology in final § 414.414(g)(1).

Comment: Many commenters disagreed with using the definition of the SBA for a ''small business'' (less than $6 million in annual receipts) because the CY 2003 Medicare data showed that at least 90 percent of suppliers had less than $1 million in allowed charges. They recommended defining a small supplier as a supplier that generates less than $3 million in annual receipts. The commenters believed that a lack of small supplier participation would negatively impact patient care. They added that small businesses would have to endure large expenses in order to participate in the Medicare DMEPOS Competitive Bidding Program.

Response: We agree with the commenters and, as we explained above, we have modified our definition of a small supplier so that it now means a supplier that generates gross revenue $3.5 million or less in annual receipts.

Comment: A few commenters indicated that conducting separate bidding processes for individual product categories is administratively burdensome. They stated that CMS' assumption that large suppliers could expand their products by offering supplies and equipment easier or more quickly than small suppliers is a false view of a company's ability to expand. They also reported that large organizations must seek approval from their boards or other stakeholders before they can undertake certain business expansion activities.

Response: We appreciate the comment but believe that conducting separate bidding processes for individual product categories will encourage the participation of small suppliers that specialize in one or a few product categories. It is our goal to allow Medicare beneficiaries an opportunity to receive all related equipment from the same supplier, thereby minimizing disruption to the beneficiary. Suppliers currently specialize in particular products, and we do not see this process being interrupted by competitive bidding.

After consideration of the public comments received, in this final rule, we are adding a definition of ''small supplier'' at § 414.402 and finalizing § 414.414(g), with revisions sets forth our methodology for ensuring that a sufficient number of small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program.

XII. Opportunity for Networks (§§ 414.402, 414.418)

In the May 1, 2006 proposed rule (71 FR 25683), we proposed to allow suppliers the option to form networks for bidding purposes (proposed § 414.418). In the proposed rule, we refer to networks as several companies joined together through some type of legal contractual relationship to submit bids for a product category under competitive bidding. This option would allow suppliers to band together to lower bidding costs, expand service options, or attain more favorable purchasing terms. We recognize that forming a network may be challenging for suppliers, and it also poses challenges for bid evaluation and program monitoring. Networking was included as an option in the Medicare competitive bidding demonstration project, but no networks submitted bids. Still, we believe that networking may be a useful option for suppliers in some cases. Therefore, we proposed to offer it as an option. If suppliers decide to form

networks, we proposed that the following rules must be met:

- A legal entity must be formed for the purpose of competitive bidding, such as a joint venture, limited partnership, or contractor/subcontractor relationship, which would act as the applicant and submit the bid. We specifically requested comments regarding other types of suitable arrangements that would not require suppliers to form a new legal entity but would allow them to form a network for purposes of submitting bids. For example, one supplier could be designated as a primary contractor and the other suppliers in the group would function as subcontractors. In this example, if the contract with the primary contractor was terminated, the contracts with the subcontractors would also be terminated, thus nullifying the entire contract.
- All legal contracts must be in place and signed before the network entity can submit a bid for the Medicare DMEPOS Competitive Bidding Program.
- Each member of the network must be independently eligible to bid. If a member of the network is determined to be ineligible to bid, the network would be notified and given 10 business days to resubmit its application.
- Each member must meet any accreditation and quality standards that are required. Each member is equally responsible for the quality of care, service, and items that it delivers to Medicare beneficiaries. If any member of the network falls out of compliance with this requirement, CMS would have the option of terminating the network contract.
- The network cannot be anticompetitive. We proposed that the network members' market shares for competitively bid item(s), when added together, cannot exceed 20 percent of the Medicare market within a CBA. We believe that, by setting the maximum size of the network's market shares at 20 percent of the marketplace, firms will be able to gain the potential efficiencies of networking while at the same time ensure that there would continue to be competition in the area. If the 20-percent rule were adopted and suppliers joined networks, there would still be at least 5 networks competing in a DMEPOS competitive bidding program, which we believe would allow for sufficient competition among suppliers. In particular, we requested comments about what percentage of the marketplace would be appropriate for networks for suppliers.
- A supplier may only join one network and cannot submit individual bids if it is part of a network. The network must identify itself as a network and identify all members in the network.
- The legal entity would be responsible for billing Medicare and receiving payment on behalf of the network suppliers. The legal entity would also be responsible for appropriately distributing payments to the other network members.

Comment: Many commenters expressed concern about potential violations of Federal antitrust laws that could arise under the proposed network provisions. For example, they expressed concern that forming a network could violate the Federal antitrust laws because those laws do not permit suppliers to reach a mutual consensus on pricing. They also stated that the proposed rule would require suppliers to agree on proposed prices for all items within a competitive bidding product category. A commenter expressed concern that networks consisting of a large number of suppliers would not be legitimate under the antitrust laws. The commenter also expressed concern that the proposed network policy could be falsely interpreted as providing a safe harbor from the antitrust laws.

Many commenters believed that the option to form a network is not a realistic solution for ensuring that small suppliers participate in the competitive bidding program. They further believed the proposed rule is complex, and that suppliers would not have sufficient time to form a network and comply with all the requirements to meet the competitive bidding implementation timelines. A commenter indicated that the network option would reduce potential burdens on small suppliers and specifically recommended limiting the network option to small suppliers.

Response: We strongly agree that networks must not violate antitrust laws and that networks must take steps to ensure that they are not in violation of Federal antitrust laws. We emphasize that suppliers that pursue the network option must comply with all applicable Federal antitrust laws, and we will reject a network bid if we believe it has been prepared in violation of those laws. We will also refer any suspected cases of Federal antitrust violations to the Department of Justice for further review. In response to comments voicing concern that the network formation process could implicate the Federal antitrust laws, we will now require that each network member sign a statement in the bid submitted by the network certifying that the supplier joined the network because it is unable to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA. The inclusion of this certification from all network members will help assure us that each network member joined the network for a legitimate, legal purpose (that is, it cannot otherwise compete because it is unable to furnish the product category throughout the entire geographic area of the CBA).

The network option is a key piece of our efforts to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. In response to comments requesting that networks be limited to small suppliers, we will limit network participation to small suppliers which, as we explained previously, will now be defined as suppliers that generate gross revenue of $3.5 million or less in annual receipts. We have revised § 414.418 to add this provision. We believe that this modification to our proposal will help ensure that the competition in each CBA is actually a competition between suppliers of all sizes and that it is not dominated by a limited number of networks comprised only of large suppliers that, in our estimation, should be able to compete independently. In addition, in response to concerns that networks would be anti-competitive if they had excessively large number of members, the size of each network will be limited to 20 suppliers because with 20 suppliers, each network member would generally be responsible for furnishing items to no more than 5 percent of the geographic area of the CBA. We believe that this limit would protect against excessively large, anti-competitive networks while allowing small suppliers to have an opportunity to be considered for participation under the Medicare DMEPOS Competitive Bidding Program.

Finally, to further implement networking rules that promote a robust competition and protect the Medicare DMEPOS Competitive Bidding Program against anticompetitive behavior, we are deleting the provision at proposed § 414.418(b)(2) that would have allowed networks 10 business days to resubmit bids that CMS rejected because we determined that a network member was ineligible to bid. In order not to allow networks with an unnecessary advantage over other suppliers, we are deleting this provision because we do not allow other suppliers not in a network this opportunity. Also, we are finalizing our proposal that at the time of bidding, the network's total market share for each product category that is the subject of the network's bid cannot

exceed 20 percent of the Medicare demand for that product category in that CBA.

Once again, we stress that these rules are intended to assist us in evaluating network bids and to protect the Medicare program against anticompetitive behavior, and they should not be interpreted as superseding any Federal laws or regulations that protect against anticompetitive behavior.

We acknowledge that forming a network may pose some challenges. However, we believe that networks are a realistic solution for small suppliers because we recognize that it may be difficult for small suppliers to service the entire CBA independently. We continue to believe that networks are an appropriate option for small suppliers that cannot independently service the entire CBA to be able to participate in the Medicare DMEPOS Competitive Bidding Program and to promote competition and efficiencies that could improve services to beneficiaries. The proposed rule was published May 1, 2006. We believe sufficient notice has been given for these suppliers to consider network options and plan accordingly. Forming a network is a business decision, and we believe that our network policy is constructed in a way that will help ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program.

Comment: A few commenters agreed with our proposal to require that suppliers participating in a network form a discrete legal entity and stated that this would prevent the commingling of Medicare funds, as well as violations of the Federal anti-kickback statute, self-referral rules and regulations, and allegations of unfair business practices among the participating network suppliers. Other commenters believed that requiring each network to bid independently defeats the entire purpose of networking. They disagreed with the primary legal entity being responsible for billing Medicare and receiving the payments. They believed that each supplier should be responsible for its own finances.

Response: We appreciate the support for our proposal that each network must form a legal entity. Each member of the network must meet all the applicable eligibility, financial, and accreditation requirements in order to be awarded a contract and this information must be included with the network bid. The legal entity that submit a bid on behalf of the network must provide all the information required for each member of the network. We agree that a primary supplier should not be responsible for submitting claims to Medicare and receiving payment on behalf of all network member suppliers and are deleting that requirement. We will now require each network member to submit its own Medicare claims and receive payment for those claims.

Comment: A few commenters believed that networks that submit bids to furnish more than one product category could create access problems for beneficiaries because not all the network members will furnish all the product categories. They recommended that CMS add requirements to ensure that network bids are scrutinized to ensure that each network has appropriate mechanisms to service the entire CBA.

Response: All the members of a network must be able to jointly service an entire CBA. While networks can choose the product categories for which they will submit a bid, once a contract is awarded to a network, each member of the network must furnish all of the items within the product categories for which the network is awarded a contract. Also, we will consider each product category separately and ensure there is sufficient supplier capacity within a CBA to meet beneficiary demand for items within all product categories.

Comment: A few commenters requested that CMS disclose the methodology that will be used to calculate the market share and monitor changes over the course of the contract. A few commenters questioned why a limit of 20 percent of the market share was assigned to the network, leaving 80 percent of the Medicare market for a large company. They suggested allowing network members to obtain market share not to exceed 35 percent, as specified in the Department of Justice monopoly guidelines.

Response: We believe that by setting the maximum size of a network's shares at 20 percent of the marketplace at the time of bidding, we will be able to ensure that there will continue to be competition in the area because if all of the winning suppliers are networks, there would still be at least 5 networks. However, once a supplier/network receives a contract, there is no limit on what percentage of the demand in the CBA that the supplier/network can furnish. After winning suppliers are selected, we will not exclude networks or suppliers from expanding and exceeding the 20 percent capacity. We believe that this will ensure sufficient suppliers, provide beneficiaries with more variety and choice, and will ensure that we select a sufficient number of contract suppliers for each product category in each CBA.

Comment: Some commenters suggested that CMS allow suppliers to join up to two networks, stating that many suppliers currently participate in several networks. They believed that this would ensure that the participating supplier is not disadvantaged by a requirement to commit to a single network bid.

Response: We agree with the commenters. We will allow small suppliers to join more than one network, but a small supplier cannot join more than one network that submits a bid to furnish items in the same product category in the same CBA. We believe that this rule is necessary because, without it, the competitive bidding process would be undermined if small suppliers were allowed to bid against themselves to furnish the same product category in the same CBA. In addition, a small supplier would not be able to submit an individual bid to furnish the same product category in the same CBA for which the network in which it is a member is also submitting a bid. However, a small supplier that wishes to furnish two different product categories in a single CBA would be able to join one network that submits a bid to furnish one of the product categories, and another network that submits a bid to furnish the other product category. Provided the small supplier did not join a network to furnish the same product category in the same CBA, the small supplier would also be able to submit an individual bid to furnish the product category.

Comment: A few commenters asked how networks would obtain a supplier billing number.

Response: The Medicare competitive bidding implementation contractor will assign each network a bidder number that will be used to monitor the network. As stated earlier, each member of the network will be allowed to submit its own claims and receive Medicare payments directly.

Comment: A few commenters requested that CMS clarify whether each supplier that is a member of a network would be required to furnish all of the items for the product category for which the network submits a bid.

Response: Each member of the network would be required to furnish all the items within the product category for which the network submits a bid. This is consistent with our requirement that all contract suppliers must furnish all items in a product category. However, as explained above,

network members would not be required to furnish the items in the product category throughout the entire geographic area of the CBA, provided that the network as a whole can fulfill this requirement.

After consideration of the public comments we received, we are adding a definition of the term ''network'' to § 414.402 that provides that a network is an entity meeting the requirements of § 414.418. We are also finalizing § 414.418 as discussed above and with additional technical changes.

XIII. Education and Outreach for Suppliers and Beneficiaries

In the May 1, 2006 proposed rule (71 FR 25683 through 25684), we proposed to undertake a proactive education campaign to provide suppliers and beneficiaries with information about the Medicare DMEPOS Competitive Bidding Program. In the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354), we responded to public comments we received on the May 1, 2006 proposed rule on our education and outreach services proposal and finalized our rule. We refer readers to the FY 2007 IRF final rule for a full discussion of these provisions.

As we indicated in the proposed rule, we have established the following Web site; *https://www.cms.hhs.gov/competitiveacqfordmepos/01_overview.asp* where RFBs and other pertinent program information will be posted and we plan to alert the supplier community by email of all postings on this Web site. In addition, we will be providing education and outreach to suppliers on requirements for submitting RFBs. Suppliers must fully complete the RFB in order to be considered for participation in a competitive bidding program. The RFBs will require suppliers to complete, at a minimum, such documents as an application, bidding sheet, bank and financial information, and referral source references. We stated that we will establish an administrative process to ensure that all information that the supplier submitted is accurately captured and considered in the bid evaluation process. This process will ensure that all the information submitted by each supplier is included as part of the bid evaluation process.

XIV. Monitoring and Complaint Services for the Medicare DMEPOS Competitive Bidding Program

In the May 1, 2006 proposed rule (71 FR 25684), we stated that moving to a competitive bidding environment would not adversely affect CMS' program integrity efforts in reviewing claims and rooting out fraud, waste, or abuse. Claims would still be reviewed for medical necessity, coordination of benefits status, and benefits integrity. Any suspected instances of DMEPOS competitive bidding market manipulation and collusion would be referred to the appropriate Federal agencies that are responsible for addressing these issues.

We also proposed to establish a formal complaint monitoring system to address complaints in each CBA. Beneficiaries, referral agents, providers, and suppliers, including physicians, hospitals, nurses, and HHAs, would be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in a CBA. Some examples of problems that we would consider serious include: contract suppliers refusing to furnish items to beneficiaries in the CBA for which they were awarded a contract; contract suppliers furnishing items that are inferior in quality to those that they bid to furnish; and contract suppliers violating assignment and billing requirements.

In addition, we proposed to monitor Medicare claims data to ensure that competitive bidding does not negatively affect beneficiary access to medically necessary items. Claims data would be monitored to identify trends, spikes, or decreases in utilization and changes in utilization patterns within a product category.

Comment: One commenter strongly supported CMS' efforts to detect any abuse that may occur under competitive bidding and urged CMS to be especially aggressive and timely in its oversight for monitoring equipment safety. The commenter believed that there is a potential for one supplier to harm thousands of beneficiaries and recommended that CMS notify affected beneficiaries if a breach of quality has been identified.

Response: Equipment safety is addressed in the DMEPOS quality standards under the heading ''Product Safety.'' The CMS-approved accreditation organizations will monitor supplier compliance with these requirements as part of the accreditation process. In addition, as we proposed, the CBIC will develop and implement a complaint monitoring system for competitively bid items and services. This system will be outlined in more detail through sub-regulatory guidance and enable beneficiaries, referral agents, providers, and suppliers to report problems or difficulties they experience with respect to the furnishing of items under the competitive bidding programs. Additional details will be posted on our Web site, or made publicly available by other means.

Comment: Two commenters believed that beneficiary avoidance of certain contract suppliers would provide a strong indication that the Medicare DMEPOS Competitive Bidding Program is not meeting physician and beneficiary needs in the area. The commenters stated that this activity should be monitored as a measure of whether contract suppliers are providing beneficiaries with a suitable level of quality and access.

Response: We appreciate this comment and will consider it as we develop our monitoring program. The CBIC will be monitoring items furnished by contract suppliers to ensure they are the same quality as the items for which the contract supplier submitted a bid and was awarded a contract. The RFB will require suppliers to indicate the manufacturer, make and model numbers for each type of item the supplier would furnish if awarded a contract. In addition, we will require under the contracts that each contract supplier submit a quarterly report that indicates the items that were actually furnished to beneficiaries. We also note that we will be conducting a comprehensive education campaign to ensure that suppliers, beneficiaries, providers, and referral agents understand that Medicare will only pay for competitively bid DMEPOS items and services if they are furnished by contract suppliers, unless an exception outlined in this final rule applies. For more information about our plans for education on the Medicare DMEPOS Competitive Bidding Program, we refer readers to the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354).

Comment: One commenter encouraged CMS to specify clearly in the final rule or require CBICs to identify the necessary telephone and Internet resources that beneficiaries may use to raise questions and concerns related to the Medicare DMEPOS Competitive Bidding Program. The commenter stated that it is extremely important that beneficiaries have readily available access to information during their transition from their former suppliers to their new contract suppliers. The commenter recommended that CMS establish a survey mechanism so that beneficiaries will be able to rate their satisfaction with contract suppliers they have chosen, as recommended in the September 2004 GAO report entitled ''Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies.'' The commenter also stated the proposed rule

fails to provide a method to obtain feedback from beneficiaries concerning their satisfaction level with contract suppliers and disseminate this valuable information to other beneficiaries. The commenter noted that, without such an evaluation system, CBICs would be ill-equipped to judge and, thus, monitor either the quality of products that contract suppliers are furnishing or the accessibility of needed supplies for beneficiaries.

Response: We are establishing an ombudsman program that will require ombudsmen to identify, investigate, and resolve complaints made by, or on behalf of beneficiaries. The telephone numbers and resources will be published through program instructions or by other means, including postings on our Web site. We agree that beneficiaries must have readily available access to information during their transition from their former suppliers to new contract suppliers. We plan to implement an extensive education campaign for beneficiaries as well as for suppliers and referral agents. Our plans for education are described in more detail in the DMEPOS provisions of the FY 2007 IRF final rule (71 FR 48354). We note that the CBIC would administer beneficiary surveys throughout the program to regularly monitor beneficiary experiences with the program. We also expect to have two ombudsmen assigned to each DME MAC region. The CBIC will be providing oversight of this program. We are in the process of assessing the appropriate vehicles to disseminate the information that we collect through the beneficiary survey.

Comment: One commenter supported CMS's plans to establish a formal complaint monitoring system and believed that the information collected will be particularly helpful as CMS prepares to expand competitive bidding. The commenter recommended that CMS include in its complaint monitoring system a collection of brand-specific information on medical complications related to competitively bid items, especially for blood glucose monitoring products and enteral products (if included in competitive bidding) because of the potential for complications to arise with these items. The commenter also recommended that CMS collect data on contract suppliers that do not furnish particular brands of equipment specified by physicians. The commenter further recommended that CMS release timely reports on the results of its complaint monitoring system to encourage public dialogue and analysis regarding the competitive bidding program, and ensure that adequate data are available to guide development of subsequent phases of the program.

Response: We appreciate the suggestions of the commenters and will consider them as we operationalize the monitoring program. As we stated above, we will direct the CBIC to establish a monitoring program that includes beneficiary satisfaction indicators and supplier performance indicators. All parties affected by competitive bidding (for example, beneficiaries, referral agencies, suppliers, and providers) will be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in CBAs. However, in the event we receive complaints regarding medical complications with products, we will convey that information to the FDA.

Comment: One commenter urged CMS to monitor contract suppliers aggressively to ensure that they are not providing a different item than prescribed by the physician or treating practitioner, pressuring the physician to revise his or her order, or delaying delivery of the item. The commenter stated that such actions could result in delays in patient care and increase the risk that the patient will be injured. Another commenter urged CMS to monitor aggressively the impact of the Medicare DMEPOS Competitive Bidding Program on patient access to care. The commenter stated that this is an entirely new and complex program that will significantly change the market dynamics for furnishing certain DMEPOS to beneficiaries, and CMS must ensure that these market changes do not unintentionally limit the current variety of DMEPOS available, thereby adversely affecting beneficiary access to these important Medicare items.

Response: If the contract supplier provides an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare, as this is considered a noncovered item. Our complaint and monitoring system will ensure that contract suppliers either furnish the items prescribed by a physician or treating practitioner, or assist the beneficiary in finding another contract supplier to furnish the item under the circumstances. We expect that contract suppliers will advise beneficiaries regarding the expected time frames for delivery of items, as required under the ''Consumer Services'' section of the quality standards, and that beneficiaries will receive competitively bid items in a timely fashion. In addition, we will, as part of our monitoring system, be evaluating beneficiary access to competitively bid items, for example, through beneficiary surveys and quarterly reports that will require contract suppliers to disclose exactly what items they have furnished to beneficiaries.

Comment: One commenter asked CMS to clarify how it will monitor the quality of items based on the bid submissions. Another commenter suggested that CMS monitor complaints to ensure there are no problems with inferior products being furnished to beneficiaries. The commenter stated that if the HCPCS codes were too vague, CMS would have problems with monitoring the quality of items. Another commenter acknowledged that although it agrees that it would be a serious problem if a contract supplier furnished items inferior in quality to those for which it bid but urged CMS to monitor this or address complaints if the HCPCS codes are too vague or include multiple technologies. The commenter suggested that, in order for the monitoring policy to be effective, the HCPCS codes that are associated with competitively bid items must include the necessary level of detail and specificity.

Response: As part of the RFB requirements for submission of bids, we are asking suppliers to list the items they will furnish by manufacturer, make, and model number. Under the contracts, we are requiring contract suppliers to submit a quarterly report in which they are required to indicate the items they have supplied under the Medicare DMEPOS Competitive Bidding Program. We note that the MMA requires the Secretary to submit a report to Congress evaluating this program. This report will be finalized in July 2009 and, based on beneficiary surveys, will include information on access to and quality of items and services, and satisfaction of individuals. As discussed in section IX.A. of this final rule, suppliers will be required to allow beneficiaries to select items from the same range of items furnished to non-Medicare beneficiaries.

Comment: One commenter stated that, while claims monitoring may be effective for some purposes, using it to suggest that a spike in certain items' utilization may be attributable to competitive bidding is narrow-minded. The commenter stated that product utilization may have nothing to do with competitive bidding for various reasons, such as baby boomers entering the Medicare program in disproportionately high numbers, the higher incidence of certain diseases in specific areas of the United States, and the development of new products and technologies that

enable a larger number of patients to remain independent at home.

Response: We continue to believe that it is useful to conduct claims monitoring, and we would expect to monitor claims for each CBA. If we identify a utilization spike in a particular item, we can further investigate the cause of the spike, to identify whether the spike happened because of competitive bidding. Our claims monitoring system will allow us to review claims data for each item within a CBA.

Comment: One commenter stated that in a September 2004 report entitled ''Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies,'' the GAO emphasized the importance of ensuring continued quality, especially given that the implementation of competitive bidding will create an added incentive for suppliers to cut costs. The commenter noted that, in GAO's view, the central focus of these efforts should be ''continued monitoring of beneficiary satisfaction,'' perhaps through a toll-free complaint hotline and through beneficiary surveys. The commenter stated that it would be unrealistic to expect beneficiaries to monitor and provide feedback on the quality of the enteral formula they receive, through a hotline, through surveys, or otherwise. The commenter further noted that, given the importance of assuring continued quality during a transition to a significantly revised pricing system, it would be prudent for CMS initially to focus on those items and supplies for which quality can be readily assessed and assured through monitoring efforts.

Response: As part of the monitoring system, we will collect data to evaluate changes in beneficiary satisfaction, service, quality, access and cost-sharing as a result of the new program. Several questions will be customized to suit the particular product line surveyed. These data will also be used to prepare the congressionally mandated study and report due in July 2009, under section 1847(d) of the Act.

Comment: Two commenters urged CMS to ensure that suppliers are distributed throughout the CBAs to ensure beneficiary access. The commenters stated that patients (especially when injured) or the caretaker should not have to travel long distances to obtain needed DMEPOS, as this could put patients at risk and increase Medicare costs.

Response: We are requiring contract suppliers to service the entire CBA, which means that if a beneficiary cannot travel to his or her chosen contract supplier, the contract supplier will still be required to furnish the item to the beneficiary, whether by delivery or mail. Suppliers must include in their bids the cost of providing the item and any requisite services directly associated with the item, such as delivery, set-up, and retrieval. Therefore, we do not believe it is necessary to create special provisions regarding geographic distribution of contract suppliers.

Comment: One commenter agreed that an effective complaint monitoring system is needed as part of the competitive bidding program. The commenter noted that this should be a simple process that incorporates existing mechanisms that allow Medicare beneficiaries to voice complaints, such as an ombudsman program, and should not attempt either to recreate what exists in another section of the program or overcomplicate the process. The commenter noted that the current supplier standards require that suppliers show the NSC the complaint resolution process through onsite inspection prior to the issuance of a supplier number. The commenter also suggested that patients be directed to call their suppliers first regarding any alleged service issues before calling the ombudsman or other contractor.

In addition, the commenter asked that CMS define ''items of inferior quality.'' The commenter believed that, in determining whether a supplier is experiencing a high level of complaints, CMS must view complaints not in an isolated, numerical manner but expressed as a percentage of the total number of in-home deliveries made to Medicare patients in a given month.

Another commenter stated that the proposed rule provides no specifics about the proposed monitoring system. The commenter asked that the final rule provide more information about this system. The commenter urged CMS to assure that ombudsmen are designated for each CBA because they play an important role in addressing and resolving beneficiary complaints.

Response: We agree that an effective complaint monitoring system is needed as part of the Medicare DMEPOS Competitive Bidding Program. As we currently do, we plan to use competitive bidding ombudsmen who will be geographically distributed in each of the DME MAC regions to assist with monitoring activities. The CBIC is responsible for the monitoring program and will be issuing additional information. We plan to have a complaint process in place so that everyone affected by the Medicare DMEPOS Competitive Bidding Program, including beneficiaries, referral agents, suppliers, and providers, will be able to report problems or difficulties that they encounter regarding the ordering and furnishing of DMEPOS in a CBA. The monitoring system will also include a complaint resolution process, as well as a process by which we can track claims data to ensure that items are being properly furnished under the program. CMS or the CBIC will issue additional details regarding this process through program instruction or by other means, such as the RFB, and post them on our Web site. When we referred in the proposed rule to an item being of ''inferior quality,'' we meant items that beneficiaries or referral agents complained were of inferior quality, which would include any product that the contract supplier furnishes to the beneficiary that does not meet the medical needs of the patient.

After consideration of the public comments received, we are finalizing our proposal to implement a monitoring and complaint system under the Medicare DMEPOS Competitive Bidding Program.

XV. Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids

Section 1847(a)(5)(A) of the Act provides authorization to the Secretary to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome on the individual. In the May 1, 2006 proposed rule (71 FR 25684), we proposed to implement this statutory provision in proposed § 414.420 (in the proposed rule, the regulatory provision was erroneously cited in the preamble as § 414.440), and to also apply it to certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists, because these practitioners also order DMEPOS for which Medicare makes payment. Because a HCPCS code may contain many brand products made by a wide range of manufacturers, we expect that suppliers will choose to offer only certain brands of products within a HCPCS code. This is a common practice used by suppliers to reduce the amount of inventory they maintain. However, we proposed that the physician or treating practitioner would be able to determine that a particular item would avoid an adverse medical outcome, and that the physician or treating practitioner would have discretion to

specify a particular product brand or mode of delivery.

We proposed that when a physician or other treating practitioner requests a particular brand, or mode of delivery of an item, contract suppliers would be required to furnish that particular brand or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that brand item or mode of delivery, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary. If, after consulting with the contract supplier, the physician or treating practitioner is willing to revise his or her order, that decision must be reflected in a revised written prescription. However, if the contract supplier decides to provide an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare, as this would be considered a non-covered item under Medicare.

For the Medicare DMEPOS Competitive Bidding Program, we did not propose to require a contract supplier to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. Nonetheless, we noted that this issue will be studied in more detail by the OIG in 2009. At that time, we will evaluate the need for a specific process for certain brand names or modes of delivery.

In addition, section 1847(b)(7) of the Act provides authority to establish separate categories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes. Currently, HCPCS codes are developed for items that are similar in function and purpose. For this reason, items within the same code are paid at the same rate. We believe that the HCPCS process has worked well in the past, and we believe that it adequately separates items based on their function.

Comment: One commenter stated that CMS should address the quite-common situations in which a supplier does not carry a particular item, or does not know how it works or how it must be maintained. The commenter noted that mandating a contract supplier to furnish an item it does not routinely supply could raise concerns about patient and employee safety and other liability concerns. The commenter further stated that as long as some contract suppliers in the CBA can supply that particular item, this situation should be acceptable to CMS.

Response: We recognize the commenter's concerns, and we note that we did not propose that a contract supplier would be required, no matter what the circumstance, to furnish a brand name item or specific mode of delivery to a beneficiary. We also recognize that the wording of proposed §§ 414.420(b)(1) and (b)(2) and the preamble to the proposed rule may not have been sufficiently clear regarding whether a contract supplier must furnish an item that it does not routinely carry to a beneficiary. Therefore, we are clarifying, in final §§ 414.420(b)(1) through (b)(3) the process that contract suppliers must follow to address the situation where a physician or treating practitioner orders a specific brand or mode of delivery to avoid an adverse medical outcome. If a physician or treating practitioner prescribes a brand name item or specific mode of delivery to avoid an adverse medical outcome, the contract supplier must make a reasonable effort to furnish that brand name item or mode of delivery. If the contract supplier cannot furnish that brand name item or mode of delivery, it must contact the physician or treating practitioner to determine if a substitution can be made (and if so, the contract supplier must obtain a revised written prescription). If a substitution cannot be made, the contract supplier must assist the beneficiary in finding another contract supplier that can furnish the brand name item or mode of delivery prescribed by the physician or treating practitioner.

Comment: One commenter stated that the proposed rule does not establish an appeal or dispute resolution system for cases when the contract supplier in a CBA fails to provide the specific equipment selected by the physician.

Response: As we state in this final rule in § 414.420(d), a contract supplier would be prohibited from billing Medicare if it furnishes an item different from that specified in the written prescription from the beneficiary's physician or treating practitioner.

Comment: One commenter stated that CMS should exercise its discretion under section 1847(a)(5) of the Act, and not permit such brand-specific prescriptions for items within a CBA. As an alternative, the commenter suggested that CMS consider making a finding that, under such circumstances, the competitive bidding is not likely to result in significant savings and, accordingly, exempt these items from the competitive bidding process under section 1847(a)(5) of the Act. The commenter indicated that there is concern that if CMS implements section 1847(a)(5) of the Act, the demand for brand-specific items, will increase even though the ''brand name'' may have the same clinical benefits of other products.

Several commenters opposed the manner in which CMS interpreted the authority of the treating practitioner to order brand-specific items and equipment. They believed that the proposed rule mandates serious financial consequences for the supplier and creates unnecessary uncertainty in the bids to be submitted. They added that forcing suppliers to carry all possible items and equipment will be burdensome and costly for suppliers. The commenters stated that contract suppliers may be financially responsible to provide items outside their normal product line. However, they added that, if a contract supplier does not carry that product, the contract supplier may refer the beneficiary to another contract supplier. The commenters asked that CMS consider an exception process to compensate contract suppliers for provisions of items that are very expensive compared to other products within the same HCPCS code. They also suggested that CMS define ''what is a reasonable effort to locate an alternative supplier.''

Response: We disagree with the commenters. Section 1847(a)(5) of the Act provides the Secretary with the authority to establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service to the beneficiary to avoid an adverse medical outcome. We proposed that this process would also apply to certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists, because these practitioners also order DMEPOS for which Medicare makes payment. We stress that this process can only be used when a physician or treating practitioner determines that there is a need for the use of a particular item or mode of delivery to avoid an adverse medical outcome. Because bids will be submitted for HCPCS codes, which are carefully written to include items that perform the same therapeutic function, we do not believe there will be many instances in which a particular brand or mode of delivery is necessary to avoid an adverse medical outcome. Nevertheless, because it is possible such a prescription may be necessary in a few cases, we believe it is important for patient safety to retain this provision. Therefore, we are clarifying that a physician or treating practitioner must document in the beneficiary's medical

records the medical necessity of a particular brand or mode of delivery of an item or service to avoid an adverse medical outcome, if a particular brand or mode of delivery is prescribed. We note that section 1847(a)(5)(B) of the Act provides that a prescription written for a particular brand of item or mode of delivery will not affect the amount of payment otherwise applicable for the item under the HCPCS code involved, and that we do not currently pay a supplier an additional amount for furnishing a particular brand of item or mode of delivery. We also note that a contract supplier would not be required to furnish every brand of item. It would be able to work with the physician or treating practitioner to find a suitable alternative and, if that effort is unsuccessful, to help the beneficiary find another contract supplier that can furnish the item.

We agree that the use of the term ''reasonable effort'' is nebulous and may be subject to misinterpretation. We are deleting the term ''reasonable effort''. Because of the importance for beneficiaries to receive medically appropriate items, we are now requiring that a supplier follow the process set out in final § 414.420(b)(1) though (b)(3).

Comment: Several commenters argued that physician choice for determining appropriate wound care products is of paramount importance. They were concerned that physician choice and access to certain wound care products could be restricted as a result of competitive bidding, specifically Negative Pressure Wound Therapy (NPWT), code E2402. In recent months, new products have been added to code E2402 despite the fact that these new products are clinically different from the original NPWT product. The commenters stated that because of the newer items, it is conceivable that wound healing would be compromised.

Response: A physician or treating practitioner may prescribe a particular brand or mode of delivery to avoid an adverse medical outcome for the beneficiary. We note that HCPCS codes are carefully defined to ensure that only items that have the same therapeutic function fall within particular codes. Therefore, we believe it is unlikely that there would be many instances in which a particular brand within a HCPCS code would be necessary to avoid an adverse medical outcome.

Comment: Several commenters requested that CMS add language to the rule acknowledging that physical therapists and occupational therapists play a key role in specifying the need for a particular brand.

Response: Although we recognize that physical therapists and occupational therapists may furnish certain DMEPOS as part of their professional practice, current Medicare rules only allow physicians, nurse practitioners, clinical nurse specialists, and physician assistants to prescribe DMEPOS items.

Comment: Several commenters asserted that it is not fair that contract suppliers be required to furnish any item within a HCPCS code if their bid was accepted based on an item that they carry in their stock. The commenters stated that if no additional payments would be made for more specific expensive products that are ordered by physicians or treating practitioners, this may result in significant financial losses for the contract supplier if the contract supplier is required to furnish the particular brand or mode of delivery at the single payment amount. Several commenters supported the physician/treating practitioner authorization proposal because it provides a safety net for the beneficiary. Another commenter argued that when a physician or treating practitioner specifies a product for his or her patient, the physician or treating practitioner should have continuous access to the latest innovative technologies.

Response: As stated earlier in this section, we believe that it will rarely be necessary for a physician or treating practitioner to prescribe a particular brand or mode of delivery to avoid an adverse medical outcome. Furthermore, in this final rule, we are specifically providing the contract supplier with a specific process to follow when a physician or treating practitioner requests a specific brand item or mode of delivery to avoid an adverse medical outcome. Under this process, the supplier is required to furnish the item or mode of delivery as prescribed, and if it cannot furnish the item or mode of delivery as prescribed consult with the physician or treating practitioner to find a suitable alternative and have the physician or treating practitioner revise his or her order, and if the physician or treating practitioner does not revise the order, assist the beneficiary in finding another contract supplier. We do not believe these requirements will place an undue financial burden on a contract supplier because there are provisions in this process that give the contract supplier the opportunity to substitute the item or arrange to have another contract supplier furnish the item. We agree that physicians and treating practitioners should have continuous access to the latest innovative technologies and be able to order them for their patients.

Comment: Several commenters stated that the physician/treating practitioner authorization proposal does not provide sufficient details. They pointed out that the term ''adverse medical outcome'' has not been defined. The commenters urged CMS to develop a streamlined and quick process to facilitate the role of a physician or treating practitioner as a key decision maker for each patient. Several commenters argued that it is crucial for the Medicare DMEPOS Competitive Bidding Program to allow health care providers to prescribe specific items with special features when medically necessary. They stated that the proposed rule does not adequately ensure that beneficiaries with diabetes will have access to the products for which their health professionals find are most appropriate and medically necessary for their individualized needs. The commenters remained concerned that contract suppliers will limit products to a narrow range that do not account for a wide spectrum of diabetes-related medical needs, and they will not receive additional payment for providing such items.

The commenters recommended that CMS modify the rule to allow for an adequate variety of diabetes supplies to suit a range of individualized needs of beneficiaries with diabetes. They stated that CMS must create a less burdensome process to ensure that these supplies are rapidly available upon documentation of medical need. The commenters added that it is possible that adjusting the payment rate for these special items upward will encourage contract suppliers to provide them in all cases.

Response: We believe that it is appropriate for physicians and treating practitioners to have the discretion to determine when it is medically necessary to prescribe a particular brand or mode of delivery of an item to avoid an adverse medical outcome. We consider the adverse medical outcome determination to be part of the more general medical necessity requirement that must be met in order for Medicare to pay for an item under section 1862(a)(1)(A) of the Act. As with all medical necessity determinations, there must be documentation in the beneficiary's medical record to support the need for the particular brand or mode of delivery. Therefore, the physician or treating practitioner must note in the beneficiary's medical record the reason why the specific brand or mode of delivery is necessary to avoid an adverse medical outcome so that contract suppliers can make a reasonable effort to furnish the item, then consult with the physician or

treating practitioner to find a suitable alternative, and then make a reasonable effort to assist the beneficiary in locating a contract supplier that can furnish the item. We believe that these requirements, along with other requirements that we have previously discussed in this final rule, will ensure that beneficiaries have access to the most appropriate items for their medical condition under the Medicare DMEPOS Competitive Bidding Program.

Comment: One commenter objected to the statement in the proposed rule that suppliers should not discriminate against beneficiaries in a CBA and that contract suppliers must furnish the same items to beneficiaries that they do to other individuals. The commenter argued that this appears to conflict with the requirement that a supplier must provide product-specific items, if ordered by the physician or treating practitioner.

Response: The nondiscrimination provision in this final rule (§ 414.422(c)) specifies that discrimination against beneficiaries is prohibited under the Medicare DMEPOS Competitive Bidding Program. All Medicare beneficiaries to whom a contract supplier furnishes competitively bid items must have the same choice of items that the contract supplier provides to other customers. We proposed to implement this provision to protect beneficiaries from receiving sub-standard or inferior items in terms of quality. However, we do not believe that this provision conflicts with the physician/treating practitioner authorization rules being implemented in this final rule. Under these rules, a physician or treating practitioner can prescribe a brand name item or mode of delivery to avoid an adverse medical outcome for the beneficiary, and the contract supplier must follow the process outlined in § 414.420(b) upon receiving the prescription. Nothing in these rules would prevent a contract supplier that furnishes a particular brand or mode of delivery from making that brand or mode of delivery available to other beneficiaries or customers.

Comment: One commenter noted that the rule requires a contract supplier get a revised written prescription if the physician treating practitioner allows for a modification of a brand-specific product. The commenter stated that verbal orders are acceptable in most States, and this imposes a significant administrative burden on contract suppliers and physicians/treating practitioners.

Response: The requirement of a written order is consistent with current Medicare rules. The item provided must match the written order in order for the contract supplier to bill Medicare.

After consideration of the public comments we received, we are revising and finalizing proposed § 414.420 as discussed above.

XVI. Other Public Comments Received on the May 1, 2006 Proposed Rule

Comment: Several commenters suggested issuing an interim final rule, with a full 60-day notice and comment period to allow for a more detailed proposal for public comment. In addition, several commenters suggested publishing initial responses to the public comments as a new proposed rule. The commenters believed that this suggestion is consistent with section 1871(a)(4) of the Act that states that a final rule will be treated as a proposed rule if it includes provisions that are not logical outgrowths of a previously published notice of proposed rulemaking. The commenters indicated that another proposed regulation would allow the public to consider and comment on CMS' responses to issues on which CMS requested comment in the May 1, 2006 proposed rule. Other commenters requested that the comment period on the proposed rule be extended until at least 90 days following the publication of the final DMEPOS quality standards.

Several commenters were concerned about Administrative Procedure Act compliance, which states that administrative rulemaking must be sufficiently descriptive of subjects and issues involved so that interested parties may offer informed criticism and comments. The commenters also gave other cites: Agency notices must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision making. Finally, the commenters noted that an agency commits a serious procedural error when it fails to reveal portions of technical basis for a proposed rule in time to allow for meaningful commentary.

Response: The proposed rule presented for public comment our proposed rules that will govern the Medicare DMEPOS Competitive Bidding Program. This final rule does not include any provisions that are not logical outgrowths of our proposals in the May 1, 2006 proposed rule. In addition, we believe that our proposed rules were sufficiently detailed to enable the public to provide meaningful comments on them. Indeed, we received over 2,000 comments on the proposed rule, and we have both considered and responded to those comments in this final rule. Therefore, we believe that issuance of an interim final rule is not necessary. We also note that this rule does not finalize the DMEPOS quality standards and that section 1834(a)(20)(E) of the Act explicitly permits us to establish the DMEPOS quality standards by program instruction or otherwise. The quality standards were published on August 15, 2006, and are available on the following Web site: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp.* We note that the draft quality standards were published on September 26, 2005, which was more than 7 months prior to the publication of the proposed rule. We also note that the quality standards apply to all suppliers, not just suppliers that wish to participate in the Medicare DMEPOS Competitive Bidding Program, and that we provided a 60-day period for the public to comment on them.

Comment: Several commenters suggested that CMS schedule a meeting of the PAOC (1) After we publish an interim final rule; (2) when we publish the MSAs and the DMEPOS items subject to competitive bidding; and (3) when the final regulation is issued. The commenters noted that scheduling a PAOC meeting following publication of an interim final rule would allow CMS to obtain industry input before publishing a final rule and initiating program implementation. Further, several commenters suggested that CMS include the PAOC in the review of the public comments received during the comment period on the proposed rule and in the development of the final rule. They stated that excluding the important counsel and advice of the PAOC in a critical process would not be consistent with the purpose for which the PAOC was established.

Response: The PAOC meets periodically to review policy considerations and to provide advice on the development and implementation of the Medicare DMEPOS Competitive Bidding Program. Since its establishment, the PAOC has met on five occasions and will continue to be available to provide us with advice until the end of 2009. Section 302 of the MMA gives CMS discretion on when to schedule PAOC meetings. We also discussed with the PAOC the full range of competitive bidding issues, and we continued to consider its advice and counsel as we reviewed the comments and developed this final rule.

Comment: Several commenters noted that the Web site address for the PAOC

that was in the proposed rule was incorrect.

Response: We recognize the importance of having a Web site available to distribute information in a timely manner and regret the error. Our PAOC Meeting Information Web site can be found at the following link: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp.* Included on the Web site are materials relating to each PAOC meeting such as agendas, meeting summaries, and presentations.

Comment: One commenter suggested that the PAOC be subject to the Federal Advisory Committee Act (FACA), which requires public access to meetings and proceedings. The commenter believed that the PAOC has great power within the DMEPOS industry and that other affected members of the industry have not had an opportunity to review or respond to PAOC assertions or recommendations.

Response: Section 1847(c)(4) of the Act provides that the provisions of the FACA do not apply to the PAOC. However, the PAOC meetings have been open to the public, and we have published summaries of the meetings on our PAOC Web site *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp.* Information about the Medicare DMEPOS Competitive Bidding Program has also been made available through other methods, such as electronic supplier listserv messages and open door forums. CMS offers an electronic mailing list service for those interested in receiving news from CMS. From the following link, individuals can subscribe to the ''Homehealth_Hospice DMEODF–L'' listserv to receive notices of upcoming open door forums: *http://www.cms.hhs.gov/apps/mailinglists/.*

Comment: Numerous commenters requested that CMS publish an updated implementation timeline with expected completion dates. The commenters expect that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan. The commenters suggested that the timeline should identify and provide expected completion dates for items such as the publication of the quality standards, approval of the accrediting organizations, and issuance of final regulations. The commenters further suggested that CMS push back the implementation date of October 1, 2007, to a more reasonable timeframe. The commenters believed that a delay in implementation will allow adequate time for small suppliers to create networks and to prepare their organizations for accreditation.

Response: Section 1847(a)(1)(B)(i)(I) of the Act requires that the Medicare DMEPOS Competitive Bidding Program be phased in such that competition under the programs occurs in 10 of the largest MSAs in CY 2007. We are committed to meeting this statutory mandate. We are mindful of the many key tasks that must be completed to ensure the success of this program and are moving forward to complete these tasks expeditiously. We note that the final DMEPOS quality standards were issued on August 15, 2006, and that applications for participation in the DMEPOS accreditation program were solicited from independent accrediting organizations in a **Federal Register** notice published on August 16, 2006 (71 FR 47230). Therefore, we do not believe it is necessary to publish a specific timetable of expected completion dates for other activities. However, we will provide the public with sufficient notice as we proceed with implementation activities.

Comment: One commenter suggested that CMS allow all beneficiaries to opt out of the Medicare DMEPOS Competitive Bidding Program, select the supplier of their choice, and receive DMEPOS items for which payment is made based on the current fee schedule amounts.

Response: Under section 1847(a) of the Act, we are required to establish and implement competitive bidding programs throughout the United States for the furnishing of certain items for which payment is made under Part B of the Medicare program. To the extent that we implement a competitive bidding program in a particular CBA, we do not believe that we have authority to allow any beneficiary who need items in that CBA to ''opt out'' of receiving those items from contract suppliers and receive Medicare payment. We also note that section 1847(a)(6) of the Act provides that, for each CBA in which a competitive bidding program is implemented, the payment basis established under the competitive bidding program shall be substituted for the payment basis that would otherwise apply (which, in most cases, would be based on a fee schedule). In accordance with section 1847(b)(5)(A) of the Act, we are required to establish a new payment amount for each item in each CBA. This new payment amount is what we would pay to contract suppliers. Under the Medicare DMEPOS Competitive Bidding Program, beneficiaries will be able to select among the winning suppliers. However, we believe that permitting beneficiaries to opt out of the program would create an exception that would significantly undermine the goal of the program to achieve savings.

Comment: One commenter stated that one aspect of the DMEPOS competitive bidding demonstration projects that was never studied was Medicare patient rehospitalization and/or emergency room visit rates. The commenter stated that this is a key outcome measure that CMS should have evaluated to determine if savings created through Medicare Part B were actually resulting in expenditures under Medicare Part A. The commenter believed that it is possible that a price-oriented DMEPOS model might actually lead to higher levels of institutional care. The commenter indicated that it would be prudent for CMS to study this aspect in the CY 2007 round of bidding.

Response: We do not agree that competitive bidding savings will result in higher expenditures under Medicare Part A. Under the Medicare DMEPOS Competitive Bidding Program, beneficiaries will receive items from contract suppliers that have satisfied our quality, accreditation, financial, and eligibility standards. In addition, contract suppliers will be required to furnish to beneficiaries in a CBA the same level of services and quality items that they furnish to other customers. Through our physician and treating practitioner authorization rules, beneficiaries who maintain a permanent residence in a CBA will continue to receive items that meet their medical needs. Because we are enacting safeguards to ensure the quality of items that are furnished under the competitive bidding programs by contract suppliers, as well as rules that we expect will ensure that beneficiaries have access to new technology, we do not believe that expenditures under Medicare Part A will rise or that it is necessary to undertake a study. Moreover, we will monitor the entire program to make sure that complaints are addressed and resolved. We also believe that it would be difficult to develop a study evaluating increases in Medicare Part A costs as a result of adverse competitive bidding outcomes because there are too many intervening variables, such as physician and treating practitioner quality, that affect final patient outcome.

XVII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In response to the May 1, 2006 proposed rule (71 FR 25654), we received several public comments that were submitted on the proposed rule that more appropriately pertain to provisions on the PRA process. We note that specific information requested from suppliers as part of the bid submission and many of the terms and conditions that will be included in the contracts under the Medicare DMEPOS Competitive Bidding Program are discussed in detail in sections VI.G., VII.C., and IX.A. of this final rule. In these sections, we summarize the public comments we received on these specific information requirements and respond to those comments. Other comments and responses on the general paperwork burden that we outlined in the proposed rule follow:

Comment: Two commenters submitted general comments on the specific paperwork burden outlined in the proposed rule. The commenters believed that, due to the lack of specificity in the proposed rule, it is impossible for commenters, or CMS, to estimate accurately the amount of incremental time that will be required of suppliers to complete the bid process to participate in the program. The commenters indicated that only two demonstration projects were performed, and they did not include many of the requirements that we have proposed. The commenters also indicated that, overall, competitive bidding is an administratively burdensome program for suppliers, Medicare, and its contractors, and represents an incremental administrative process that is layered on top of an already complex Medicare Part B system. The commenters urged CMS to adopt existing accreditation standards, existing patient satisfaction tools, existing patient complaints and resolution processes, and existing financial reports, rather than attempt to ''reinvent the wheel,'' in order to reduce both the paperwork and administrative burden. The commenters believed that competitive bidding will increase costs for both suppliers and CMS in the form of increased staff and reporting procedures.

Two commenters stated that they assumed CMS arrived at its estimate of 70 hours per bid for each supplier to furnish information by using the median of the hours that suppliers estimated were required during the two less complicated demonstration projects, and that this estimate was per location. The commenters pointed out that it is unclear as to whether this 70-hour estimate includes time spent attending bidders conferences and preparing internal analyses or whether it is simply an estimate of the amount of time needed to complete the application bidding process. The commenters indicated that if they considered in the estimate the time that executive and mid-level management spent reviewing, analyzing, and responding to the proposed rule, plus an estimated 70 hours per their 25 branches for the application process and the first round of competitive bidding for CY 2007, the companies would invest 1,750 hours in preparing competitive bids.

In regard to the total number of hours that suppliers would invest in regard to the CY 2007 programs, one commenter pointed out that CMS' own estimate is that 1,158,150 hours would be needed by the industry (16,545 bids). The commenters pointed out that if a conservative $35 per hour average salary rate is used, this amounts to an incremental $41 million attributable to the first 10 CBAs alone. The commenter added that, in CY 2008, this escalates dramatically to an incremental 5,100,550 hours needed to prepare 72,865 bids, which in turn computes to $178.5 million in supplier labor, and that these costs have to be accounted for in the bid that suppliers submit to CMS. Two commenters stated that the proposed bid process and certain other provisions of the proposed rule are too paper-intensive and gave recommendations for ways in which CMS could save a significant amount of paperwork for itself and suppliers: (1) Automating the supplier bid process and accreditation organization application process by making it Web-based and allowing an attachment feature; (2) allowing the bid review team to start reviewing those bids that meet the quality and financial standards first before proceeding to review the bid prices; (3) allowing any multi-site supplier that is owned by the same corporate parent or tied to the same tax number to provide certain standard information only one time; (4) adopting a standardized Medicare patient satisfaction questionnaire for DMEPOS; (5) keeping the beneficiary and supplier education simple and low cost; (6) eliminating the brand-specific requirement and associated paperwork; (7) rather than requiring a separate bid for every competitively bid product category in a given MSA, consolidating the application form itself into a check-box format; and (8) rather than creating an all-new government infrastructure that essentially duplicates what exists in the private sector, subcontracting with several large managed care organizations to administer the program for Medicare beneficiaries nationwide.

Response: We need detailed information on suppliers with whom we may enter into a contract. This information will be used to evaluate the suppliers. This is important because both Medicare and the beneficiaries will be dependent on the contract suppliers. We need to evaluate capacity issues in order to ensure that suppliers' capacity meets beneficiary demand; we need to evaluate financial stability in order to ensure that contract suppliers are solvent and will be in business during the contract period; and we need to obtain identification information in order to ensure management is dependable and that the bidding supplier is not excluded from participating as a Medicare supplier.

Our estimate of the time burden required for filling out the forms is based on reports from suppliers that participated in the DMEPOS competitive bidding demonstrations, which implemented competitive bidding in two MSAs. The demonstrations included RFB forms similar to those that will be included in this program and both small and large suppliers filled out the forms. Estimates of the required time ranged from 40 to 100 hours, and we used the midpoint for our estimates. The estimates include internal decision-making processes but do not include the time spent attending bidders' conferences. Based on our consideration of the public comments received, we have eliminated the requirement to submit reviewed and/or audited financials, as well as information regarding investigations. We believe this will lessen the burden on suppliers.

Section 414.412 Submission of Bids Under a Competitive Bidding Program

Section 414.412 outlines the requirements associated with submitting bids under the competitive bidding process. Specifically, § 414.412(a) states that unless an exception applies, suppliers must submit a bid and be

awarded a contract under a competitive bidding program in order to receive payment from Medicare for furnishing the items.

The burden associated with this requirement is the time and effort associated with drafting, completing, and submitting a bid. We estimate that, on average, it will take a supplier 68 hours to complete and submit a bid. We believe that we will receive 15,973 bids for a total annual burden of 1,086,164 hours.

In addition, as part of the Medicare DMEPOS Competitive Bidding Program, beneficiaries will be surveyed to gather information pertaining to their experiences with suppliers. We estimate that the burden associated with completing the survey is 15 minutes per beneficiary. We estimate that the total annual burden associated with this information collection requirement is 2,000 hours.

Section 414.414 Conditions for Awarding Contracts

Section 414.414 contains the rules pertaining to the evaluation and selection of suppliers for contract award purposes under the Medicare DMEPOS Competitive Bidding Program. Specifically, § 414.414(b)(1) states that each supplier must meet the enrollment standards specified in § 424.57. The burden associated with this requirement is subject to the PRA. This requirement is currently approved under OMB control number 0938–0717, with an expiration date of November 30, 2007.

Section 414.420 Physician or Treating Practitioner Authorization and Consideration of Clinical Efficiency and Value of Items

Section 414.420(a) states that a physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under competitive bidding or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary and documents this determination in the beneficiary's medical record. The burden associated with this requirement is the time and effort associated with evaluating the beneficiary and, if necessary, determining the best brand item or mode of delivery to avoid an adverse medical outcome. In addition, there is burden associated with the time and effort involved in writing the prescription for the brand item or the mode of delivery and documenting the medical record. The burden associated with this requirement is not subject to the PRA as stated under 5 CFR 1320.3(b)(2) and (h)(5).

Section 414.422 Terms of Contracts

Section 414.422(d) requires contract suppliers to notify CMS if they are considering or negotiating a change of ownership. The notification must be made 60 days prior to the anticipated effective date of the change. In addition, a supplier must submit a novation agreement to CMS 30 days before the anticipated change of ownership takes effect, stating that it will assume responsibility for meeting all of the terms and conditions of the competitive bidding contract. The new supplier must submit the same documentation required of the original contract supplier unless it has already submitted such documentation during the bidding process and that documentation is still current.

The burden associated with this requirement is the time and effort associated with drafting and submitting the required notification to CMS. While this burden is subject to the PRA, we currently have no way to quantify the number of potential respondents. We will continue to monitor the program requirement and seek OMB approval should the number of respondents surpass the threshold of 10 individuals or entities as specified in 5 CFR 1320.3(c)(4).

TABLE 10.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Requirement	OMB control No.	Respondents	Responses	Burden per response (in hours)	Total annual burden (in hours)
§ 414.412(a)	0938—New	15,973	15,973	68	1,086,164
	0938—New	8000	8000	.25	2,000
	0938—New	15,973	15,973	.166667	2662
§ 414.414(b)(1)	0938—0717	35,000	35,000	8	280,000
Total					1,370,826

As required by section 3504(h) of the PRA, we have submitted this final rule to OMB for its review and approval of the information collection requirements.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuance Group, Attn.: William N. Parham, III, CMS–1270–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Carolyn Lovett, CMS Desk Officer, CMS–1270–F, E-mail: *carolyn_lovett@omb.eop.gov*, Fax: (202) 395–6974.

XVIII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final 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.

1. Executive Order 12866

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 (that is, a final rule that would have an annual effect on the economy of $100 million or more in any 1 year, or would

adversely affect in a material way the economy, a sector or the economy, productivity, competition, jobs, the environment, public health or safety, or communities). We have determined that this final rule is an economically significant major rule and thus have prepared a regulatory impact analysis.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of section 604 of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 85 percent of DMEPOS suppliers are considered small businesses according to the Small Business Administration's size standards, with total revenues of $6.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. We expect that this final rule will have a significant impact on a substantial number of small suppliers. The RFA requires that we analyze regulatory options for small businesses and other entities. The analysis must include a justification concerning the reason action is being taken, the kinds and numbers of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. We have provided this analysis in section XVIII.B. of the preamble to this final rule.

3. Small Rural Hospitals

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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. We have determined that this rule will not have a significant effect on small rural hospitals. Rural health care facilities should not be significantly impacted as the program is expected to operate primarily within relatively large MSAs.

4. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. We do not expect this final rule will result in direct costs that exceed $120 million per year on State, local, or tribal governments in the aggregate or the private sector, and thus the UMRA would not apply.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this final rule will not have substantial direct effects on the rights, roles, and responsibilities of States.

B. Regulatory Flexibility Analysis

1. Summary

The May 1, 2006 proposed rule did not include a separate initial Regulatory Flexibility Analysis. However, information concerning small suppliers was included throughout the proposed rule preamble and regulatory impact analysis. This document consolidates and summarizes components of the regulation concerning small businesses into a single RFA. Its contents are included in more detail in various parts of the regulatory impact analysis and the regulation preamble.

2. The Need for and Objectives of the Final Rule

Payment for DMEPOS is currently based generally on fee schedule amounts. Section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of Health and Human Services to replace the current fee schedule methodology for certain items with a competitive acquisition contracting program that will result in an improved Medicare methodology for setting payment amounts for certain durable medical equipment and supplies, enteral nutrition equipment, nutrients and supplies, and off-the-shelf orthotics. This new bidding process will result in CMS awarding contracts with to winning suppliers. Contracts will stipulate the terms, conditions, and payment rates for items and services for under the program. Generally, only suppliers that submit winning bids and are awarded contracts will be permitted to furnish items under the program and reimbursement for those items from Medicare.

In developing bidding and contract award procedures, section 1847(b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii) of the Act also states that the needs of small providers must be taken into account when evaluating whether an entity meets applicable financial standards.

Set out below is a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

3. Comments Regarding Small Suppliers

The May 1, 2006 proposed rule did not include a separate initial regulatory flexibility analysis, but all information required for an RFA was contained elsewhere in the regulatory impact analysis or the regulation preamble. Below we list major comments on aspects of the proposed rule which directly concern small suppliers that are included in the final rule.

a. Comments on Small Supplier Focus Groups

Several commenters requested that CMS share the findings from the 9 small supplier focus group meetings that were conducted during April and May 2005. Representatives of DMEPOS suppliers that had less than $3 million in gross revenue and employed up to 10 FTE employees met with CMS' contractor staff and were invited to share thoughts and opinions on the potential impact of quality standards, accreditation, competitive bidding, and financial standards requirements on their businesses. We presented an overview and results of the focus groups related to quality standards and accreditation to the PAOC on September 26, 2005 (access at *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/PAOCMI/list.asp#TopOfPage*).

The results of the focus groups related to competitive bidding and financial standards were presented to the PAOC on May 23, 2006. Several focus group participants remarked that the competitive bidding process would force many small suppliers out of business. The participants suggested alternatives to competitive bidding, including: (1) CMS should determine product prices and allow all willing suppliers to provide products at the set price; and (2) CMS should reserve a percentage of winning bids for small suppliers. Many participants believed

that lower payment rates for suppliers would inevitably lead to lower quality goods and services. Participants were particularly emphatic in their belief that CMS continues to neglect the valuable service component that small suppliers provide to their customers. They believed that it is their commitment to service that sets them apart from the national companies. A number of participants were concerned about the possibility of requiring small winning supplier to furnish items in the entire MSA, given the fact that some MSAs cross State boundaries. There was also a consensus among these small suppliers that the impact of competitive bidding would differ by product line. They believed that items involving high-end technology equipment, respiratory equipment, and customized products are more service intensive than other products, such as standard wheelchairs, that involve fewer repairs, set-up time, and patient education.

Finally, many participants in the focus groups believed that tax returns, quarterly standard financial statements, and Dun & Bradstreet were helpful sources of information about a business's credit history and cash flow. The participants noted that suppliers that grossed over $3 million in revenue used audited financial statements, whereas suppliers that grossed less than $3 million in revenue used cash basis accounting principles. A summary of the PAOC discussion related to the focus group results can be accessed at: *http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/PAOC_summary.pdf.*

We have used the comments from the focus groups as well as public comment process in developing our final policies for the Medicare DMEPOS Competitive Bidding Program.

b. Comments on the Definition of Small Suppliers

Some comments concerned the definition of small suppliers. Some commented on practitioner and providers, reporting that there are currently 40,000 practitioners and providers enrolled as suppliers, including approximately 1,078 physical therapists. The commenters stated that health care practitioners who provide DMEPOS as an integral part of their professional services specialize in providing items for specific conditions. They added that these suppliers offer considerable expertise in evaluating both the patient and the item in order to provide the patient with the best possible outcome.

Many commenters disagreed with using the definition of the SBA (less than $6 million in annual receipts) because the CY 2003 Medicare data showed that at least 90 percent of suppliers had less than $1 million in allowed charges. They recommended defining a small supplier as a supplier that generates less than $3 million in annual receipts. The commenters believed that a lack of small supplier participation would negatively impact patient care. They added that small businesses would have to endure large expenses in order to participate in the Medicare DMEPOS Competitive Bidding Program. Most suggested that we define a small supplier as a supplier having fewer than 10 FTE employees. They also believe that small suppliers serve rural and underserved urban communities where larger suppliers may not operate.

We agree with the commenters and recognize the importance of small supplier participation and understand that there are upfront costs associated with submitting a bid under the program. In the final rule, we revised our policies to ensure that small suppliers have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. To assure multiple suppliers, storefront locations, beneficiary access, and increased participation by small suppliers, we have in cooperation with the SBA, revised the final rule such that the definition of a ''small supplier'' is a small supplier that generates gross revenue of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue (§ 414.402).

c. Comments on the Protections for Small Suppliers

Several commenters noted that section 1847(b)(6)(D) of the Act is entitled ''protection'' of small suppliers and not the mere identification of small suppliers. The commenters proposed the following policies: (1) At least 50 percent of suppliers that receive a contract should be small suppliers (based on $3 million or less in revenue or less than 10 FTE employees); (2) CMS should allow suppliers with less than 10 FTE employees to furnish items to less than the entire CBA; (3) CMS should award contracts to small suppliers with the lowest bids that exceed the pivotal bid; (4) CMS should allow truly small suppliers to promise to accept the single payment amount; and (5) CMS should establish a certain volume of items in each geographic area that will be ''set-aside'' for small suppliers.

The statute at section 1847(b)(6)(D) of the Act requires that the Secretary shall take appropriate steps to ensure that small supplies of items and services have an opportunity to be considered for participation in the program under this section. We recognize the concerns raised by the commenters and have considered the suggested alternatives provided during the small supplier focus groups and through the public comment process. We also recognize the importance of maintaining storefront capabilities to meet the needs of beneficiaries. To help small suppliers have an opportunity to participate in the Medicare DMEPOS Competitive Bidding Program and to support our Departmental goals for contracting with small suppliers, we have established a target for small suppliers' participation in the final rule. Our target for small supplier's participation in each product category will be determined by multiplying 30 percent times the number of suppliers that meet our bidding requirements and whose composite bids are at or lower than the pivotal bid. The number resulting from this multiplication represents our goal for small supplier participation for the product category (§ 414.414(g)(1)(i)). If this 30-percent target is not achieved as a result of this process, we will offer contracts to small suppliers with submitted bids that are above, but closest to, the pivotal bid until we reach the target number or there are no additional small supplier bidders (§ 414.414(g)(1)(iii)). In addition, we are requiring that all contract suppliers must service the entire CBA, and we have clarified that this can be done where appropriate either through home delivery, mail order, or storefront. However, small suppliers that cannot service the entire area independently can join together and bid as a network (§ 414.418). The network, rather than each individual supplier, would be required to service the entire CBA.

d. Comments on Bidding Requirements for Physicians and Other Providers

Several commenters suggested that CMS not require physicians, including podiatric physicians, to participate in the competitive acquisition program for certain DMEPOS. The commenters noted that under the physician self-referral (''Stark'') provisions under section 1877 of the Act, a physician in a group practice may not refer Medicare beneficiaries to the group practice, and the group practice may not bill for any DME except crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors. The commenters also requested that CMS not require physician assistants, physical therapists, and occupational therapists to participate in the Medicare DMEPOS Competitive Bidding Program because those health care professionals are

licensed by State boards. According to the commenters, if a physician or non-physician practitioner does not participate in the competitive bidding program, he or she should be reimbursed at the competitive bid rate for any DME items that are furnished to his or her own patients. In addition, the commenters requested that CMS clarify how the requirement for physicians to submit bids and provide all items within a product category does not violate the physician self-referral law. Other commenters stated that there is no reason to treat occupational therapists and physical therapists differently from physicians.

Based on these comments, we modified the proposed rule by expanding the definition of the term ''physicians'' and by exempting physicians and other treating practitioners from bidding requirements to provide limited DMEPOS to their own patients (§ 414.402 and § 414.404(b)(1)). We are also modifying the regulation to give physical therapists in private practice and occupational therapists in private practice the option to furnish certain types of competitively bid items without participating in the competitive bidding program (§ 414.404(b)(2)).

e. Comments on Bidding by Product Category

We received numerous comments concerning the definition and use of product categories. We believe that conducting separate bidding processes for individual product categories will encourage the participation of small suppliers that specialize in one or a few product categories. It is our goal to allow Medicare beneficiaries the opportunity to receive all related equipment from the same supplier, thereby minimizing disruption to the beneficiary. Suppliers currently specialize in particular products, and we do not see this process being interrupted by competitive bidding. The use of product categories is intended as a compromise that will maximize beneficiary convenience while still permitting suppliers, particularly small suppliers, to specialize in a certain product category.

A few commenters indicated that conducting separate bidding processes for individual product categories is administratively burdensome. They stated that CMS' assumption that large suppliers could expand their products by offering supplies and equipment easier or more quickly than small suppliers is an erroneous view of a company's ability to expand. They also reported that large organizations must seek approval from their boards or other stakeholders before they can undertake certain business expansion activities.

We received comments arguing that product categories should be defined narrowly or broadly. Others stated that the product categories should not differ from the SADMERC policy groups, believing that combining medical policies may affect beneficiary access or quality of services. Suppliers also noted that suppliers are already familiar with the policy groups as that is how the CMS Web site is organized and this is accessed by suppliers frequently for information. Some commenters suggested that product categories should be uniform and as stable as possible because keeping track of differently defined categories would be very difficult. Some commenters also called for subcategories within product groups.

Based on public comments, we have revised the proposed definition of the term ''product category'' in § 414.402 to mean, ''a grouping of related items that are used to treat a similar medical condition''. The list of product categories and the items included in each product category that is included in each competitive bidding program will be identified in the request for bids document for that competitive bidding program or by other means. The policy groups will serve as the starting point for establishing product categories. Product categories may generally be consistent with the policy groups that are established by the SADMERC, unless CMS determines that a policy group should be redefined for the purposes of competitive bidding. The SADMERC established policy groups for the purposes of developing Medical review policies and for data analysis. However, the product categories for which we would request bids could be a subset of items from a SADMERC policy group or a combination of items from different policy groups. There may be items in a policy group that are not subject to competitive bidding or that we would want to exempt from competitive bidding using our authority to exempt items. In response to the suggestion that we include subcategories within a product category, we do not believe this approach would be consistent with the purpose and definition of product categories because a product category is a group of related items used to treat a medical condition and it would be designed to be appropriate for Medicare competitive bidding purposes. In addition, we do not believe that there is a need for subcategories because we would create a new product category instead of a subcategory.

f. Comments on Financial Standards

Several comments argued that the financial standards were too strict for certain suppliers and should be flexible enough to regulate mail order companies, small local suppliers, SNFs, outpatient departments of hospitals, retail pharmacies, and publicly-traded and privately-held family firms. Other commenters argued that the reporting requirements of the proposed financial standards are too burdensome and discourage small suppliers from participating. They recommended that CMS define different standards for small suppliers and pharmacies. The commenters stated that if financial standards are too restrictive, qualified suppliers may be eliminated from the Medicare Part B program. They added that, conversely, if financial standards are too lax, suppliers may be financially unable to meet the challenges of a competitive market.

We agree with the commenters that it is important to have financial standards that ensure suppliers are able to meet the challenges of competitive bidding and can fulfill their contract obligations. After further consideration and in response to comments, we believe that the financial documentation discussed in the proposed rule is too burdensome, particularly for small suppliers. We have determined that we could obtain the necessary information through collection of a limited number of financial documents and believe that the submission of this information will be less burdensome for all suppliers, including small suppliers. We are clarifying in the final rule that the RFB will specify what financial documents will be required (§ 414.414(d)) so that we can obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process. This financial information will provide enough information to allow us to determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier's financial viability. We believe we have balanced the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier.

g. Comments on Supplier Networks

The May 1, 2006 proposed rule included a proposal to permit small suppliers to form a legally binding network with other small suppliers for the purpose of submitting a bid. Many commenters believed that the option to

form a network is not a realistic solution for ensuring that small suppliers participate in the competitive bidding program. They expressed concern that forming a network could violate the Federal antitrust laws because those laws do not permit suppliers to reach a mutual consensus on pricing. They also stated that the proposed rule would require suppliers to agree on proposed prices for all items within a competitive bidding product category. They further believed the proposed rule is complex, and that suppliers would not have sufficient time to form a network and comply with all the requirements to meet the competitive bidding implementation timelines.

We agree that forming a network may pose a challenge for some suppliers. However, forming a network is a business decision and we continue to believe that networks should be an option for small suppliers to promote competition and efficiencies that could improve services to beneficiaries. The proposed rule was published May 1, 2006. We believe sufficient notice has been given for suppliers to consider network options and plan accordingly. We believe that our network policy is constructed in a way that maximizes participation of suppliers.

Suppliers that pursue the network option must comply with all applicable Federal antitrust laws. We have taken steps to ensure that each network is not in violation of Federal antitrust laws or exhibits otherwise anticompetitive behavior by including the following requirements:

Network participation will be limited to small suppliers that cannot compete in competitive bidding because they cannot independently service the entire CBA. A written certification will be required from each network supplier that it is unable to compete (that is, cannot service the entire CBA on its own) without joining a network (§ 414.418(b)(6)). We believe this provision will help ensure that a small supplier has a legitimate need to participate in a network. This will minimize the potential for anticompetitive behavior and will assist small suppliers by expanding their opportunity to participate. Network members' Medicare market share at the time of bidding when added together cannot exceed 20 percent of the Medicare market (§ 414.418(b)(7)). This would guard against excessive network market share. Network membership in any one network will be limited to 20 small suppliers to help promote competition among suppliers. Our rationale for limiting the number of small suppliers to no more than 20 is the following:

- This would help avoid collusion which could lead to less competition and higher bids.
- It would ease administrative burden and reduce the overall cost of evaluating each network.
- A 20-supplier network would be able to serve an entire CBA even if each of its members is small. Networks are required to form a legal entity that functions as the bidder. We do not believe that a network should include more members than is necessary to service an entire CBA because other suppliers who are not in networks have to service an entire CBA.

The network provisions do not establish a safe harbor or a safety-zone or in any way protect anticompetitive behavior. All of the Federal laws and regulations that govern anticompetitive behavior, including the Federal antitrust laws, will fully apply.

A few commenters agreed with our proposal to require that suppliers participating in a network form a discrete legal entity and stated that this would prevent the commingling of Medicare funds, as well as violations of the Federal anti-kickback statute, self-referral rules and regulations, and allegations of unfair business practices among the participating network suppliers. Other commenters believed that requiring each network to independently bid defeats the entire purpose of networking. They disagreed with the primary legal entity being responsible for billing Medicare and receiving the payments. They believed that each supplier should be responsible for its own finances.

We appreciate the support for our proposal that each network must form a legal entity. We agree that the primary legal entity should not be responsible for billing Medicare and receiving the payments and have revised § 414.418(b)(4) to reflect this rule. We are requiring each member of the network to submit its own Medicare claims and are specifying that each member will be paid directly for Medicare products and services furnished as part of its individual business. This is consistent with our current Medicare policies for each supplier to submit claims to receive Medicare payments.

A few commenters believed that networks that provide multiple product categories pose a risk because not all the network members will furnish all the product categories; therefore, beneficiaries may not have access to services. They recommended that CMS add requirements to ensure that networks bids are scrutinized to ensure that each network has appropriate mechanisms to service the entire CBA. The commenters recommended that each beneficiary have a single point of contact for the network to ensure satisfactory resolution of performance problems or other issues across the CBA. They also asked if subcontractors needed to meet the same requirements as a contract supplier. Based on these concerns we are requiring that networks form a legal entity, such as a joint venture or limited partnership. Each network member will also be required to satisfy all applicable bidding requirements. Each network member is equally responsible for the quality of care, service, and items that it delivers to Medicare beneficiaries. If any member of the network falls out of compliance with this requirement, we have the option of terminating the network contract.

A few commenters questioned why a limit of 20 percent of the market share was assigned to the network, leaving 80 percent of the Medicare market for a large company. They suggested allowing network members to obtain market share not to exceed 35 percent, as specified in the Department of Justice monopoly guidelines. A few commenters requested that CMS disclose the methodology that will be used to calculate the market share and monitor changes over the course of the contract.

In this final rule, we have decided to finalize the proposed 20-percent market share limitation on the capacity of networks. However, once a network receives a contract, there is no limit on what percentage of the demand in the CBA that the network can furnish. We believe that this will ensure a sufficient number of contract suppliers and provide beneficiaries with more variety and choice.

Some commenters suggested that CMS allow suppliers to join up to two networks, recognizing that many suppliers currently participate in several networks. They believed that this would ensure that the participating supplier is not disadvantaged by a requirement to commit to a single network bid. We agree with the commenters. We will allow suppliers to join more than one network, but a supplier cannot join more than one network for purposes of furnishing items in the same product category in the same CBA. We believe that this policy is necessary because, without it, the competitive bidding process would be undermined by allowing suppliers to bid against themselves for the same product category. In other words, if a

supplier wants to independently furnish items for a product category, it would not be able to join another network that furnishes the same product category in the same CBA. However, a supplier that wishes to furnish products that are in two different product categories would be able to join a different network for each product category or submit a bid as an individual supplier for one product category while joining a network for the other product category.

A few commenters asked how networks would obtain a supplier billing number. The Medicare competitive bidding implementation contractor will assign each network a bidder number that will be used to monitor the network. As stated earlier, each member of the network will be allowed to submit its own claims and receive Medicare payments directly.

A few commenters requested that CMS clarify whether each supplier that is a member of a network would be required to provide all of the items for the product category for which the network submits a bid. The member of the networks would be required to provide all the items within the product category for which the network submits a bid. This is consistent with our requirement that all winning suppliers must furnish all items in a product category. Therefore, each member of the network must be able to provide all items within the product categories for which the network has submitted bids. Although the network must provide items to any beneficiary throughout a CBA, each member of the network is not responsible for providing an item throughout the entire CBA.

4. Description and Estimate of the Number of Small Entities

As of January 2006, the SBA defines a small business as generating less than $6.5 million in annual receipts. We worked with the SBA to define small supplier for the Medicare DMEPOS Competitive Bidding Program. In this final rule, we are defining a small supplier as a supplier that generates gross revenue of $3.5 million or less in annual receipts. Before we receive supplier bids, we do not have information on each supplier's total revenue. We only have information on suppliers' Medicare revenues. As a result, we had to make an assumption about what percent of a supplier's revenues come from Medicare. We looked at filings by public DMEPOS companies and, based on that information, we assume one-half of the average supplier's revenues come from Medicare DMEPOS.

Suppliers that furnish products in a CBA in at least one product category selected for competitive bidding will be affected by this program. A supplier that does not furnish competitively bid items and services to beneficiaries in a CBA will not be affected. Based on analysis of CY 2005 Medicare DMEPOS claims, we estimate the number of suppliers affected in the Regulatory Impact Analysis as described below. This analysis preceded finalization of the product categories and selection of bidding areas and is thus based on a number of assumptions, as detailed in the Regulatory Impact Analysis. Based on CY 2005 claims data, the average MSA in the top 25 MSAs, excluding New York, Los Angeles, and Chicago, has 2,896 DMEPOS suppliers that furnish any DMEPOS product and 1,972 suppliers that furnish products subject to competitive bidding and could potentially be affected by competitive bidding. We estimate that 28,960 suppliers will provide competitive bid items in the CBAs that we initially designate. If suppliers furnish products in more than one MSA, we counted them more than once because they are affected in more than one MSA. Not all products are subject to competitive bidding; therefore, we estimate that 68 percent of suppliers will furnish products subject to competitive bidding and will be affected by competitive bidding during the initial round of competitive bidding. This means in CY 2007, the remaining 32 percent of suppliers in the 10 selected CBAs will not be affected by competitive bidding because they do not furnish products subject to competitive bidding. However, the actual percentage of affected suppliers may be smaller if we do not select all eligible product categories for competitive bidding.

NUMBER OF SMALL SUPPLIERS [1]

[$3.5 million or less in Medicare allowed charges]

Bidding year	Number of affected small suppliers	Total number of affected suppliers	Percent
2007	16,762	19,720	85
2008	90,500	106,470	85
2009	97,031	114,154	85
2010	103,562	121,838	85
2011	103,562	121,838	85
2012	103,562	121,838	85

[1] Some suppliers furnish products in more than one selected MSA. Consequently, some suppliers may be counted more than once.

5. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The primary compliance cost of the proposed rule will be the cost of bid submission. As part of a separate rule, all DMEPOS suppliers will be required to gain and maintain accreditation which may lead to significant compliance costs. However these costs are not considered under the competitive acquisition program, and thus we concentrate on the costs of bidding which includes time devoted to supplier education efforts, completing forms, and providing documentation.

Bidders must decide whether to bid, request or download an RFB, attend a bidders conference (optional) and read outreach materials, decide how much to bid for each item, and prepare and submit a bid. In the demonstration, bidders in Polk County, Florida reported spending a total of 40 to 100 hours submitting bids. In the proposed rule we assumed that suppliers would use the midpoint number of hours, 70 hours. We have reduced our estimate of the required hours to 68, due to changes we made to condense the bidding forms requirements, based on comments we received on the proposed rule. According to 2005 Bureau of Labor Statistics (BLS) data, the average hourly wage for an accountant and auditor was $25.54 (National Compensation Survey: Occupational Wages in the United States, June 2005, U.S. Department of Labor, Bureau of Labor Statistics, Bulletin 2568, August 2006. *http://www.bls.gov/ncs/ocs/sp/ncbl0832.pdf*).

Accounting for inflation and overhead, we assume suppliers will incur $33.87 per hour in wage and overhead costs. Based on this information, we assume that a supplier that bids will spend $2,303.16 ($33.87 * 68) to prepare its bid, taking into consideration that the number of product categories included in a bid, on average, will vary by supplier. We calculate the total cost for all supplier bids, including those of both future winning and future losing suppliers. Therefore, we expect that CY 2007 total supplier bidding costs for 15,973 bids will be $36,788,375 ($2,303.16 * 15,973). This estimate is clearly dependent on our assumption that 81 percent of eligible suppliers will bid. Our estimates incorporate the fact that a single organization may submit bids in more than one CBA in each round. For example, a supplier that has 15 offices in the country and currently serves all 10 of the CBAs to be included in the initial round of bidding is counted 10 times in our estimates. Our estimate of the time required for bidding assumes that suppliers in the competitive bidding program will bid on about the same number of individual product categories as suppliers bid on during the demonstration project. We expect that supplier bidding costs will rise with the number of product categories bid upon; however, because there are fixed costs associated with deciding whether to participate in the competitive bidding program and some of the bidding forms are only filled out once, the increase in costs associated with each additional product category may be relatively small. Therefore, our estimate of the time required per bid should be reasonably accurate unless suppliers bid on significantly more or fewer product categories than they bid on during the demonstration.

6. Agency Efforts to Minimize the Significant Economic Impact on Small Entities

Small suppliers constitute the large majority of DMEPOS firms, and we anticipate they will form the majority of contract suppliers. Therefore, consideration of small suppliers influenced virtually all aspects of the final rule. We detailed the aspects of the final rule that, in particular, are intended to minimize the impact on small entities. These aspects and the respective section of the preamble of this final rule are as follows:

- Grandfathering of suppliers (see section VI.D.3.a of this final rule).
- Requirement for physicians and certain nonphysician practitioners to submit bids (see section VI.G.3 of this final rule).
- Product categories for bidding purposes (see section VI.G.4 of this final rule).
- Financial standards (see section VII.C, of this final rule)
- Selection of small suppliers (see section XI. of this final rule).
- Opportunity for networks (see section XII. of this final rule)

C. Anticipated Effects

We can anticipate the probable effects of this final rule, but the actual effects will vary depending on which CBAs and product categories are ultimately selected for competitive bidding under the Medicare DMEPOS Competitive Bidding Program. The analysis that follows, taken together with the rest of this preamble, constitutes the final regulatory impact analysis.

As a result, for the purpose of this impact analysis, it is necessary to make several assumptions. These assumptions are due to the uncertainty concerning the actual number of suppliers that will participate, the associated bid amounts, and the specific items and areas for which competitive bidding will be conducted.

First, we assume that the first round of bidding will occur in CY 2007, with prices taking effect in April 2008, and the second round of bidding will occur in CY 2008, with prices taking effect in April 2009. We also assume rebidding will only occur every 3 years.

Second, we assume that competitive bidding will occur in 10 of the largest MSAs in CY 2007, excluding New York, Chicago, and Los Angeles. We exclude the three largest MSAs in CY 2007 because we are not including them in the initial phase of implementation. We are excluding the three largest MSAs because we would like to gain more experience in smaller markets before we enter into the largest markets. For the initial competition, we assume that bidding will take place in CY 2007, bids will be evaluated in CY 2007, and prices will go into effect on April 1, 2008. The second round of bidding will take place in 70 of the largest MSAs in CY 2008, and the prices will go into effect on April 1, 2009. The next round of bidding will take place in 10 additional MSAs and will occur in CY 2009, with bid prices going into effect on January 1, 2010. An additional round of bidding will include 10 MSAs and will occur in CY 2010, with bid prices going into effect on January 1, 2011.

Third, we made some assumptions about which product categories would be selected for competitive bidding. We recognize that potential savings, implementation costs, the number of affected suppliers, and supplier bid costs all depend on which product groups are ultimately selected. The product categories have yet to be decided. We expect that approximately 10 product categories will be selected for competitive bidding for CY 2007 and as many as 7 or 8 of the selected product categories will be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories will come from the top 20 policy groups ranked by allowed charges. Table 11 shows the top 20 eligible DMEPOS policy groups and their CY 2005 allowed charges.

TABLE 11.—CY 2005 ALLOWED CHARGES: TOP 20 ELIGIBLE DME POLICY GROUPS

Rank	Policy group	Allowed charges 2005*	Percent of eligible DMEPOS charges
1	Oxygen Supplies/Equipment	$2,669,015,203	34
2	Wheelchairs/POVs	1,512,581,843	19
3	Diabetic Supplies & Equipment	1,176,121,037	15
4	Enteral Nutrition	582,085,753	7.5
5	CPAP	378,084,371	4.9
6	Hospital Beds/Accessories	320,372,566	4.1
7	Support Surfaces	184,266,860	2.4
8	Negative Pressure Wound Therapy	169,012,105	2.2
9	Infusion Pumps & Related Drugs**	157,396,292	2.0
10	Respiratory Assist Device	135,023,095	1.7

TABLE 11.—CY 2005 ALLOWED CHARGES: TOP 20 ELIGIBLE DME POLICY GROUPS—Continued

Rank	Policy group	Allowed charges 2005*	Percent of eligible DMEPOS charges
11	Walkers	106,661,034	1.4
12	Nebulizers	97,574,696	1.3
13	Ventilators	70,625,578	0.9
14	Commodes/Bed Pans/Urinals	47,861,299	0.6
15	Patient Lift	27,768,236	0.4
16	TENS	23,536,834	0.3
17	Seat Lift Mechanism	17,159,455	0.2
18	CPM Device	17,023,378	0.2
19	Suction Pump	14,096,633	0.2
20	Off-the-shelf Orthotics	13,807,205	0.2
Total for 20 Groups		7,719,487,197	99

*2005 allowed charges projected based on 98 percent claims processed through March 2006.
** Includes $50 million in allowed charges for drugs.

However, we reiterate that the discussion in this impact analysis should in no way be interpreted as signifying which product categories will be selected for the actual competitive bidding program. Our product category selection for this impact analysis is only to assist us in estimating the potential savings, costs of implementation, and supplier and beneficiary impacts.

Fourth, we assume that the Medicare DMEPOS fee schedule will increase at the rate of inflation for those years in which a statutory freeze has not been put in place by the Act. We base our estimates on the expected growth in Medicare Part B expenditures from the Trustees Reports. (Tables IV.F.2 and IV.F.3 of the 2004 Medicare Trustees Report.).

This final rule is expected to affect the Medicare program and its beneficiaries, certain CMS contractors, and DMEPOS suppliers. Although the workload of referral agents, including hospital discharge planners and some health care practitioners, appeared to increase during implementation of the demonstration, we do not anticipate that competitive bidding will result in a large, ongoing burden on referral agents. For many DMEPOS product categories, referral agents play an important role in helping beneficiaries select DMEPOS suppliers that can meet the beneficiaries' needs. During the demonstration, those referral agents who previously referred beneficiaries to non-demonstration suppliers had to change their referral patterns. It is difficult to quantify this burden because we have no data on the number of referral agents who will be affected, nor do we have information on the effort associated with identifying a new supplier. We note that we plan to take steps to mitigate any burden that might arise for referral agents. For example, we are planning an extensive educational campaign for suppliers, referral agents, and beneficiaries. Educational materials, including an on-line supplier directory, will expedite the process for identifying and locating contract suppliers and therefore minimizing any burden. In addition, we will post on the internet the list of brands that each contract supplier furnishes. This brand information should be extremely useful for referral agents and may even reduce burden under the program.

The DMEPOS supplier industry is expected to be significantly impacted by this final rule. However, not all suppliers will be affected directly by the competitive bidding program. Suppliers that furnish products in a CBA in at least one product category selected for competitive bidding will be affected. A supplier that does not furnish competitively bid items and services to beneficiaries in a CBA will not be affected. Based on analysis of CY 2005 Medicare DMEPOS claims, we estimate that approximately 30,000 suppliers offer at least one product eligible for competitive bidding and are located in one of the largest 100 MSAs and, therefore, could be impacted by the program. Some of these suppliers will be affected in multiple CBAs if they offer products in more than one CBA.

Based on our analysis of CY 2005 claims data, we also estimate that approximately 85 percent of registered DMEPOS suppliers are considered small according to the SBA definition. According to the SBA, ''A small business is a concern that is organized for profit, with a place of business in the United States, and which operates primarily within the United States or makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor. Further, the concern cannot be dominant in its field, on a national basis. Finally, the concern must meet the numerical small business size standard for its industry. SBA has established a size standard for most industries in the U.S. economy.'' The size standard for NAICS code 532291, Home Health Equipment Rental, is $6.5 million. (See the Web site: *http://www.sba.gov/size/sizetable2002.html*, read November 30, 2006.)

Many of these suppliers provide minimal amounts of DMEPOS, and thus the remaining larger suppliers control significant market share. We anticipate that the fixed costs required to undergo the bidding process may be a larger deterrent to small businesses than larger firms. Because suppliers can choose whether to submit a bid for the Medicare DMEPOS Competitive Bidding Program, this final rule imposes no direct costs and, therefore, does not reach the $120 million direct cost threshold under the UMRA. While not included in this final rule, we expect that the separate MMA requirement for accreditation of suppliers will result in added supplier costs beyond those included in this final rule.

Comment: One commenter stated that the RFA analysis of the impact of the proposed regulation was incomplete and inadequate because it did not consider the impact of the proposed regulation on long-term care hospitals and Medicare beneficiaries who reside in these facilities. Other commenters suggested that long-term care facilities would incur increased costs and the quality of treatment received by their patients would be diminished if they are included in the Medicare DMEPOS Competitive Bidding Program and offered alternatives to competitive

bidding that they believed would achieve cost savings.

Response: We considered the impact of the Medicare DMEPOS Competitive Bidding Program on all suppliers. We believe our estimates reflect the costs on average that will be incurred by the suppliers that participate in the program. If a long-term care hospital decides to submit a bid to furnish items and services under the program, its bid should reflect its costs to furnish those items and services. In addition, the quality standards for DMEPOS suppliers require that suppliers furnish quality items and services.

Comment: One commenter disagreed with CMS' assumption that the DMEPOS fee schedule will increase at the rate of inflation for those years in which a statutory freeze is not in effect and that total charges will increase at the same rate as Medicare Part A and Medicare Part B expenditures (71 FR 25691). The commenter suggested that non-DME, non-home health care costs are the driving forces causing increases in these programs. Other commenters suggested that home care expenditures are not increasing and that rising hospital, nursing home, physician, and medication costs were the causes of rising overall Medicare expenditures.

Response: Based on the public comments we received, we have clarified in this final revised impact analysis that our estimates on expected growth will be based on Medicare Part B expenditures. DMEPOS expenditures have been growing at varying rates in recent years (expenditures for 26 product categories rose 5 percent between 2004 and 2005 and 21 percent between 2002 and 2005), and the rate of growth has varied widely between product categories, making precise estimates of growth for DMEPOS difficult. We believe that the overall growth rate for Medicare Part Be expenditures provides a reasonable estimate of the growth rate for DMEPOS because both growth rates are driven by changes in Part B enrollment and overall growth in medical care use. To address inflation, we will be asking the suppliers to submit bids that include all costs associated with furnishing each item for all 3 years of the contract.

Comment: A number of commenters objected to the data in Table 11 of the proposed rule (71 FR 25691) indicating that 2003 allowed charges for infusion pumps and related devices were approximately $149 million. These commenters believed that the correct amount was approximately $87 million. The commenters believed that the $149 million amount inappropriately includes charges for insulin and insulin pumps which are not provided by infusion pharmacies.

Response: The data in the proposed analysis include allowed charges for insulin and infusion pumps. Although these items may not be furnished by infusion pharmacies, they are included because they are subject to competitive bidding under the Act.

Comment: Several commenters disagreed with the statement in the preamble of the proposed rule (71 FR 25692) that the UMRA does not apply to this rule. One commenter suggested that virtually all affected suppliers would submit bids (and thus would incur costs) and even using CMS estimates (that the commenter believed to be too low), the costs for the CY 2008 round of bidding would be $178 million, an amount that the commenter believed exceeded the UMRA's threshold of $120 million.

Response: We have updated our estimates in this final rule using CY 2005 data. Based upon the estimated number of suppliers that will submit bids, the costs of submitting bids, and the fact that the average number of suppliers per CBA will decrease in future rounds of competitive bidding, we do not expect that costs will exceed the UMRA's $120 million threshold.

D. Implementation Costs

CMS will incur administrative costs in connection with the implementation and operation of the Medicare DMEPOS Competitive Bidding Program, which can affect the net savings that can be expected under this final rule. However, many of the variable costs associated with bid solicitation and evaluation will ultimately depend on how many suppliers choose to participate in competitive bidding. Because of this uncertainty, we are not able to estimate bid solicitation and evaluation costs at this time.

We will incur initial startup costs. CMS estimates internal costs and costs to its contractors to be approximately $1 million in immediate fixed calendar year costs for contractor startup and system changes for the initial competitive bidding phase in CY 2007. In addition to the initial startup costs, we will also incur maintenance costs and bid solicitation and evaluation costs. We will need to pay maintenance costs every year for the running of the program. However, we will only need to pay bid costs in the years in which competitive bidding is conducted. Yearly maintenance costs will depend on the number of CBAs in which the program has been implemented, while bid solicitation and evaluation costs will depend on the number of sites that have bidding that year.

Our maintenance costs will include a small staff to oversee the program, office costs for the staff, as well as staff travel costs, and overhead. In addition, the CBIC(s) will be responsible for most of the program maintenance. The maintenance costs could also include the costs for an ombudsman(s) to assist suppliers, beneficiaries, and referral agents with the competitive bidding process and questions. We also expect to incur costs for education and outreach expenses such as staff resources and material costs for producing education materials and supplier directories.

We will incur bid costs in the years in which we conduct competitive bidding and when we evaluate bids. These costs will be a direct result of the bid solicitation and evaluation process. Bid solicitation costs include costs associated with mailing necessary information to suppliers, printing, duplicating, and the cost of administering an electronic bidding program. The actual costs will vary by CBA and will depend on the number of potential suppliers. We will incur bid evaluation costs whenever bidding occurs in a CBA. According to the DMEPOS evaluation report, it took about 9.4 hours during the demonstration to evaluate each bid and the supplier to ensure that only quality suppliers were selected. However, because the Medicare DMEPOS Competitive Bidding Program uses quality standards and accreditation as a separate process, we expect that the time required to evaluate bids will be less than in the demonstration. The total bid evaluation costs will ultimately depend on the number of suppliers that choose to submit bids.

Comment: Several commenters believed that the regulatory analysis in the proposed rule significantly underestimated the administrative costs associated with implementing the competitive bidding program, further reducing any net savings. One commenter referred to a study that estimated that CMS would need 1,600 new staff to implement the proposed regulation.

Response: As explained in the proposed rule, we are making the best estimates based on the experience in the demonstrations. Even though these estimates will be affected by the number of suppliers and items for which we do competitive bidding, nevertheless they represent our best estimates. After careful review of the study referenced by the commenter, we disagree with the estimate of the number of extra staff

needed to implement the proposed regulation. We believe our original estimates better reflect the resource needs for the competitive bidding program.

E. Program Savings

We estimate significant savings from the Medicare DMEPOS Competitive Bidding Program. Our estimates of gross savings utilize as a starting point the results in the demonstration. Excluding surgical dressings, which are not eligible for competitive bidding, the average product group savings rate in the demonstration ranged from 9 to 30 percent per round, with most product groups having about a 20-percent savings. Table 12 shows the savings rate for selected product groups and CBAs by round during the DMEPOS demonstration.

TABLE 12.—DMEPOS COMPETITIVE BIDDING DEMONSTRATION SAVINGS RATES

Product group	Polk County Round 1	Polk County Round 2	San Antonio
Oxygen Equipment and Supplies	$2,364,811 (17%)	$1,525,490 (20%)	$2,096,707 (19%)
Hospital Beds and Accessories	$290,715 (23%)	$195,140 (31%)	$644,514 (19%)
Urological Supplies	$36,169 (18%)	$12,585 (9%)	Not included
Surgical Dressings	−$30,321 (−12%)	−$637 (−1%)	Not included
Enteral Nutrition	$342,251 (17%)	Not Included	Not included
Wheelchairs and Accessories	Not included	Not included	$796,617 (19%)
General Orthotics	Not included	Not included	$89,462 (23%)
Nebulizer Drugs	Not included	Not included	$1,020,072 (26%)

Source: Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report (November 2003), pages 90 and 92.

Under this final rule, we will set prices for individual items equal to the median winning bid for that item. In contrast, the demonstration used a more complicated pricing rule that adjusted fees for each item to ensure that each suppliers overall payment was equal to the pivotal bid. In our estimates, we have taken into account that some DMEPOS prices have been adjusted downward since CY 2000. We assume that if prices for an individual item have already been reduced by 10 percent after the demonstrations were completed, prices would most likely fall 10 percent rather than 20 percent. Therefore, we found that the median pricing rule would have produced fees that were approximately 5 percentage points lower than those produced by the demonstration method, assuming that the median pricing rule would not have affected the number of winning bidders who signed contracts or the suppliers' bidding strategies. We have incorporated the effects of the median pricing rule into our estimates of savings from the program. We assumed a 25 percent savings in the estimate because of the median pricing methodology. We netted out any statutory reductions in prices that have already occurred, such as the CY 2005 reductions in oxygen supplies and equipment. These numbers also reflect the reductions in Medicare payments that resulted from the DRA provisions on capped rental DME and oxygen payment, as well as the wheelchair recoding initiative recently undertaken by CMS.

Table 13 shows the impact on the FFS program for the 10 policy groups. In the table, savings are reported as negative values. The savings are attributable to the lower payment amounts anticipated from competitive bidding. The table shows the reduction in Medicare allowed charges, without any impact on the Medicare Advantage program, associated with the program for the calendar year. The impact includes reductions in Medicare payments (80 percent) and reductions in beneficiary coinsurance (20 percent).

TABLE 13.—PROGRAM IMPACT FOR 10 POLICY GROUPS

[in millions] *

	Calendar Year					
	2007	2008	2009	2010	2011	2012
Allowed Charges	$0	−$108	−$766	−$1126	−$1224	−$1301
Medicare Share of Allowed Charges (80 percent of allowed charges)	0	−86	−613	−901	−979	−1041
Beneficiary Costs (20 percent of allowed charges)	0	−22	−153	−225	−245	−260

* Numbers may not add up due to rounding.

Table 14 presents the impact differently than Table 13. In contrast to Table 13, which is on a Medicare allowed charge-incurred basis and does not consider the Medicare Advantage program impact, Table 14 considers fiscal year cash impact on the entire Medicare program, including Medicare Advantage for the fiscal year rather than calendar year. The fiscal year–calendar year distinction is an important one when comparing savings. For example, the prices for the Medicare DMEPOS Competitive Bidding Program will be in effect for 6 months of fiscal year 2008, but for 9 months of calendar year 2008.[1] Table 14 considers the impact on program expenditures, and does not include beneficiary coinsurance. Finally, the estimates in Table 14 incorporate spillover effects from the competitive acquisition program onto the Medicare Advantage program. The expectation is that lower prices for DME products in FFS will lead to lower prices in the Medicare Advantage market.[2]

[1] Fiscal year 2008 will begin October 1, 2007, and the Medicare DMEPOS Competitive Bidding Program payments become effective on April 1, 2008.

[2] In addition, most managed care plan rates are linked to FFS expenditures. Therefore, a decrease in FFS expenditures should translate into a

TABLE 14.—FISCAL YEAR COST ON THE MEDICARE PROGRAM

[in millions]

Fiscal year	Program impact	Beneficiary costs
2007	$0	$0
2008	−70	−20
2009	−530	−130
2010	−1,000	−250
2011	−1,240	−310
2012	−1,370	−340

Comment: Several commenters believed that the regulatory analysis overstated the potential savings of the proposed rule because many of the savings in the earlier demonstrations can no longer be achieved in other areas of the country due to changes in payment policies for major categories of DMEPOS such as oxygen, subsequent CPI freezes, and increases in supplier costs in areas such as fuel and labor. Another commenter suggested that potential savings would be reduced if suppliers submit higher bids in order to account for costs related to quality standards and accreditation costs. One commenter recommended that CMS recalculate these estimates. Another commenter stated that some of these factors also resulted in understating the adverse impact of the proposed regulations on suppliers.

Response: We have updated the tables in the impact analysis of this final rule to reflect all of the recent changes in policy related to items subject to competitive bidding, including any payment reductions. The impact analysis builds in the statutory reimbursement cuts into the baseline DME spending. For instance, the DRA section 5101 is estimated to yield $880 million savings over 5 years (2008 through 2012). The FEHBP reductions are built into the baseline DME spending and yielded a 5 year savings (2008 through 2012) of $2,180 million. We believe that the demonstrations are an appropriate gauge for estimating projected savings. We also believe that the competitive bidding financial standards and the DMEPOS quality standards we have issued will result in more efficiently operating DMEPOS suppliers.

decrease in Medicare Advantage plan payment rates. The rate calculations for the Medicare Advantage program reflect all the FFS adjustments, including the Medicare DMEPOS Competitive Bidding Program savings. The Managed Care add-on increases the FFS savings by 24.9 percent in CY 2008. This is a dynamic number that increases over time.

F. Effect on Beneficiaries

Possible impacts on beneficiaries are a primary concern during the design and implementation of the Medicare DMEPOS Competitive Bidding Program. While there may be some decrease in choice of suppliers, there will be a sufficient number of suppliers to ensure adequate access. We also expect there will be an improvement in quality because we will more closely scrutinize the suppliers before, during, and after implementation of the program. The evaluation of the impact of the DMEPOS competitive bidding demonstration on patient access to care and quality showed minimal adverse results (Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; *http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf).* Moreover, because of the quality standards and the provisions in this final rule to ensure access to and the furnishing of quality products, we assume that there will be few negative impacts on beneficiary access, as a sufficient number of quality suppliers will be selected to serve the entire market.

We acknowledge that implementation of competitive bidding may result in some beneficiaries needing to switch from their current supplier if their current supplier is not selected for competitive bidding. However, we anticipate that the necessity of switching suppliers will be minimized because of the existence of grandfathering policies for rental products such as capped rentals. For purchased items that are not grandfathered, some beneficiaries currently using DMEPOS will have to switch from noncontract to contract suppliers. This switch will not be very burdensome, because the beneficiaries will already be making new purchases. We note that, if a beneficiary owns an item subject to competitive bidding, the beneficiary has the choice of having the item serviced by either a noncontract or contract supplier. Beneficiaries who maintain a permanent residence in a CBA who are traveling and need to rent or purchase DMEPOS during their travels will have to make arrangements to receive their equipment either from a contract supplier in their CBA, from a contract supplier in the visited area if that area is in a CBA and the item is included in the competitive bidding for that CBA, or—if the visited area is not in a CBA—from a noncontract supplier who must accept the reimbursement rate from the beneficiaries home CBAs. It is not clear whether this will have a large impact on beneficiaries. There is little evidence on how frequently beneficiaries receiving DMEPOS travel outside their CBA. Under current policy, a traveling beneficiary must already make arrangements for receipt of his or her DMEPOS during travel and payment is already based on the fee schedule for the beneficiary's residence. We do not believe that our policy will have a large impact on beneficiaries because we will ensure that we have a sufficient number of contract suppliers to meet beneficiary demand.

Because beneficiaries face a 20 percent coinsurance rate for DMEPOS, we assume that beneficiary out-of-pocket expenses will decrease by 20 percent of program gross savings for those products for which we do competitive bidding (Table 15).

TABLE 15.—BENEFICIARY COINSURANCE ANNUAL SAVINGS ESTIMATES FOR 10 PRODUCTS

[in millions]

Calendar year	10 products
2007	$0
2008	22
2009	153
2010	225
2011	245
2012	260

Comment: One commenter argued that since the analysis projects that 37 percent of suppliers will not become contract suppliers, the impact on beneficiaries, especially those requiring diabetic supplies and equipment, will be greater than the analysis indicates.

Response: Our methodology will ensure that beneficiaries requiring diabetic supplies and equipment will have access to a sufficient number of suppliers to meet their needs. As explained in various sections of the preamble to this final rule, we will be taking several steps to ensure that there will be a sufficient number of suppliers to meet beneficiary demand. These steps include the following:

- Evaluating the bidding suppliers' capacity to ensure that there is enough supplier capacity to meet the Medicare demand for each product category in each CBA.
- Implementing a small supplier target under which we will attempt to offer a sufficient number of small suppliers the opportunity to participate in the Medicare DMEPOS Competitive Bidding Program.
- Requiring that all commonly owned or controlled suppliers must submit a single bid on behalf of all locations

within the CBA, and additional locations that would furnish items in the CBA.

- Establishing a capacity calculation methodology that caps the estimated capacity of each bidding supplier capacity at 20 percent for purposes of determining the pivotal bid for the product category.

In addition, our estimates indicate that beneficiaries will save money on their diabetic supplies and equipment under the program.

G. Effect on Suppliers

We expect DMEPOS suppliers to be significantly impacted by the implementation of this final rule. We assume that suppliers may be affected in one of three ways as follows:

- Suppliers that wish to participate in competitive bidding will have to incur the cost of submitting a bid.
- Noncontract suppliers that furnished competitively bid items before the Medicare DMEPOS Competitive Bidding Program took effect (including suppliers that do not submit bids) will see a decrease in revenues because they will no longer receive payment from Medicare for competitively bid items.
- Contract suppliers will see a decrease in expected revenue per item as a result of lower allowed charges from lower bid prices. However, because there will be fewer suppliers, a contract supplier's volume could increase. As a result, because we do not know which effect will dominate, the net effect on an individual contract supplier's revenue is uncertain prior to bidding. The increase in the supplier's volume could help offset the decrease in revenue per item.

1. Affected Suppliers

Based on CY 2005 claims data, the average MSA in the top 25 MSAs, excluding New York, Los Angeles, and Chicago, has 2,896 DMEPOS suppliers that furnish any DMEPOS product and 1,972 suppliers that furnish products subject to competitive bidding and could potentially be affected by competitive bidding.

We estimate that 28,960 suppliers will provide DMEPOS items in the CBAs that we initially designate. If suppliers furnish products in more than one MSA, we counted them more than once because they are affected in more than one MSA. Not all products are subject to competitive bidding; we estimate that 68 percent of suppliers will furnish products subject to competitive bidding and will be affected by competitive bidding during the initial round of competitive bidding. This means in CY 2007, the remaining 32 percent of suppliers in the 10 selected CBAs will not be affected by competitive bidding because they do not furnish products subject to competitive bidding. However, the actual percentage of affected suppliers may be smaller if we do not select all eligible product categories for competitive bidding.

Deciding whether or not to submit a bid is a business decision that will be made by each DMEPOS supplier. We expect that most suppliers providing competitively bid items will choose to participate in order to maintain and expand their businesses. For the calculations in the proposed rule, we assumed that 90 percent of suppliers that furnish items that we choose to include in the program would submit a bid. We assumed the remaining 10 percent of suppliers would not bid based on the low level of the Medicare revenue received for the items subject to competitive bidding or because they had not received the necessary accreditation. Based on comments we received on the May 1, 2006 proposed rule, we will permit physicians and certain nonphysician practitioners to furnish certain limited items as part of their professional practice without submitting a bid and being awarded a contract, provided certain conditions are met. These physicians and non-physician practitioners would be required to submit bids and be awarded contracts if they wish to furnish other types of competitively bid items. These physicians and non-physician practitioners account for about 10 percent of all DMEPOS suppliers, according to the NSC. Therefore, we now assume that 81 percent (= 0.9 *0.9) of affected suppliers will submit bids. Based on this assumption, 15,973 suppliers will submit a bid because they will want the opportunity to continue to provide these products to Medicare beneficiaries and to expand their business base. We also assume, based on the results of the demonstration, that at least 60 percent of bidding suppliers will be selected as winners in at least one product category. This assumption is slightly different than our assumption in the proposed rule, where we stated, ''We also assume, based on the results of the demonstration, that 50 percent of bidding suppliers will be selected as winners because approximately 50 percent of those who submitted bids during the demonstration were selected as contract suppliers.'' The 50 percent in the proposed rule was based on the demonstration experience within individual product categories; approximately 50 percent of the bidders who submitted a bid in a product category were selected as a winner in that product category. Overall during the demonstration, about 60 percent of suppliers who submitted bids in any categories were selected as winners in at least one product category. We believe the 60 percent figure represents a more accurate assessment of the probability that a bidding supplier will be selected as a winning bidder in at least one product category. The bidding DMEPOS suppliers that are not awarded a contract because they did not submit a winning bid would represent about 22 percent of the total DMEPOS suppliers in these CBAs. We expect that losing bidders will be distributed roughly proportionately across the selected CBAs, but the exact distribution will depend on the distribution of bids received and the number of winners selected in each CBA. We also note that if a supplier submitted a bid in multiple product categories, its probability of becoming a contract supplier would increase.

It is difficult to estimate the impact the Medicare DMEPOS Competitive Bidding Program will have on noncontract suppliers. The effect will depend on how much revenue the supplier previously received from Medicare and whether the supplier continues to provide services to existing beneficiaries under the grandfathering policies. Estimates can be made by making assumptions about these factors. For example, if bidding occurred in 10 product categories, losing suppliers previously provided 50 percent of allowed charges in these product categories, and losing suppliers did not continue to serve any existing beneficiaries, the average lost Medicare allowed charges per losing supplier per CBA would be between $35,000 and $40,000. Under these assumptions, the total allowed charges lost by losing suppliers would be $275 million in CY 2008, the first full year after the prices take effect, and increase to almost $2 billion in CY 2011. These estimates reflect our best assumptions. As noted, because of the nature of competitive bidding, winning bidders will absorb much of the allowed charges lost by losing suppliers.

Suppliers that submit bids will incur a cost of bidding. Bidders must decide whether to bid, request or download an RFB, read the RFB, attend a bidders conference (optional) and read outreach materials, decide how much to bid for each item, and prepare and submit a bid. In the demonstration, bidders in Polk County, Florida reported spending a total of 40 to 100 hours submitting bids. In the proposed rule we assumed

that suppliers would use the midpoint number of hours, 70 hours. We have reduced our estimate of the required hours to 68, due to changes we made to condense the bidding forms requirements, based on comments we received on the proposed rule. According to 2005 Bureau of Labor Statistics (BLS) data, the average hourly wage for an accountant and auditor was $25.54 (National Compensation Survey: Occupational Wages in the United States, June 2005, U.S. Department of Labor, Bureau of Labor Statistics, Bulletin 2568, August 2006. *http://www.bls.gov/ncs/ocs/sp/ncbl0832.pdf*). Accounting for inflation and overhead, we assume suppliers will incur $33.87 per hour in wage and overhead costs. Based on this information, we assume that a supplier that bids will spend $2,303.16 ($33.87*68) to prepare its bid, taking into consideration that the number of product categories included in a bid, on average, will vary by supplier. We calculate the total cost for all supplier bids, including those of both future winning and future losing suppliers. Therefore, we expect that CY 2007 total supplier bidding costs for 15,973 bids will be $36,788,375 ($2,303.16*15,973). This estimate is clearly dependent on our assumption that 81 percent of eligible suppliers will bid. Our estimates incorporate the fact that a single organization may submit bids in more than one CBA in each round. For example, a supplier that has 15 offices in the country and currently serves all 10 of the CBAs to be included in the initial round of bidding is counted 10 times in our estimates. Our estimate of the time required for bidding assumes that suppliers in the competitive bidding program will bid on about the same number of individual product categories as suppliers bid on during the demonstration project. We expect that supplier bidding costs will rise with the number of product categories bid upon; however, because there are fixed costs associated with deciding whether to participate in the competitive bidding program and some of the bidding forms are only filled out once, the increase in costs associated with each additional product category may be relatively small. Therefore, our estimate of the time required per bid should be reasonably accurate unless contract bidders bid on significantly more or fewer product categories than they bid on during the demonstration.

Comment: One commenter believed that the statement in the impact section of the proposed rule that not all suppliers will be affected directly by the competitive bidding process (71 FR 25691) is not accurate because the commenter believed that costs for mandatory accreditation alone will force small suppliers out of business. The commenter asked questions relating to the basis for determining that an accountant would prepare the bid and that the cost per hour of $31.25 is appropriate. The commenter believed that it would cost small suppliers more to prepare and submit bids because large suppliers have more experience with managed care contracts and may be bidding in multiple MSAs.

Response: The accreditation program is mandatory and affects all DMEPOS suppliers; therefore, it is not a cost attributable to the Medicare DMEPOS Competitive Bidding Program. As we explained in the proposed rule (71 FR 25694), we used 2003 BLS data, adjusted for inflation and overhead, to arrive at our estimate of $31.25 per hour in wage and overhead costs for an accountant and auditor to prepare a supplier's bid. In our current estimates, we have used 2005 BLS data on wages, and adjusted this number to account for inflation through 2007. We took the midpoint of the reported number of hours to prepare bids for the demonstration projects to develop our estimate of the number of hours needed to prepare a bid. We believe that these average estimated costs would be the same for large or small suppliers. We are not requiring that suppliers use accountants or auditors to prepare the bid submission form. However, to calculate cost estimates for completing the form, we used the wages for accountants or auditors as a benchmark to determine the estimated costs to the supplier.

In CY 2008, we will conduct competitive bidding in 70 MSAs, which may include New York, Los Angeles, and Chicago; and in CYs 2009 and 2010, we will add additional areas. This will increase the number of affected suppliers, contract suppliers, and noncontract suppliers. For the purposes of the impact analysis, we assume that there will be at least 10 additional large CBAs added in both CYs 2009 and 2010. We also assume bid cycles will be 3 years in length. Under our assumptions, we will conduct bidding for the initial 10 CBAs in CY 2007, for 70 additional CBAs in CY 2008, and for additional areas in CYs 2009 and 2010. We note that the estimated average number of suppliers per CBA decreases over time. This is because smaller CBAs with fewer beneficiaries and/or lower allowed charges have fewer suppliers. Table 16 summarizes the effect on suppliers for CYs 2007 through 2012. The table includes the costs of rebidding for the first 10 CBAs in 2010, for 70 CBAs in 2011, and for 10 CBAs in 2012. We assume that rebidding will require the same resources as the initial bids. However, it is possible that suppliers will need less time for bidding after gaining experience during their initial round of bidding. Table 16 differs from the corresponding table in the proposed rule because—(1) The number of suppliers is now based on 2005 claims data; (2) the cost per hour to prepare a bid has been increased from $31.25 to $33.87 to reflect wage increases through 2007; (3) the number of hours required to submit bids has been reduced from 70 to 68; and (4) we now estimate that 81 percent (rather than 90 percent) of suppliers will submit bids.

TABLE 16.—SUPPLIERS BIDDING YEARS: CYS 2007–2012

[10 product categories]

	Bidding year					
	CY 2007	CY 2008	CY 2009	CY 2010	CY 2011	CY 2012
Average number of suppliers per CBA	2,896	1,960	1,866	1,791	1,791	1,791
Average number of affected suppliers per CBA	1,972	1,331	1,268	1,218	1,218	1,218
Total number of suppliers	28,960	156,767	167,921	179,075	179,075	179,075
Total number of affected suppliers	19,720	106,470	114,154	121,838	121,838	121,838
Number of bidding suppliers	15,973	70,268	6,224	22,197	70,268	6,224
Cost of bidding	$36,788,375	*$161,838,447	$14,334,868	$51,123,243	$161,838,447	$14,334,868
Number of contract suppliers	9,584	51,744	55,479	59,213	59,213	59,213
Number of noncontract suppliers	10,136	54,726	58,675	62,625	62,625	62,625

TABLE 16.—SUPPLIERS BIDDING YEARS: CYS 2007–2012—Continued

[10 product categories]

	Bidding year					
	CY 2007	CY 2008	CY 2009	CY 2010	CY 2011	CY 2012
Noncontract suppliers as a percent of total suppliers	35%	35%	35%	35%	35%	35%

[1] Actual numbers will depend on CBAs selected, product groups selected, number of suppliers that choose to submit a bid, the prices bid, and the number of contract suppliers selected.
[2] Some suppliers furnish products in more than one selected CBA. Consequently, some suppliers may be counted more than once.
[3] Numbers in the table are rounded.
* The spike in the private sector costs in CY 2008 is due to the addition of 70 additional CBAs that will be included in competitive bidding, which would include the costs to suppliers submitting bids.

As noted in the start of this section, affected suppliers will be impacted by any reduction in Medicare allowed charges that results from the competitive bidding program. The estimated overall reduction in allowed charges is shown in the first row of Table 13.

As previously noted, noncontract suppliers that furnished competitively bid items before the program took effect (including suppliers that do not submit bids) will see a decrease in revenues because they will no longer receive payment from Medicare for competitively bid items. Contract suppliers will see a decrease in expected revenue per item as a result of lower allowed charges from lower bid prices, but this decrease may be offset by an increase in volume. As a result, because we do not know which effect will dominate, the net effect on an individual contract supplier's revenue is uncertain prior to bidding.

2. Small Suppliers

As of January 2006, the SBA defines a small business as generating less than $6.5 million in annual receipts. The SBA definition refers to small businesses rather than ''small suppliers.'' We worked with the SBA to define small supplier for the Medicare DMEPOS Competitive Bidding Program. In cooperation with the SBA, we are defining a small supplier as a small business that generates gross revenue of $3.5 million or less in annual receipts in accordance with 13 CFR 121.104. We are using this new small supplier definition to focus on the smallest of the DMEPOS suppliers in each CBA. Before we receive supplier bids, we do not have information on each supplier's total revenue. We only have information on suppliers' Medicare revenues. As a result, we had to make an assumption about what percent of a supplier's revenues come from Medicare. We looked at filings by public DMEPOS companies and, based on that information, we assume one-half of the average supplier's revenues come from Medicare DMEPOS. Table 17 shows our estimate of the number of affected small suppliers and total affected suppliers. Some suppliers are counted more than once if they are affected in more than one CBA. These estimates are based on 10-digit National Supplier Clearinghouse (NSC) identification numbers. Some organizations have multiple NSC codes representing multiple locations; however, these organizations tend to be larger suppliers. For the purpose of designating small suppliers for program purposes on the basis of revenue, revenue will be calculated based on an organization's tax identification number.

TABLE 17.—NUMBER OF SMALL SUPPLIERS [1]

[$3.5 million or less in Medicare allowed charges]

Bidding year	Number of affected small suppliers	Total number of affected suppliers	Percent
2007	16,762	19,720	85
2008	90,500	106,470	85
2009	97,031	114,154	85
2010	103,562	121,838	85
2011	103,562	121,838	85
2012	103,562	121,838	85

[1] Some suppliers furnish products in more than one selected CBA. Consequently, some suppliers may be counted more than once.

Small suppliers are likely to have similar costs for submitting bids as large suppliers. As discussed in the previous section, the average cost of submitting a bid in one CBA is $2,125. The cost of bidding as a share of Medicare revenue will depend on the size of the small supplier's Medicare revenue. The share for a supplier with $50,000 in Medicare revenue would be 4.4 percent; the totals for suppliers with $100,000, $1 million, and $3 million would be 2.2 percent, 0.2 percent, and less than 0.01 percent, respectively.

We considered the following options for minimizing the burden of competitive bidding on small businesses. The first two options were included in the demonstration project. Some of the new options may increase Medicare potential savings, while others may lower or have no effect on potential savings.

• Networks: As stated in section XII. of this final rule, we discuss the option for suppliers to form networks for bidding purposes. Networks are several small suppliers joining together to submit bids for a product category under competitive bidding. This option will allow small suppliers to band together to lower bidding costs, expand service options, or attain more favorable purchasing terms. We recognize that forming a network may be challenging

for suppliers but believe it is still a viable and worthwhile option. Networking was allowed in the demonstration project, but no networks submitted bids. If suppliers can form networks efficiently, they may be able to submit lower bids than the individual suppliers could submit, possibly increasing Medicare savings.

• Not requiring bids for every product category: As discussed in section VII. of this final rule, we will conduct separate bidding for items grouped together in product categories rather than conduct a single bidding program for all items. Therefore, small suppliers will have the option of deciding how many product categories for which they want to submit bids. We believe this will help minimize the burden on small suppliers. This option was available during the demonstration projects, and most suppliers did not bid in every product category. We believe these provisions will allow suppliers to bid on the product category that they can most efficiently supply, and therefore contributes to Medicare savings.

• Small supplier target: Our goal for small supplier participation in each product category will be determined by multiplying 30 percent times the number of suppliers whose composite bids are at or lower than the pivotal bid for the product category. This target was not included in the demonstration project. However, small suppliers were selected in most product categories. We expect that this provision will not affect potential Medicare savings because (1) The target may be met through the normal selection process; and (2) if the target is not met, the additional small suppliers that are selected will have to agree to accept the single payment amount.

• Capacity limit: The capacity limit was not included in the demonstration project. It is possible that the limit will increase the pivotal bid because it may take more suppliers to reach the estimated need for capacity. The higher pivotal bid will reduce potential Medicare savings. We have established a capacity limit for purposes of calculating the pivotal bid such that no supplier's or network's estimated capacity can be considered to meet more than 20 percent of the total need for capacity. Once winning suppliers are selected, we will not exclude networks or suppliers from expanding and exceeding the 20-percent capacity. This will increase the opportunity for small suppliers to be considered and participate in the program. It will also help ensure that we meet the requirement at section 1847(b)(4) of the Act that the Secretary shall award contracts to multiple entities and ensure that we have sufficient contract suppliers to meet the anticipated needs of beneficiaries for competitive bid items on a timely basis.

• Streamlined financial standards: We have streamlined the financial standards to require submission of certain tax information and other basic financial information such as a compiled balance sheet. This provision, which was not included in the demonstration, should make it easier for small suppliers to bid. This has the potential to increase Medicare savings, but it is not clear by how much.

• Permitting physicians and certain non-physician practitioners to furnish certain limited items. We will permit physicians and certain practitioners to furnish certain limited items that are provided to beneficiaries as part of their professional practice without submitting a bid and being awarded a contract, provided that certain conditions are met. These physicians and non-physician practitioners would be required to submit bids if they wished to furnish any other competitively bid items. This provision was not included in the demonstration projects. We do not believe it will have a significant effect on Medicare savings, because relatively few items will be covered.

• Another option we considered but did not adopt would have allowed small suppliers to be exempted from the requirement that a contract supplier must service an entire CBA. However, we note that if a small supplier joined a network, an exception to this rule would apply. This option is also discussed in further detail in section XI. of the preamble of this final rule.

Comment: Several commenters believed that the analysis in the proposed rule suggests potential capacity issues for successful bidders. These commenters argued that if 37 percent of existing suppliers will become noncontract suppliers as a result of not bidding or not submitting successful bids as projected in Table 15 of the proposed rule (71 FR 25695), and the current ratio of beneficiaries to suppliers is roughly the same for contract and noncontract suppliers, each contract supplier will experience, on average, a 59 percent increase in the number of beneficiaries that it must serve. The commenters stated that CMS indicated in the preamble to the proposed rule that the PAOC, during its February 28, 2006 meeting, suggested ''that most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor'' (71 FR 25676). The commenters argued that the proposal creates the possibility that contract suppliers may, therefore, need to expand capacity beyond the 20-percent PAOC estimate. Two commenters noted that such expansions could raise accreditation and licensure issues.

Response: Our methodology will ensure that we select a sufficient number of suppliers to meet the needs of Medicare beneficiaries for competitively bid items. We also note that, as we stated in the preamble to the proposed rule (71 FR 25676), the PAOC indicated that suppliers of products such as diabetes supplies that require relatively little labor may be able to expand capacity even more. We will be selecting multiple contract suppliers, and we will be asking suppliers that plan to increase their capacity to submit plans on how they will achieve this increased capacity. However, no contract supplier will be required to increase its capacity. In addition, as a general rule, for a selection tool, we would not assign more than 20 percent of the total Medicare demand for a product category to any one supplier in estimating how many suppliers we need in a given CBA. Based on these factors, we do not believe that contract suppliers will experience capacity problems.

Comment: A number of commenters believed that the regulatory analysis in the proposed rule minimized the impact of the proposed rule on small businesses because CMS estimates that half of the bidding suppliers will not be selected as contract suppliers. The commenters believed that this group would be disproportionately comprised of small businesses that are now providing DMEPOS and that many, faced with the loss of Medicare business for competitively bid items, would go out of business.

Response: Our current estimates indicate that, of all the DMEPOS suppliers in a CBA, only 22 percent would be noncontract suppliers because they submitted a losing bid. Many DMEPOS items are not subject to competitive bidding. Therefore, many small suppliers such as suppliers of specialty items, for example, are not likely to be affected by competitive bidding. For those suppliers that currently furnish competitively bid items, we are taking specific steps to ensure that they have the opportunity to participate in the competitive bidding program. These steps include offering suppliers the opportunity to form networks, small supplier targets, and

not requiring suppliers to submit bids for all product categories.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the following table 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 decreased expenditures in Medicare payments under the Medicare DMEPOS Competitive Bidding Program as a result of the changes presented in this final rule. All expenditures are classified as transfers to the Federal Government from DMEPOS suppliers.

TABLE 18.—ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2007 TO FY 2012

Category	Transfers
Annualized Monetized Transfers	547.9 (in Millions).
From Whom To Whom?	To Federal Government from Medicare DMEPOS Suppliers.
Annualized Monetized Transfers	137.0.
From Whom To Whom?	To Beneficiaries from Medicare DMEPOS Suppliers.

I. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the OMB.

List of Subjects

42 CFR Part 411

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.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 411—EXCLUSIONS FOR MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Exclusions and Exclusions of Particular Services

■ 2. Section 411.15 is amended by adding a new paragraph (s) to read as follows.

§ 411.15 Particular services excluded from coverage.

* * * * *

(s) Unless § 414.404(d) or § 414.408(e)(2) of this subchapter applies, Medicare does not make payment if an item or service that is included in a competitive bidding program (as described in Part 414, Subpart F of this subchapter) is furnished by a supplier other than a contract supplier (as defined in § 414.402 of this subchapter).

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 3. 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)).

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

■ 4. New §§ 414.400, 414.402, and 414.404 are added to Subpart F to read as follows:

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers.

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

Grandfathered item means any one of the following items for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish the items in accordance with § 414.408(j):

(1) An inexpensive or routinely purchased item described in § 414.220.

(2) An item requiring frequent and substantial servicing, as described in § 414.222.

(3) Oxygen and oxygen equipment described in § 414.226.

(4) Other DME described in § 414.229.

Grandfathered supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug, and Cosmetic Act, as defined in § 414.202 of this part and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

Nationwide competitive bidding area means a CBA that includes the United States, its Territories, and the District of Columbia.

Nationwide mail order contract supplier means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

Network means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

Noncontract supplier means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

Physician has the same meaning as in section 1861(r) of the Act.

Pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Product category means a grouping of related items that are used to treat a similar medical condition.

Regional competitive bidding area means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

Regional mail order contract supplier means a mail order contract supplier that furnishes items in a regional competitive bidding area.

Single payment amount means the allowed payment for an item furnished under a competitive bidding program.

Small supplier means, a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

Weighted bid means the item weight multiplied by the bid price submitted for that item.

§ 414.404 Scope and applicability.

(a) *Applicability.* Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions.* (1) Physicians and treating practitioners may furnish certain types of competitively bid items without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

(i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME.

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service.

(iii) The items are billed under a billing number assigned to the physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

(2) A physical therapist in private practice (as defined in § 410.60(c) of this chapter) or an occupational therapist in private practice (as defined in § 410.59(c) of this chapter) may furnish competitively bid off-the-shelf orthotics without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with § 414.408(a).

■ 5. Section 414.406 is amended by adding paragraphs (b), (c), and (d) to read as follows:

§ 414.406 Implementation of programs.

* * * * *

(b) *Competitive bidding areas.* CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas.* CMS may revise the CBAs designated under paragraph (b) of this section.

(d) *Competitively bid items.* CMS designates the items that are included in a competitive bidding program through program instructions or by other means

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■ 6. New §§ 414.408, 414.410, 414.412, 414.414, 414.416, 414.418, 414.420, 414.422, 414.424, and 414.426 are added to Subpart F to read as follows:

§ 414.408 Payment rules.

(a) *Payment basis.* (1) The payment basis for an item furnished under a competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under Subpart C or Subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§ 411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another CBA and the item is included in the competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, or occupational therapist in private practice may furnish an item in accordance with § 414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished, and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(h) *Rented equipment.* (1) *Capped rental DME.* Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) *Additional payment to certain contract suppliers for capped rental DME.* (i) Except as specified in paragraph (h)(2)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(2)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(3) *Maintenance and servicing of rented DME.* Separate maintenance and servicing payments are not made for any rented durable medical equipment.

(4) *Payment for rented enteral nutrition equipment.* Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. The contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the equipment until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary.

(5) *Maintenance and servicing of rented enteral nutrition equipment.* Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(6) *Payment for inexpensive or routinely purchased durable medical equipment.* Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(7) *Payment amounts for rented DME requiring frequent and substantial servicing.* (i) *General rule.* Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception.* The single payment amounts for continuous passive motion exercise devices are calculated based on the bids submitted and accepted for the furnishing of these items on a daily basis.

(i) *Monthly payment amounts for oxygen and oxygen equipment.* (1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up

to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment.* (1) *Supplier election.* (i) A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the beneficiary maintains a permanent residence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in § 414.220(a), payment is made in the amount determined under § 414.220(b).

(ii) For other durable medical equipment or capped rental items described in § 414.229, payment is made in the amount determined under § 414.229(b).

(iii) For items requiring frequent and substantial servicing described in § 414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in § 414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in § 414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Payment for accessories and supplies for grandfathered items.* Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items.*

(1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with § 414.210(e)(1) of Subpart D.

(ii) Payment for parts that are not items (as defined in § 414.402) is made in accordance with § 414.210(e)(1) of Subpart D.

(iii) Payment for parts that are items (as defined in § 414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with §§ 414.210(e)(2) and (e)(3) of subpart D for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for the replacement item in accordance with paragraph (a)(1) of this section.

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs in—

(1) 10 of the largest MSAs in CY 2007;

(2) 80 of the largest MSAs in CY 2009;

(3) Additional CBAs after CY 2009.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

(1) The total population of an MSA.

(2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.

(3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.

(4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in § 412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

§ 414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under § 414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must

submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Bids are submitted for items grouped into product categories.

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.

(c) *Furnishing of items.* A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(d) *Separate bids.* For each product category that a supplier is seeking to furnish under a competitive bidding program, the supplier must submit a separate bid for each item in that product category.

(e) Commonly-owned or controlled suppliers. (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(f) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

§ 414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in § 424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) *Quality standards and accreditation.* Each supplier must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved accreditation organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards.* Each supplier must submit along with its bid the applicable financial documentation specified in the request for bids.

(e) *Evaluation of bids.* CMS evaluates bids submitted for items within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the items in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category;

(3) Establishing a composite bid for each supplier and network that submitted a bid for the product category.

(4) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(5) Calculating the pivotal bid for the product category;

(6) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under Subpart C or Subpart D.

(g) *Special rules for small suppliers.* (1) *Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under § 414.416 of this subpart.

(h) *Sufficient number of suppliers.*

(1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the

product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under § 414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

§ 414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for an item furnished under a competitive bidding program is equal to the median of the bids submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. If there is an even number of bids, the single payment amount for the item is equal to the average of the two middle bids.

(2) The single payment amount for an item must be less than or equal to the amount that would otherwise be paid for the same item under Subpart C or Subpart D.

§ 414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

(b) The following rules apply to networks that seek contracts under this subpart:

(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in § 414.414(b) through (d).

(3) A small supplier may join one or more networks but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member of more than one network if those networks submit bids to furnish the same product category in the same CBA.

(4) The network cannot be anticompetitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

§ 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item or mode of delivery prescribed.* A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that submits a claim prohibited by this paragraph.

§ 414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items that the contract supplier makes available to other customers.

(d) *Change of ownership.* (1) A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change.

(2) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if—

(i) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) The successor entity submits to CMS the documentation described under § 414.414(b) through (d) if that documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. This documentation must be submitted within 30 days prior to the anticipated effective date of the change of ownership. A successor entity is not required to duplicate previously submitted information if the previously submitted information is still current;

(iii) The successor entity is acquiring the assets of the existing contract supplier, it submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(iv) A new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(iii) of this section for CMS review. The successor entity must submit to CMS, within 30 days after the effective date of the change of ownernship and executed novation agreement acceptable to CMS.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(f) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions:

(i) Require the contract supplier to submit a corrective action plan;

(ii) Suspend the contract supplier's contract;

(iii) Terminate the contract;

(iv) Preclude the contract supplier from participating in the competitive bidding program;

(v) Revoke the supplier number of the contract supplier; or

(vi) Avail itself of other remedies allowed by law.

§ 414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

§ 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 14, 2006.

Leslie Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 13, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–1701 Filed 4–2–07; 4:15 pm]

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Federal Register

Tuesday,
April 10, 2007

Part III

Department of Transportation

Federal Aviation Administration
14 CFR Parts 61, 65, 67, and 183
Modification of Certain Medical Standards and Procedures and Duration of Certain Medical Certificates; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 65, 67, and 183

[Docket No. FAA–2007–27812; Notice No. 07–08]

RIN 2120–AI91

Modification of Certain Medical Standards and Procedures and Duration of Certain Medical Certificates

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This proposal would extend the duration of first- and third-class medical certificates for certain individuals. A first-class medical certificate is required when exercising airline transport pilot privileges and at least a third-class medical certificate when exercising private pilot privileges. Certain conforming amendments to medical certification procedures and some general editorial amendments also are proposed. The intent of this action is to improve the efficiency of the medical certification program and service provided to medical certificate applicants.

DATES: Send your comments on or before June 11, 2007.

ADDRESSES: You may send comments identified by Docket Number FAA–2007–27812 using any of the following methods:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- Fax: 1–202–493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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://dms.dot.gov*, including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of this document. *Docket:* To read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Judi Citrenbaum, Office of the Federal Air Surgeon, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–9689; e-mail: *Judi.M.Citrenbaum@faa.gov.*

SUPPLEMENTARY 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. We ask that you send us two copies of written comments.

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. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also review the docket using the Internet at the Web address in the **ADDRESSES** section.

Privacy Act: Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov.*

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 late if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

Proprietary or Confidential Business Information

Do not file in the docket information that you consider to be proprietary or confidential business information. Send or deliver this information directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document. You must mark the information that you consider proprietary or confidential. If you send the information on a disk or CD ROM, mark the outside of the disk or CD ROM and also identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), when we are aware of proprietary information filed with a comment, we do not place it in the docket. We hold it in a separate file to which the public does not have access, and place a note in the docket that we have received it. If we receive a request to examine or copy this information, we treat it as any other request under the Freedom of Information Act (5 U.S.C. 552). We process such a request under the DOT procedures found in 49 CFR part 7.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

(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. Make sure to identify the docket number, notice number, or amendment number of this rulemaking.

Authority for This Rulemaking

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 III, Section 44701 and 44703.

Background

Title 14 of the Code of Federal Regulations, part 67 provides for the issuance of three classes of medical certificates. A first-class medical certificate is required for operations requiring an airline transport pilot certificate. At least a second-class medical certificate is required for operations requiring a commercial pilot certificate or an air traffic control tower operator certificate. At least a third-class medical certificate is required for operations requiring a private pilot certificate, a recreational pilot certificate, a flight instructor certificate (when acting as pilot in command or serving as a required flight crewmember in operations other than glider or balloon), or a student pilot certificate.

An applicant who is found to meet the appropriate medical standards, based on a medical examination and an evaluation of the applicant's history and condition, is entitled to a medical certificate without restriction or limitation other than the prescribed limitation as to its duration. The duration standards are set forth under existing § 61.23, paragraph (d).

The FAA has not reviewed the medical duration standards since 1996 when it extended the duration of third-class medical certificates from 2 years to 3 years for individuals under age 40. The medical examination duration standards under existing § 61.23 (d) represent what the agency determined years ago to be a reasonable, minimum timetable to impose for required examinations and an optimum schedule in terms of estimated detectable pathology in the airman population. The FAA is proposing to further extend certain § 61.23 (d) provisions in order to provide a more reasonable, updated examination timetable for certain medical certificate holders and with a view to more efficiently managing the airman medical certification program overall.

Discussion of the Proposal

The FAA proposes, primarily, to amend § 61.23(d) to extend the duration of first- and third-class medical certificates for individuals under the age of 40. Existing § 61.23 prescribes the duration of validity and privileges of each class of medical certificate. Currently the maximum validity on a first-class medical certificate is 6 months regardless of age and, on a third-class medical certificate, 36 months for individuals under age 40. Decreasing the frequency of medical examinations by increasing the duration of validity from 6 months to 1 year on first-class medical certificates for individuals under age 40 and from 36 months to 60 months on third-class medical certificates for individuals under age 40 would reflect the FAA's assessment of the current, appropriate interval for younger airmen. It also would decrease routine workflow thereby allowing the FAA to focus on the most safety-critical certification cases and provide more efficient service to other applicants waiting to be processed.

The FAA finds that, because medical standards were last evaluated in 1996, this rulemaking action also provides the opportunity to make certain minor, but necessary, amendatory modifications. In addition to proposed amendments to § 61.23 (d), the FAA also proposes to:

- Add new section § 67.4.
- Amend § 183.15.
- Edit §§ 61.29, 65.16, 67.3, 67.401, 67.405, 67.411, 67.413, and 183.11.

Proposed Amendments

Section 61.23 Medical Certificates: Requirement and Duration

Rationale for the Change

The FAA extended the duration of third-class medical certificates from 24 to 36 months for individuals under age 40 in 1996 [61 FR 11243; March 19, 1996]. After careful consideration of the comments and testimony received during that rulemaking action, the FAA determined an extended duration would pose no detriment to safety in the case of younger individuals because they are much less likely to suffer medical incapacitation. Ten years of experience with extended duration on the third-class medical certificate has had no adverse impact on safety.

The FAA has no experience extending the duration of first-class medical certificates beyond the current 6-month limit. The FAA developed this proposal through review of relevant medical literature, its own aeromedical certification data, and accident data. Additionally, the FAA considered the long-standing International Civil Aviation Authority (ICAO) standard requiring revalidation of medical certification annually for airline transport and commercial pilots in multi-crew settings and also the ICAO standard adopted in November 2005 extending revalidation for private pilots from 2 years to 5 years under age 40. Existing U.S. medical certificate validity standards for commercial pilots under age 40 in a multi-crew setting currently are the same as ICAO's; therefore, the FAA sees no need to consider a change to FAA second-class medical certificate validity standards. The FAA is proposing to modify existing, more restrictive U.S. medical certificate validity standards for airline transport and private pilots under age 40 in part because of the international application of less restrictive standards that has had no reported adverse impact on safety.

To explore whether the re-examination period for pilots under age 40 holding an FAA first-class medical certificate could be safely extended from 6 months to 12 months, FAA researchers randomly selected a sample of 100 airmen issued a first-class medical certificate under age 40 from its medical certification database and reviewed medical records over a 36-month period for the presence of 91 predetermined pathology codes defined as significant. Significant codes represent serious medical conditions that would negatively impact aviation safety. The proportion of significant pathology codes assigned to airmen who were examined at 6- and 12-month intervals were compared.

Comparison of the 6- and 12-month intervals revealed one medically significant pathology code (Code 551, colitis and ileitis) at the 6-month interval and one medically significant pathology code (Code 343, pneumothorax) at the 12-month interval. The FAA determined that there was no significant difference between the proportion of medically significant pathology codes assigned to pilots who recertified at 6-month intervals and 12-month intervals.

FAA certification trends consistently indicate no significant increase either in undetected pathology between required medical examinations or in medical disability among younger applicants. While applicants of any age manifesting medical conditions that represent a risk to safety are denied certification under § 67.409, the trends reveal that the percentage of younger applicants being denied medical certification is consistently lower than that of older applicants. It is also consistently evident that older applicants are more likely to have to apply for special issuance under § 67.401 than are younger applicants.

Aviation Safety Information Analysis and Sharing (ASIAS) accident database queries on airline transport and private pilots under age 40 reveal relatively few accidents and incidents, when total number of enplanements is considered, related to pilot medical events. The National Transportation Safety Board

(NTSB) Accident and Incident Data System was searched for medical events for pilots under age 40 from 1983 to the present. Under the general categories of incapacitation and physical impairment, various sub-queries were performed to find accidents or incidents due, for example, to incapacitation or physical impairment due to cardiovascular, loss of consciousness, neurologic, visual, or other organic problems. Search of these categories revealed 6 incidents and 21 accidents over the 23-year period that met the criteria of the database query, with only 9 of these deemed appropriate to consider for this analysis.

The data considered revealed what the NTSB data characterizes as one commercial (air carrier) aviation incident, one commercial (air taxi) aviation incident, and one commercial (air taxi) aviation accident attributed to incapacitating medical cause. Both the air carrier and air taxi incidents involved emergency landings made by captains due to incapacitations of the first officers. The air carrier incident was fatal for the first officer. The air taxi incident was non-fatal. The first officer involved in the air taxi incident was able to be treated and was diagnosed as suffering from a viral syndrome. The air taxi accident was non-fatal involving the unspecified incapacitation of the pilot in command with the first officer taking control and landing the airplane without further incident.

The data also revealed what the NTSB data characterized as four general aviation accidents attributed to incapacitation and one incident attributed to physical impairment. Two of the incapacitating accidents, both fatal, were due to heart attack of the pilots in command. Two non-fatal, incapacitating accidents were attributed to pilots, one a low-time pilot and one a student pilot, losing consciousness upon landing while performing certain practice maneuvers. The accident reports indicated inexperience and nervousness as contributing to the accidents. The non-fatal incident attributed to physical impairment involved a pilot taking sinus medication 90 minutes after takeoff and then further medication 30 minutes later that, apparently, may have incapacitated him.

Considering the limited findings revealed by reviewing ASIAS and FAA aeromedical certification data, the FAA believes the incremental risks associated with extending the duration of medical certificates would be minimal. Additionally, the ancillary benefit this proposal would provide by allowing the FAA to shift resources otherwise involved in processing routine cases to the more safety-critical medical certification cases would go a long way toward improving customer service. The FAA has been making incremental changes over a considerable period of time to improve the workflow of the medical certification process; this proposal would provide an additional opportunity for continuous improvement.

Proposed Implementation of the Change

The FAA intends that the proposed, extended validity periods would be effective upon issuance of the final rule. Therefore, it would not matter whether an individual had a medical examination the day before or the day after the effective date of the final rule. Validity standards are applied according to the date of examination placed on the medical certificate and in accordance with the duration periods specified under § 61.23(d).

Under this proposal, § 61.23(d) would be simplified into a more user-friendly chart format.

Section 67.3 Issue

The FAA proposes an editorial amendment to delete a reference to a non-existent § 67.5. On October 5, 1998 [63 FR 53532] the FAA removed several regulatory provisions under 14 CFR that restricted the licensing of foreign persons outside of the United States. The restrictive language was originally placed in the regulations because of administrative concerns that are no longer applicable and that came to be regarded as restricting harmonization efforts. Section 67.5 was removed in this 1998 final rule; however, the FAA inadvertently did not remove the reference to former § 67.5 in existing § 67.3. This proposal would remove that erroneous reference and leave § 67.3 otherwise unchanged.

Section 67.4 Application

The FAA proposes to add a new section, § 67.4.

Proposed paragraph (a) would add a provision to require individuals to make application for FAA medical certification ''on a form and in a manner acceptable to the Administrator.'' Adding this language would clarify that it is necessary to fill out a form to apply for a medical certificate and thereby conform part 67 with existing language under § 61.13(a) that requires pilot certificate applicants to make application ''on a form and in a manner acceptable to the Administrator.''

Proposed paragraph (b) would move existing provisions regarding how individuals may locate an AME from existing § 67.405.

Proposed paragraph (c) would require applicants to present proof of age and identity when making application. While an AME currently may not conduct an examination unless the medical certificate applicant presents proof of age and identity, this practice now would be codified under the regulation.

Section 67.401 Special Issuance of Medical Certificates

Existing paragraph (j) would be deleted as it contains a reference to a previous compliance date that is no longer necessary. The section would remain otherwise unchanged.

Section 67.405 Medical Examinations: Who May Give?

Current paragraphs (a) and (b) regarding how the public may locate and contact an AME are redundant and need to be expanded. The FAA would update and move these provisions to proposed § 67.4. In addition, the FAA would change the words ''give the examination'' to ''perform the examination.'' The word ''give'' in the title of this section also would be changed to ''perform.''

Section 67.411 Medical Certificates by Flight Surgeons of the Armed Forces

The FAA proposes to remove and reserve this section. The FAA has determined that a specific section to address military flight surgeons holding AME designation is no longer necessary. The FAA has ceased designating military installations in favor of designating individual military personnel as AMEs in the same manner as civilians. Thus there no longer is a meaningful distinction between civilian AME and military flight surgeons in terms of issuing FAA medical certificates.

Section 67.413 Medical Records

The FAA proposes to simplify § 67.413 by re-formatting its provisions into more user-friendly paragraphs. This intent of this section would not change.

Section 61.29 Replacement of a Lost or Destroyed Airman or Medical Certificate or Knowledge Test Report

Section 65.16 Change of Name: Replacement of Lost or Destroyed Certificate

The FAA proposes to change the P.O. Box address listed under §§ 61.29(b) and 65.16(b) from P.O. Box 25082 to P.O. Box 26200 for individuals to use when requesting replacement of a lost or destroyed medical certificate. While the current P.O. Box is valid, replacement requests are received more

expeditiously, and therefore processed more efficiently, when sent to P.O. Box 26200.

Section 183.11 Selection

The FAA proposes to change ''his authorized representatives'' to ''his or her authorized representatives'' in order to conform to the existing language of other sections, for example, § 67.407(d), that use ''his or her.'' This section otherwise would remain unchanged.

Section 183.15 Duration of Certificates

The FAA proposes to amend § 183.15. Under rulemaking that became effective on November 14, 2005 [''Establishment of Organization Designation Authorization Program; 70 FR 59932; October 13, 2005''], the FAA amended § 183.15 to remove a specific time limit on designated authority for certain representatives of the Administrator and provide instead that designations be effective until the expiration date shown on whatever credentialing documentation or certificate is held by a particular designee. Adding such a provision has worked well among the designees of the FAA Flight Standards and Aircraft Certification Services. In addition to reducing cost and workload, it has allowed greater flexibility, in particular, in automatically extending the designation authority of valued FAA designees. Including AMEs under this process will further enhance the FAA's ability to more efficiently manage FAA designee programs.

Existing paragraph (b) would be revised to provide, in addition to Flight Standards and Aircraft Certification Service Designated Representatives, that the designation of Aviation Medical Examiners would be ''effective until the expiration date shown on the document granting the authorization.'' Therefore existing paragraph (a), a stand-alone paragraph referencing AMEs only, would no longer be needed and therefore removed. Existing paragraph (b) would be revised as proposed and become new paragraph (a). Existing paragraph (c) would become new paragraph (b) and remain unchanged except it would include the word ''her'' where necessary in the paragraph.

Paperwork Reduction Act

Currently, the reverse side of FAA Form 8500–9, the FAA medical certificate, lists the ''Conditions of Issue'' of the certificate and specifies the validity period of each class of medical certificate. If this rule is adopted, the back of FAA Form 8500–9 would have to be reprinted to reveal the new validity periods for first- and third-class medical certificate holders under age 40. Further, approximately 2,000 boxes of reprinted forms would have to be mailed from the Oklahoma City distribution site to various Aviation Medical Examiners and FAA offices across the country.

In anticipation of revising the back of the medical certificate attached to FAA Form 8500–8, the FAA will request new approval given the cost to the FAA associated with amending and reprinting it. 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.

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. This action, if adopted, would meet ICAO standard.

Economic Assessment, Initial Regulatory Flexibility Determination, Trade Impact Assessment, and Unfunded Mandates 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.

This proposal would extend the duration of first- and third-class medical certificates for medical certificate holders under the age of 40 and make certain editorial amendments to the medical certification regulations. The proposal is estimated to generate $85.0 million ($59.7 million, discounted) of cost savings while only imposing $123,000 ($115,000, discounted) of costs over 10 years.

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 proposal would not impact small entities. It would only impact 1st class and 3rd class pilots who are expected to save about $300 for each time that they do not have to renew their medical certificates. (The FAA cost-estimates on the price of a medical exam, the time for the exam, the time to fill out the form, and the travel time would total approximately $300.) Therefore, the FAA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

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 only a domestic impact and therefore no effect on international trade.

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.

The proposed rule does not contain any Federal intergovernmental or private sector mandates; therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

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.

Plain English

Executive Order 12866 (58 FR 51735, Oct. 4, 1993) requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these proposed regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain unnecessary technical language or jargon that interferes with their clarity?
- Would the regulations be easier to understand if they were divided into more (but shorter) sections?
- Is the description in the preamble helpful in understanding the proposed regulations?

Please send your comments to the address specified in the **ADDRESSES** section.

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 and involves no extraordinary circumstances.

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.

List of Subjects

14 CFR Part 61

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

14 CFR Part 65

Airmen other than flight crewmembers.

14 CFR Part 67

Aircraft, Airmen, Alcohol abuse, Drug abuse, Recreation and recreation areas, Reporting and recordkeeping requirements.

14 CFR Part 183

Aircraft, Airmen, Authority delegations (Government agencies), Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Chapter I of Title 14, Code of Federal Regulations, as follows:

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

1. 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.

2. Amend § 61.23 by revising paragraph (d) as follows:

§ 61.23 Medical certificates: Requirement and duration.

* * * * *

(d) *Duration of a medical certificate.* Use the following table to determine how long each class of medical certificate is valid:

If you hold	And you are	Conducting an operation requiring	Then your medical certificate is valid from the date of the examination, through the rest of that month, and for
(1) A first-class medical certificate.	(i) Under age 40	an airline transport pilot certificate	12 more calendar months.
	(ii) Age 40 or older	an airline transport pilot certificate	6 more calendar months.

If you hold	And you are	Conducting an operation requiring	Then your medical certificate is valid from the date of the examination, through the rest of that month, and for
	(iii) Of any age	a commercial pilot certificate or an air traffic control tower operator certificate.	12 more calendar months.
	(iv) Under age 40	a recreational pilot certificate, a private pilot certificate, a flight instructor certificate (when acting as pilot in command or a required pilot flight crewmember in operations other than glider or balloon), or a student pilot certificate.	60 more calendar months.
	(v) Age 40 or older	a recreational pilot certificate, a private pilot certificate, a flight instructor certificate (when acting as pilot in command or a required pilot flight crewmember in operations other than glider or balloon), or a student pilot certificate.	24 more calendar months.
(2) A second-class medical certificate.	(i) Of any age	a commercial pilot certificate or an air traffic control tower operator certificate.	12 more calendar months.
	(ii) Under age 40	a recreational pilot certificate, a private pilot certificate, a flight instructor certificate (when acting as pilot in command or a required pilot flight crewmember in operations other than glider or balloon), or a student pilot certificate.	60 more calendar months.
	(iii) Age 40 or older	a recreational pilot certificate, a private pilot certificate, a flight instructor certificate (when acting as pilot in command or a required pilot flight crewmember in operations other than glider or balloon), or a student pilot certificate.	24 more calendar months.
(3) A third-class medical certificate.	(i) Under age 40	a recreational pilot certificate, a private pilot certificate, a flight instructor certificate (when acting as pilot in command or a required pilot flight crewmember in operations other than glider or balloon), or a student pilot certificate.	60 more calendar months.
	(ii) Age 40 or older	a recreational pilot certificate, a private pilot certificate, a flight instructor certificate (when acting as pilot in command or a required pilot flight crewmember in operations other than glider or balloon), or a student pilot certificate.	24 more calendar months.

3. Amend § 61.29 by revising paragraph (b) to read as follows:

§ 61.29 Replacement of a lost or destroyed airman or medical certificate or knowledge test report.

* * * * *

(b) A request for the replacement of a lost or destroyed medical certificate must be made by letter to the Department of Transportation, FAA, Aeromedical Certification Division, P.O. Box 26200, Oklahoma City, OK 73125, and must be accompanied by a check or money order for the appropriate fee payable to the FAA.

* * * * *

PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

4. The authority citation for part 65 continues to read as follows:

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

5. Amend § 65.16 by revising paragraph (b) introductory text to read as follows:

§ 65.16 Change of name: Replacement of lost or destroyed certificate.

* * * * *

(b) An application for a replacement of a lost or destroyed certificate must be made by letter to the Department of Transportation, Federal Aviation Administration, Airman Certification Division, Post Office Box 26200, Oklahoma City, 73215. The letter must—

* * * * *

PART 67—MEDICAL STANDARDS AND CERTIFICATION

6. The authority citation for part 67 continues to read as follows:

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

7. Revise § 67.3 to read as follows:

§ 67.3 Issue.

A person who meets the medical standards prescribed in this part, based on medical examination and evaluation of the person's history and condition, is entitled to an appropriate medical certificate.

8. Add § 67.4 to read as follows:

§ 67.4 Application.

An applicant for first-, second- and third-class medical certification must:

(a) Apply on a form and in a manner prescribed by the Administrator;

(b) Be examined by an aviation medical examiner designated in accordance with part 183 of this chapter. An applicant may obtain a list of aviation medical examiners from the FAA Office of Aerospace Medicine homepage on the FAA Web site, from any FAA Regional Flight Surgeon, or by contacting the Manager of the Aeromedical Education Division, P.O. Box 26200, Oklahoma City, Oklahoma 73125.

(c) Show proof of age and identity by presenting a government-issued photo identification (such as a current and valid U.S. driver's license, identification card issued by a driver's license authority, military identification, or passport). If an applicant does not have government-issued identification, he or she may use non-photo, government-issued identification (such as a birth certificate or voter registration card) in

conjunction with a photo identification (such as a work identification card or a student identification card.)

9. Amend § 67.401 by removing paragraph (j).

10. Revise § 67.405 to read as follows:

§ 67.405 Medical examinations: Who may perform?

(a) *First-class.* Any aviation medical examiner who is specifically designated for the purpose may perform examinations for the first-class medical certificate.

(b) *Second- and third-class.* Any aviation medical examiner may perform examinations for the second-or third-class medical certificate.

11. Remove and reserve § 67.411.

12. Revise § 67.413 to read as follows:

§ 67.413 Medical records.

(a) Whenever the Administrator finds that additional medical information or history is necessary to determine whether you meet the medical standards required to hold a medical certificate, you must:

(1) Furnish that information to the FAA; or

(2) Authorize any clinic, hospital, physician, or other person to release to the FAA all available information or records concerning that history.

(b) If you fail to provide the requested medical information or history or to authorize its release, the FAA may suspend, modify, or revoke your medical certificate or, in the case of an applicant, deny the application for a medical certificate.

(c) If your medical certificate is suspended, modified, or revoked under paragraph (b) of this section, that suspension or modification remains in effect until you provide the requested information, history, or authorization to the FAA and until the FAA determines that you meet the medical standards set forth in this part.

PART 183—REPRESENTATIVES OF THE ADMINISTRATOR

13. The authority citation for part 183 continues to read as follows:

Authority: 31 U.S.C. 9701; 49 U.S.C. 106(g), 40113, 44702, 44721, 45303.

14. Amend § 183.11 by revising paragraph (a) to read as follows:

§ 183.11 Selection.

(a) The Federal Air Surgeon, or his or her authorized representatives within the FAA, may select Aviation Medical Examiners from qualified physicians who apply. In addition, the Federal Air Surgeon may designate qualified forensic pathologists to assist in the medical investigation of aircraft accidents.

* * * * *

15. Revise § 183.15 to read as follows:

§ 183.15 Duration of certificates.

(a) Unless sooner terminated under paragraph (b) of this section, a designation as an Aviation Medical Examiner or as a Flight Standards or Aircraft Certification Service Designated Representative as described in §§ 183.21, 183.23, 183.25, 183.27, 183.29, 183.31, or 183.33 is effective until the expiration date shown on the document granting the authorization.

(b) A designation made under this subpart terminates:

(1) Upon the written request of the representative;

(2) Upon the written request of the employer in any case in which the recommendation of the employer is required for the designation;

(3) Upon the representative being separated from the employment of the employer who recommended him or her for certification;

(4) Upon a finding by the Administrator that the representative has not properly performed his or her duties under the designation;

(5) Upon the assistance of the representative being no longer needed by the Administrator; or

(6) For any reason the Administrator considers appropriate.

Issued in Washington, DC, on March 23, 2007.

Frederick E. Tilton,

Federal Air Surgeon.

[FR Doc. E7–6652 Filed 4–9–07; 8:45 am]

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Federal Register

Tuesday,
April 10, 2007

Part IV

The President

Executive Order 13429—Establishing an Emergency Board To Investigate a Dispute Between Metro-North Railroad and Its Maintenance of Way Employees Represented by the International Brotherhood of Teamsters

Federal Register
Vol. 72, No. 68
Tuesday, April 10, 2007

Presidential Documents

Title 3—

The President

Executive Order 13429 of April 4, 2007

Establishing an Emergency Board To Investigate a Dispute Between Metro-North Railroad and Its Maintenance of Way Employees Represented by the International Brotherhood of Teamsters

A dispute exists between Metro-North Railroad and its maintenance of way employees represented by the International Brotherhood of Teamsters.

The dispute has not heretofore been adjusted under the provisions of the Railway Labor Act, as amended, 45 U.S.C. 151–188 (the ''Act'').

A first emergency board to investigate and report on this dispute and disputes of other employees represented by other labor organizations was established on December 7, 2006, by Executive Order 13417 of December 6, 2006. The emergency board terminated upon issuance of its report. Subsequently, its recommendations were not accepted by the parties.

A party empowered by the Act has requested that the President establish a second emergency board pursuant to section 9A of the Act (45 U.S.C. 159a).

Section 9A(e) of the Act provides that the President, upon such request, shall appoint a second emergency board to investigate and report on the dispute.

NOW, THEREFORE, by the authority vested in me as President by the Constitution and the laws of the United States, including section 9A of the Act, it is hereby ordered as follows:

Section 1. *Establishment of Emergency Board (Board).* There is established, effective April 6, 2007, a Board of three members to be appointed by the President to investigate and report on this dispute. No member shall be pecuniarily or otherwise interested in any organization of railroad employees or any carrier. The Board shall perform its functions subject to the availability of funds.

Sec. 2. *Report.* Within 30 days after the creation of the Board, the parties to the dispute shall submit to the Board final offers for settlement of the dispute. Within 30 days after the submission of final offers for settlement of the dispute, the Board shall submit a report to the President setting forth its selection of the most reasonable offer.

Sec. 3. *Maintaining Conditions.* As provided by section 9A(h) of the Act, from the time a request to establish a second emergency board is made until 60 days after the Board submits its report to the President, the parties to the controversy shall make no change in the conditions out of which the dispute arose except by agreement of the parties.

Sec. 4. *Records Maintenance*. The records and files of the Board are records of the Office of the President and upon the Board's termination shall be maintained in the physical custody of the National Mediation Board.

Sec. 5. *Expiration*. The Board shall terminate upon the submission of the report provided for in section 2 of this order.

THE WHITE HOUSE,
April 4, 2007.

[FR Doc. 07–1816
Filed 4–9–07; 11:01 am]
Billing code 3195–01–P

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To provide for the construction, operation, and maintenance of an arterial road in St. Louis County, Missouri. (Mar. 28, 2007; 121 Stat. 71)

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